VOL 19 | ISSUE 2 | SEPTEMBER 2020 | MUMBAI | TOTAL 128 PAGES

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PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

Titrators for Food,Pharma & Oil

Automatic Potentiometric Titrator
AGILE - 2

On line titration curve

Online / Offline statistics

Auto burette recognitions

Connectivity to USB printer

TFT with touch screen

Karl Fischer Titrator for moisture estimation
WHIZ - 2

'NEW'

Introducing Spectrodetector for Photometric titrations

KF oven for typical samples which cannot be directly introduced in methanol

Agile - 2

- Volume determination by equivalence point, end point.
- Advanced Microporocessor ARM-11 based SOC.
- End Point Detection with Potentiometric / Voltametric.
- Calculations by selected EP, Largest EP, last EP, EP within specified ml / mV window.
- Single report with graph & signature & 100 document reports can be stored.
- Methods : FED, SVD, ASD.
- 100 user methods can be stored with more than 20 parameters per method.
- Calibration : 5 point for pH, 5 point for ISE, 2 point for ORP
- Burette : 5,10,25 ml
- Statistics : Mean value, SD, RSD & Linearity (online & offline calculation).
- Keys & Display : 7" TFT.
- USB (4), Rs232, Balance interface, Parallel Printer, PC connectivity through Ethernet

Whiz - 2

- Corrosion resistant fiber body.
- Compact design.
- Interchangeable burette module for quick change from one titration to another, with burette recognition.
- Facility to eject defined volume with dose step & delay time selection along with simultaneous display of mv.
- Auto Start of titration only after addition of sample weight as per GLP.
- Result Report with EP ml & corresponding mv along with automatic calculation in desired units using Formulae Constants.
- Provision for correction for burette volume. (Burette factor).
- Document format report print out which can be directly filed.
- Alphanumeric entry possible for sample name, batch number, operator name etc.
- Built-in software with multilevel password.
- (Levels) with admin defined access control for each user, Audit Trail, E-signature etc. & group policy for user management.
- Provision for data backup on local drive, Server or pen drive.

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Analytical Instruments and Laboratory Equipment: Trends & Developments

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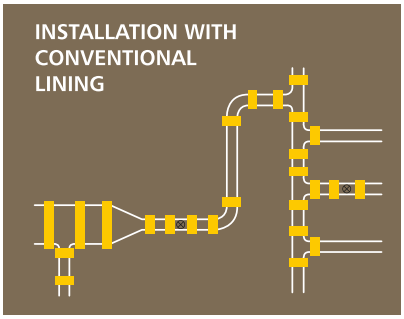
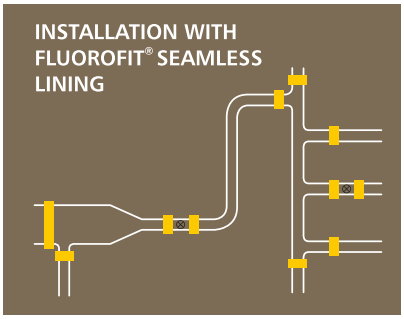
- FDA Complaint





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FEATURES & BENEFITS:

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- Optional Bar Code Scanner

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- Accessory Detection with Bar Code Detection
- Magnetic Coupling Attachment (replaces EZ-Lock)
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- LIMS Connectivity
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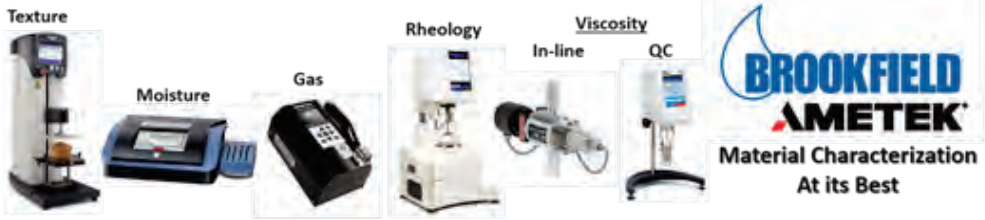

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Hetero launches the first-ever 'Patient Compliant Pack' of Favivir 800/200

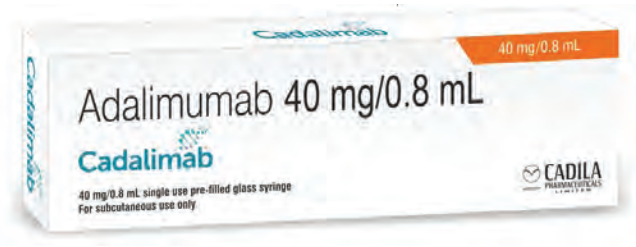
Favivir 800/200 will be available in a patient-friendly pack containing 16 tablets of Favipiravir 800mg & 2 tablets of Favipiravir 200mg, which is priced at Rs. 2640/-.

The higher strength of Favipiravir 800 mg from Hetero has been approved by the Drug Controller General of India (DCGI). The product will be marketed and distributed by Hetero Healthcare Limited.

The launch of 'Favivir 800/200' is aimed at enhancing patients' adherence to treatment regimen by reducing the number of pills they are required to consume per day. The initial regimen of Favipiravir 200mg requires patients to consume a total of 122 tablets for the 14-day treatment course. However, with the new Favivir 800/200 pack, the pill intake number is reduced to 32 tablets, effectively cutting down the pill burden by nearly 75%, leading to better treatment outcomes.

Favivir is the second drug developed by Hetero after Covifor (Remdesivir) used in the treatment of Covid-19. It is an oral antiviral medication that has shown positive clinical outcomes. The product will be made available at all retail medical outlets and hospital pharmacies across the country and sold only on prescription.

Cadila Pharmaceuticals launch Cadalimab™ for India



Cadila Pharmaceuticals announced the launch of Adalimumab biosimilar under the brand name Cadalimab™ for the domestic market. Adalimumab is a disease-modifying antirheumatic drug and a monoclonal antibody that works by inactivating tumor necrosis factor-alpha (TNF) recommended in the treatment of many diseases.

Adalimumab, popular under the brand name Humira® by Abbvie is used to treat rheumatoid arthritis, psoriatic arthritis, Ankylosing Spondylitis and psoriasis. In an effort to strengthen the biosimilar product portfolio, Cadalimab™ is the fourth biosimilar launched in the last 2 months by Cadila Pharmaceuticals.

Cadalimab™ is available in 40mg/0.8ml injection and has shown to have significant reduction in signs and symptoms of Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Psoriasis after the usage of Cadalimab™.

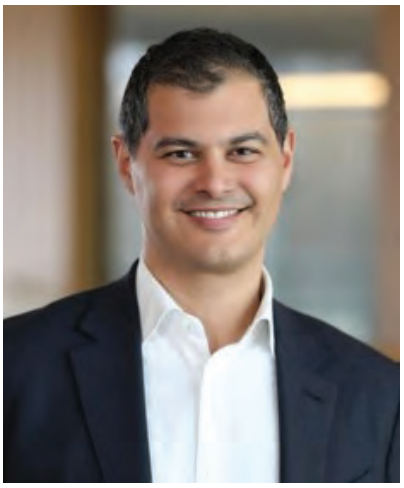
Cadila Pharmaceuticals recently launched 3 more biosimilar products in the last 2 months under the name Bevaro™, Ritucad™ and NuPTH for treatment of cancer and osteoporosis. The pharma giant has always been focused on making sure high quality, affordable and life-saving treatments are within the reach of patients. Cadila plans to launch multiple biosimilar products this year for the Indian Market.

Cytel acquires Laiya Consulting

Dr Yuan Ji, Co-founder of Laiya Consulting

Cytel Inc. has announced the acquisition of Laiya Consulting, a drug development solutions company specializing in Bayesian adaptive trial designs and implementation. The acquisition further builds Cytel's dedicated team of Bayesian experts to include several new and highly esteemed biostatisticians led by renowned Bayesian design specialist Dr Yuan Ji, who also jointly holds an appointment as Professor of Biostatistics at the University of Chicago. The deal follows the recent release of Cytel's East Alloy platform for easy access to verified Bayesian tools, and marks the latest step in Cytel's commitment to broadening industry access to the most innovative clinical trial design methods.

Faced with an increasingly competitive drug development landscape and the catastrophic financial consequences of product failure, drug developers are seeking better ways to boost success rates, accelerate timelines and reduce costs. Deploying Bayesian and other innovative methods provides an attractive option to efficiently progress clinical trials, offering the ability to leverage prior clinical information and accommodate adaptive approaches. However, the computational power, time and expertise needed to implement such methods has, until now, been a significant barrier to their widespread adoption.



Yannis Jemiai, Chief Scientific Officer at Cytel

Founded in 2010, Laiya Consulting has supported drug developers to drive success rates and maximize portfolio returns through the design and implementation of Bayesian adaptive trials, robust clinical strategies, and integrated software platforms. Laiya pioneered the delivery of trial design software using SaaS, which aligns with Cytel's goal of making all its design software available as a cloud-based service.

Signing of MoU between IACP & ACPE

The India Association of the Colleges of Pharmacy (IACP) has announced signing of a MoU with the Accreditation Council for Pharmacy Education (ACPE) to build cooperation to advance the quality of pharmacy education internationally. The MoU was signed on 1st August, 2020, by Janet P. Engle, Executive Director and Michael A. Mone, President, Board of Directors, of the ACPE and by Prof. B. Chinaswamy, President, and Dr. B. Jayakar, Secretary, of the IACP.

The MoU marks the coming together of associations dedicated to realising combined goals of standardising pharmacy education and elevating the canons and importance of the role of pharmacists. Equipped with years of learning and experience in their respective markets, both IACP and ACPE are now poised to achieve their goals by focusing on upgrading education, upskilling, and

employing the latest advancements in science and technology to the benefit of both students and practitioners.

The MoU coverage is focused on knowledge transfer in the areas including quality assurance standards, policies and procedures and tools and publications. Both associations are also enthusiastic about exchange visitor programs that will help them to observe in-depth each other's operating processes. The partnership entails no financial commitment on part of either association and is non-exclusive, thereby allowing both organisations to successfully continue existing collaborations.

Marksans Pharma appoints Dr Meena Rani Surana as Independent Woman Director

Marksans Pharma has appointed Dr Meena Rani Surana as an Independent Woman Director of the Company for a term of five consecutive years with effect from September 3, 2020. It is subject to the approval of the members at a general meeting

She is Bachelor of Pharmacy and PhD in Pharmaceutics from Indian Institute of Technology, BOO, Varanasi, India and has done a Post-Doctoral Fellowship in Pharmaceutics from Department of Pharmaceutics, University of Minnesota, Minneapolis, MN, US.

She has about 27 years of experience in pharma regulatory affairs, quality assurance, formulation and pre-formulation. Currently, she is practising as a consultant in the above fields. Dr Surana has published research articles in reputed international journals and presented research work at several conferences. She is a reviewer of internationally renowned pharmaceutical journals, including Journal of Pharmacy & Pharmaceutical Sciences (JPPS), AAPS Pharm SciTech and Pharmaceutical Research. She is affiliated to the American Association of Pharmaceutical Scientists and Indian Pharmaceutical Congress.

HMD Scaling up Production to 1 Billion Auto Disable Immunization Syringes to help in Covid-19 Vaccination

Hindustan Syringes & Medical Devices Ltd (HMD), one of the largest manufacturers of Disposable Syringes in the World and the largest for Auto Disable syringes with annual capacity of around 700 million auto-disable syringes for vaccination is scaling up production to a billion in the first half of 2021 as India gets ready for COVID-19 Vaccine.

"We have received orders from UNICEF to increase our supply of immunization AD syringes to the organisation to around 300 million to build up a stockpile of around 140 million syringes for Covid-19 by the end of the year" said Mr. Rajiv Nath, Managing Director of Hindustan Syringes & Medical Devices Ltd. "We are waiting on the Indian government to start creating a stockpile of syringes as being done by other Countries. Should the government need 100 million auto-disable syringes for Covid-19 vaccines by the end of this year, we can easily offer them to lift the outstanding orders placed with us." added Mr. Rajiv Nath.

The outbreak of COVID-19 has shifted the importance and focus to single use disposable consumables from reuse consumables and especially a change has been seen in higher deployment of auto-disable syringes even for curative injections. WHO and UNICEF also recommend that auto-disable syringes be used for administering vaccines— particularly in mass immunization programs.

At the same time, HMD, which owns DispoVan and Kojak brands of syringes fears that while it's an opportunity it also makes them nervous. "In past we did gear up to produce these as the largest manufacturer in world for AD Syringes only to find Indian Govt. buying from

China at L1 rates and expected us to match these non-remunerative rates,"explained Mr. Rajiv Nath.

With over 9 plants, HMD has created a niche for their disposable syringe —DISPOVAN which is today the most popular brand in syringe market in India with over 60% market share with Dispovan Needle and Disposable Insulin Syringes having over 70% Market Share and thereby displaced renowned MNC's – an inspirational case study for other Indian entrepreneurs.

CORONA Remedies picks up stake in La Chandra Pharmalab

Ahmedabad-based pharma major CORONA Remedies Pvt. Ltd. has picked up a minority stake in Gujarat-based Hormone API manufacturer La Chandra Pharmalab Pvt. Ltd. as a part of a strategic collaboration between the two companies.

La Chandra Pharmalab is an EU-GMP compliant API manufacturer having its production facility in Palanpur in north Gujarat. It has emerged as a leading manufacturer & supplier of pregnancy care drug Progesterone in India and holds international regulatory approvals for a range of Hormone APIs.

Commenting on the development, Priyvrat Gadhvi, Managing Director, La Chandra Pharmalab, said, "This collaboration heralds a new phase of exponential growth for us. Our technical capabilities and expertise in sunrise technologies in API manufacturing shall be greatly augmented with CORONA's market strength. This alliance will also help us leverage our strong pipeline. The deal comes at the perfect time for us with a combination of macro parameters such as high demand, technology, Indian manufacturing and regulatory strengths defining an inflection point in our growth journey."

CORONA Remedies makes a range of products for gastrointestinal therapy, pain therapy, cardiovascular therapy, gynaecological therapy, among others.

Mr. Nirav K. Mehta, Promoter & Executive Director, CORONA Remedies, said "The deal signals backward integration and thrust on Hormone Therapeutics for CORONA, and is an important milestone in our growth journey. With its dynamic growth, focus on niche APIs and strong technical expertise, La Chandra Pharmalab is the ideal collaborator for us. We are excited about the prospect of developing a range of high-potential products with this tie-up."

APIS Assay Technologies Ltd acquirers Beogenomics

Inside the laboratories at APIS - a Class 2 safety cabinet, where the company handles infectious material or potentially infectious materials.

APIS Assay Technologies Ltd, a company combining outstanding In Vitro Diagnostics (IVD) experience with integrated AI to develop biomarker-based diagnostic assays, have announced the acquisition of Beogenomics, a specialised software developer with major expertise in Bioinformatics and Artificial Intelligence (BIOX).

Beogenomics has been developing both on-prem and secure cloud-based data

analysis solutions - helping customers design, build and run custom tailored genomics & proteomics pipelines. The start-up with amazing capability will be integrated into Manchester-based APIS, supporting the launch of a new BIOX Service Line as part of the company's ongoing Biomarker Research and Development activities.

APIS develops new tests for the prediction, prevention, and diagnosis of disease from discovery to regulatory approval. The company's business model is based on three pillars: biomarker diagnostics development, molecular diagnostic contract development, and applied bioinformatics.

Bioinformatics and Artificial Intelligence are key competencies adding value to APIS' in-house capabilities and expanding APIS' service offer profile. Using AI-enabled data mining, the company aims to identify novel biomarkers, targeting oncology, inflammatory, autoimmune, infectious disease, and inherited disease areas. A tried and tested partner, Beogenomics will be fully integrated into the APIS workflow to strengthen the company's business capacity needs, creating scope for a BIOX service line capable of delivering added value to APIS customers. The company's structured R&D programme adopts a 'portfolio model' towards biomarker characterisation, linking the generated biomarker to data in relevant external datasets.

Wellcome and Ripeta partner to assess dataset availability in funded research

Ripeta and Wellcome are pleased to announce a collaborative effort to assess data and code availability in the manuscripts of funded research projects. The project will analyze papers funded by Wellcome from the year prior to it establishing a dedicated Open Research team (2016) and from the most recent calendar year (2019). It supports Wellcome's commitment to maximising the availability and re-use of results from its funded research.

Ripeta, a Digital Science portfolio company, aims to make better science easier by identifying and highlighting the important parts of research that should be transparently presented in a manuscript and other materials. The collaboration will leverage Ripeta's natural language processing (NLP) technology, which scans articles for reproducibility criteria. For both data availability and code availability, the NLP will produce a binary yes-no response for the presence of availability statements. Those with a "yes" response will then be categorized by the way that data or code are shared.

Wellcome sees the collaboration as a way to enhance the work it already sought to do. David Carr, Programme Manager for Open Research at Wellcome said: "The availability of data and code underlying published research findings is a critical element in ensuring the research can be properly scrutinized, replicated and built upon. This collaboration gives Wellcome the information it needs to push forward on its commitment to more robustly report research outcomes."

PCR Biosystems launches RiboShield™ RNase Inhibitor

RiboShield™ RNase Inhibitor

PCR Biosystems has launched RiboShield™ RNase Inhibitor. Already an important component of several PCR Biosystems kits, this robust and reliable RNase inhibitor is, for the first time, available as a standalone product. RiboShield™ RNase Inhibitor is a recombinant protein that blocks the activity of a wide range of ribonucleases to reliably protect RNA from RNase digestion. The inhibitor is designed for use in a variety of RNA-sensitive applications including RNA purification, cDNA synthesis, RT-PCR, RNA sequencing, and in-situ hybridization. With such techniques, the presence of even small amounts of RNase can be highly detrimental to RNA quality and experimental outcome. RiboShield™ RNase Inhibitor also complements PCR Biosystems's range of products to support COVID-19 research and testing.

One new application for RiboShield™ RNase Inhibitor is in saliva-based testing for the presence of SARS-CoV-2. This is currently gaining popularity as it is easy for people to collect their own samples with minimal discomfort compared with the standard nasopharyngeal swab. While the sample is simple to obtain, the digestive enzymes present in saliva make for a hostile environment for RNA. Using an RNase inhibitor is essential to provide adequate RNA protection and generate accurate test results.

RiboShield™ RNase Inhibitor performs over a wide variety of reaction conditions and can inhibit RNases at temperatures up to 65°C for at least 30 minutes. The molecule binds noncovalently at a ratio of 1:1 to inhibit the activity of a range of ribonucleases, including eukaryotic RNases of the neutral type (RNases A, B and C). The inhibitor does not hinder other enzymes, such as reverse transcriptases, RNA polymerases or Taq DNA polymerase, making it compatible with many enzymatic reactions that utilise RNA. In addition, the very rapid kinetics of association to RNases guarantees immediate protection of RNA, leading to significantly better performance in applications where RNase contamination is a concern. The RiboShield™ RNase Inhibitor protein is purified from a strain of Pichia pastoris that expresses a modified human placental gene.

Sygnature Discovery and RenaSci strengthen drug abuse leadership with appointment of Dr Andy Mead

Dr Andy Mead, Director and Head of Drug Abuse and Substance Use Disorders.

Sygnature Discovery, a world-leading integrated discovery and pre-clinical solutions provider, has appointed Dr Andy Mead as Director and Head of Drug Abuse and Substance Use Disorders at its integrated in vivo pharmacology company, RenaSci.

With 25 years' experience in the science of drug abuse and addiction across academia, biotech and pharma (including NIDA, Merck, Pfizer and AstraZeneca), Dr Mead brings strategic and scientific leadership to a well-established team of drug abuse specialists, and will drive the development and expansion of the company's non-clinical drug abuse and substance use disorders capabilities.

For Sygnature and RenaSci customers, this senior appointment adds a rare depth of expertise around non-clinical assessment and regulatory strategy, with Dr Mead bringing extensive experience across a wide range of abuse liability assessments, and will ensure expert collaboration and consultancy in meeting the regulatory requirements for drug abuse assessment during the development of novel therapeutic agents.

PrecisionLife announces appointment of SVP of Healthcare & Head of US Operations

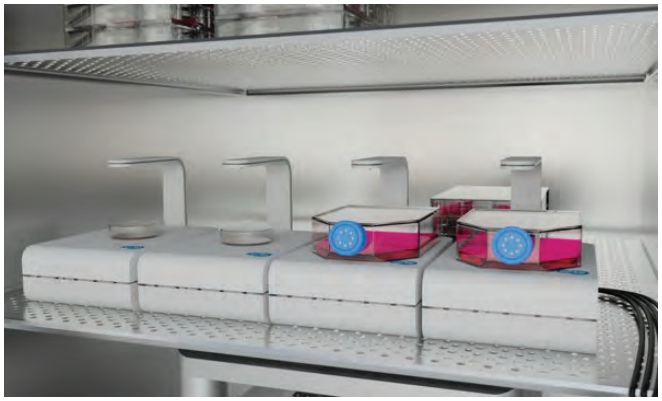
Simon Beaulah, SVP of Healthcare and Head of US Operations.

Precision medicine company PrecisionLife has appointed Simon Beaulah as SVP of Healthcare and Head of US Operations. Simon's appointment demonstrates the company's focus on developing the US market and its commercial profile within the healthcare and precision medicine fields. Simon brings with him a wealth of experience, having spent more than 20 years leading product and business strategy and teams for innovative informatics businesses in the healthcare and life science ecosystems.

Most recently, Simon was Director of Healthcare at Linguamatics, leading their healthcare business unit for seven years, driving their go-to-market and partnering strategy, product focus, and supporting the integration into IQVIA. The healthcare unit achieved significant commercial success during that time, showing consistent and

substantial annual average growth. Prior to that, he spent five years at InforSense and IDBS leading product marketing efforts and served as Marketing Director of Translational Medicine at IDBS Healthcare.

CytoSMART Technologies announces the launch Multi Lux



Combining 4 compact Lux2 devices into one system increases throughput and lab functionality.

CytoSMART Technologies announced the launch of a new automated live-cell imaging system designed for long-term experiments, comparison studies, and large laboratory teams. The CytoSMART Multi Lux is a cost-effective solution for researchers who want to carry out side-by-side comparisons between cell cultures, run long-term experiments, and monitor cells from their home's comfort.

Said Joffry Maltha, CEO at CytoSMART Technologies "An advanced live-cell imaging system consisting of four mini digital microscopes supported by automated image analysis software is especially useful for research groups that have been negatively impacted by COVID-19 restrictions and want to find new ways to continue their research. No matter how big your laboratory team is, this new Multi Lux technology lets scientists run up to four experiments simultaneously from inside the incubator at perfect culture conditions. Automated image analysis and immediate visualization of the results are accessible remotely via the CytoSMART Cloud. Besides, researchers who need to culture cells for weeks or even months, can also benefit from this long-term live-cell imaging solution without fear of needing to throw away cells because of failed experiments."

The main features and benefits of the CytoSMART Multi Lux include:

- Four sample stages for simultaneous side-by-side comparison
- Long-term non-invasive, label-free image analysis
- Full remote access: possibility to inspect cell cultures while working from the comfort of home
- Suitable for large laboratory teams
- Cost-effective solution: four imaging devices connected to a single laptop, including unlimited storage

SCHOTT AG appoints new MD for Indian pharma glass business

SCHOTT Glass India's new MD, Pawan Kumar Shukla

SCHOTT AG has announced Pawan Kumar Shukla as the new Managing Director for

SCHOTT Glass India. Shukla brings over 25 years in the glass, lighting, pipes and electronics industry and comes with a strong background in techno-commercials. An alumnus of the prestigious Indian Institute of Technology, Kanpur, in ceramic engineering as well as material science and metallurgy, Shukla has also worked with Corning JV in the CRT Division as a manufacturing head for twelve years.

At the Jambusar facility, Shukla's main aim would be to achieve the full potential of his team by empowering them with responsibility, trust and acknowledgement.

Presently, SCHOTT is delivering its highly specialised Fiolax® glass tubes to leading pharma packaging players in India and abroad for preparing primary packaging products such as vials, syringes, etc. Supporting the world's fight against COVID-19 with vials capable of holding up to 2 billion vaccination doses, the German leader has reached agreements and started supplying to leading pharmaceutical companies including key players in India.

Given the exponential rise in demand for quality glass for pharma packaging, SCHOTT had inaugurated a new tank facility in its Jambusar plant, following an investment of €21 million in 2018. Even before the Coronavirus pandemic, the company had forecasted a rapid growth trend, and had thus committed additional investments of €26 million for yet another tank facility last year. With a combined investment of €47 million and two new plants, SCHOTT's India plant is well on track to double its production capacity, enabling supply of its FIOLAX® glass tubing for both domestic and export demands.

Post-pandemic Contract Research Organization Market to Reach $63.83 Billion by 2024, Says Frost & Sullivan

Frost & Sullivan's recent analysis, Hybridization of Clinical Trial Designs Reviving Global CRO Market Post-pandemic; 2019-2024, reveals that hybrid clinical trials and remote patient monitoring are key trends driving the global contract research organization (CRO) market. However, with the increased threat of COVID-19 and worldwide lockdowns in effect, the CRO market is experiencing interruptions in ongoing clinical trials and delays in new trials. Recovery is expected to commence from 2023; although it will be staggered, it will take revenue to the original growth trajectory by 2024–2025. As per the revised forecast after the impact of the COVID-19 pandemic, the market is estimated to garner revenue of $63.83 billion by 2024 from $43.03 billion in 2019, at a compound annual growth rate (CAGR) of 8.2%.

"Due to the impact of the coronavirus, many large pharmaceutical companies have placed new trials on hold and numerous small, mid-size, and large enterprises have suspended ongoing ones, thereby demonstrating the magnitude of the disruption," said Unmesh Lal, Transformational Health Industry Principal at Frost & Sullivan. "Going forward, to minimize the adverse effect of the pandemic,

organizations such as site management organizations (SMOs) and patient recruitment organizations (PROs), that operate traditionally, will have to explore collaboration opportunities with emerging virtual trial platform vendors, eRecruitment providers, and remote monitoring solutions providers to expand the capability to support distributed/ hybrid CT models."

Lal added: "Owing to COVID-19, pharmaceutical companies' revised research and development (R&D) spending is expected to decrease by 2%–3% in comparison to the original forecast. This will affect outsourcing to CROs and further decrease revenue across both segments—drug discovery and preclinical. Further, from a regional perspective, North America and Europe will be the most affected. However, rapid recovery is anticipated due to the proliferation of new clinical trial approaches/models, which make use of virtual trial tools and evolving regulatory policies. Similarly, Asia-Pacific (APAC) will also recover when sites go online as the pandemic eases. The rest of the world (ROW), however, will see a slow recovery period because of correspondingly slower adoption of clinical trial IT solutions."

Hybrid trials are taking center stage during the COVID-19 pandemic, presenting immense growth prospects for CRO market participants by:

- Enabling uninterrupted trials and cost savings of 15%–20%.
- Focusing on long-term collaborations that offer substantial cost advantages with 8%-13% savings across different trial phases.
- Leveraging new technologies, such as risk-based monitoring, eConsent, wearables, and telemedicine patient visits for virtual trials.
- Implementing the direct-to-patient model to ensure the continuity of clinical supplies by partnering with supply chain specialists.

Thermo Fisher Scientific Announces Collaborations

Thermo Fisher Scientific, the world leader in serving science, today announced new collaborations of the Thermo Fisher Precision Medicine Science Center (PMSC) with AstraZeneca and the University of Nebraska Medical Center as part of its ongoing development of innovative solutions for unmet needs in clinical biomarker discovery. The new alliances strengthen the PMSC's mission of creating standardized workflows with pharma and academic partners to streamline the transition from biomarker research to clinical implementation, creating new opportunities for precision medicine.

"Precision medicine is becoming a greater area of interest across a range of different diseases and has, therefore, faced challenges effectively scaling to meet clinical needs," said Emily Chen, senior director, Precision Medicine Science Center, Thermo Fisher Scientific.

Ongoing and planned studies with both AstraZeneca and the University of Nebraska Medical Center will utilize standardized plasma protein profiling workflows, including Thermo Fisher's newly developed ultra-high throughput plasma protein profiling (uHTPPP) workflow, for biomarker discovery, for a range of conditions. The standardized workflows consist of automated sample preparation for untargeted and targeted methods in combination with the Thermo Scientific Orbitrap Exploris 480 and Thermo Scientific Orbitrap Exploris 240 mass spectrometers.

Subsequently, the University of Nebraska Medical Center is collaborating with Thermo Fisher's PMSC to utilize the company's standardized plasma protein profiling workflows to analyze clinical samples in an aneurysm study. The study is supported by the National Institutes of Health-National Institute

on Aging (NIH-NIA) and done in collaboration with Vanderbilt University, the University of Maryland and the University of Wisconsin.

Arctoris and Syntekabio form research partnership

Arctoris, the creator of the world's first fully automated drug discovery platform, has signed a MoU with listed Korean company Syntekabio, Inc. to collaborate on drug discovery efforts. The first project under the agreement sees the two companies work together to assess small molecule therapeutics for COVID-19.

The MoU brings together two highly complementary technologies: Syntekabio is a leading AI-driven drug discovery company that uses machine learning and supercomputing to discover new drugs, and Arctoris is a British technology company that has developed a fully automated drug discovery platform enabling rapid generation of high-quality drug discovery data. Syntekabio will use Arctoris' unique technology platform for biochemical and cell-based experiments including target-based assays and viability assessments.

Access to the Arctoris platform enables the company's clients and partners to conduct their drug discovery processes in full automation. Available services include dataset generation for AI model training and validation, hit-to-lead, lead optimisation and candidate selection.

Under the terms of the MoU, Syntekabio and Arctoris work together to identify and screen a series of potential candidate molecules for COVID-19 treatment, not only saving development time, but also ensuring a greater degree of confidence in the experimental results.

The MoU with Syntekabio is the latest in a series of partnerships formed by Arctoris this year, which includes publicly announced partnerships with Insilico Medicine and Molecule. Financial details were not disclosed.

SPT Life Sciences Announces Acquisition of LBD Life Sciences

SPT Life Sciences, a global group of innovative technology companies focused on supporting the life sciences industry to deliver more effective research, has today announced the completion of the acquisition of LBD Life Sciences, a leading supplier of instrumentation to the drug discovery market in China. SPT Life Sciences backed by technology-focused investment firm Battery Ventures, had previously held a minority stake in LBD Life Sciences. This latest deal sees the purchase of all remaining shares.

As a result of this acquisition SPT Life Sciences extends its commercial reach into the rapidly growing Chinese life sciences research market. LBD Life Sciences will join the family of companies including SPT Labtech Ltd and Quantifoil who together will be better placed to meet the rapidly evolving needs of the Chinese research community.

Patrick Bennett, Group CEO of SPT Labtech, said, "We are delighted to complete the deal and we are very excited to bring LBD into the group. This investment highlights SPT Life Sciences commitment to developing a global portfolio of companies with a range of specialisms that help life science professionals world-wide to achieve their research goals. For over 10 years the team at

LBD have supported the growing life science research community in China and we believe that this investment will ensure they are able to do so going forward."

Medovate's game-changing anaesthesia device SAFIRA® receives European CE regulatory approval

A revolutionary new technology that transforms regional anaesthesia into a one-person procedure

Alan Finnerty, Technology Director, Medovate, with the certification.

SAFIRA® is a revolutionary new technology that transforms regional anaesthesia into a one-person procedure, putting control in the hands of the anaesthetist. The Class II medical device provides a unique safety solution that monitors and limits injection pressure, helping to improve patient safety by reducing the risk of nerve damage following injection. In addition, economic modelling shows it has the potential to generate significant time and cost savings.

Alan Finnerty, Technology Director, Medovate commented, "We are thrilled to announce CE mark approval for our pioneering technology. Given the significant benefits SAFIRA® brings to both clinicians and patients, we are confident that our ability to enter the European market will help deliver improved outcomes for patients undergoing regional anaesthesia procedures, as well as generate unique cost optimisation benefits for healthcare."

Developed in collaboration with anaesthetists in the UK National Health Service (NHS), the device was successfully launched in the US earlier this year, having secured FDA clearance, bringing Medovate's first medtech innovation to market.

Successful CE certification marks a key milestone for the fast-growing company, itself established just over two years ago. As a UK-based enterprise, this regulatory approval is essential as it continues to expand in territories across the world.

The European and American Societies of

Regional Anaesthesia have recently produced joint COVID-19 recommendations stating that regional anaesthesia should be preferred over general anaesthesia whenever surgery is planned for suspected or confirmed COVID-19 patients. This is because regional anaesthesia, which involves numbing only the area of the body that requires surgery, preserves respiratory function and avoids aerosolisation and the potential for transmission of COVID-19 compared to general anaesthesia. In enabling regional anaesthesia to be carried out as a one-person procedure, Medovate's innovative technology, SAFIRA®, further compliments these recent recommendations.

Now, with both CE Mark Approval and FDA Clearance, SAFIRA® can be readily integrated into healthcare markets across Europe and the US.

US Congressman commends the contribution of SP Industries in the fight against COVID-19

Congressman Brian Fitzpatrick, Republican member of the US House of Representatives addresses employees during the visit to SP corporate headquarters

SP Industries, Inc. (SP), has hosted a visit by US Congressman, Brian Fitzpatrick, who was on a fact-finding mission to find out more about the work SP is doing to support Operation Warp Speed, and discuss SP's plans for increasing capacity and capabilities.

Operation Warp Speed (OWS), an initiative of the US Department of Health & Human Services (HHS), aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. OWS engages with private firms and other federal agencies to coordinate existing HHS-wide efforts, including the National Institutes of Health (NIH)'s Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, and NIH's Rapid Acceleration of Diagnostics (RADx) initiative.

During the tour of the facilities, Congressman Fitzpatrick – Republican member of the US House of Representatives representing PA first district, which includes Warminster, PA, the home of SP corporate headquarters - met with members of the SP Executive Leadership Team. He was briefed on SP's comprehensive design and manufacturing capabilities for pharmaceutical fill-finish equipment and freeze dryers. Freeze drying is often a crucial step in the production of diagnostics, vaccines and biologics, in order to maintain quality and efficacy, as well as extend shelf life. In response to the COVID-19 crisis and OWS, SP has recently scaled-up and re-designed its engineering, production and supply chain in order to complete several large, high-profile, COVID-19-related orders within unprecedented timescales.

Congressman Fitzpatrick addressed SP's on-site employees, thanking them for their efforts in supporting Operation Warp Speed, and explained that they are making a real and tangible difference working on the front lines of the fight against COVID-19. He went on to say how SP's contribution, together with US government departments and other corporations, are providing the tools and capabilities to be successful during this

unprecedented situation.

In appreciation of SP's work providing cutting-edge equipment to diagnostic and pharmaceutical companies, which enables them to manufacture high quality tests and treatments for COVID-19, Congressman Fitzpatrick presented SP's President and CEO, Brian Larkin, with a certificate and a flag that has flown over the US Capitol Building.

Europital launches as a science-driven full service CRO

Europital – a globally-focused full service CRO serving small and mid-tier innovators – announces a significant expansion as it launches new capabilities across project management, clinical monitoring, biostatistics, pharmacovigilance, regulatory affairs and data management, in addition to its existing services of Medical Affairs and Medical Writing. The expanded clinical research offering will see Europital support clients as a full service CRO in over 40 countries from IND through to commercial launch.

Europital has regional offices in Belgium, Hungary and the UK and their customers are based in both Europe and the USA. Innovators developing therapies for oncology, infectious diseases, inflammatory and autoimmune diseases will be the major beneficiaries of Europital's multi-functional and operational capabilities. Sponsors who will particularly benefit are those that require a full range of CRO services for complex molecules and trial designs that necessitate senior medical and scientific oversight.

In addition to its regional offices in Europe, Europital has built a global network of trusted partners over the last 10 years with local operational expertise and preferential supply trial site agreements in the USA, Canada, Russia, India, the Middle East and North Africa and Australia.

Toyo Ink Europe Specialty Chemicals Develops Near-Infrared Sortable Black Masterbatch

Toyo Ink Europe Specialty Chemicals S.A.S. (TIESC), a member of the Toyo Ink Group, has developed a whole new range of Lioplax® black plastic masterbatch for near-infrared (NIR) sorting and subsequent material recovery. The new packaging masterbatch supports the recyclability of black plastic waste that is currently destined for landfill, thus helping our customers in closing the loop on the circular economy.

Presently, plastic waste sorting is based on

automatic optical sorting methods with the majority of sorting equipment relying on the reflectance of NIR wavelengths. Standard black masterbatches are typically produced with carbon black pigments. Since carbon black absorbs infrared light, identification by optical sensors is impossible. This results in undetected black or dark-coloured packaging waste being sent to landfill or incineration. Addressing the recycling issue, TIESC developed a new alternative to standard carbon black masterbatch.

The Lioplax® series of NIR-sorting black masterbatches are specially formulated for use in PP trays, PET preforms, films, bottles and other packaging applications. Different grades are available in varying black color shades, grades of resins (polyolefin, PET) and processing compatibility such as injection, extrusion and blow moulding. The advantage for brand owners is that they can keep their black packaging market product codes whilst becoming more sustainable.

Lioplax NIR-sortable black masterbatch

Sun Pharma Announces the Launch of ILUMYA®

Sun Pharmaceutical Industries Limited announced that its wholly-owned Japanese subsidiary has launched ILUMYA® Subcutaneous Injection 100 mg Syringe (Nonproprietary name: tildrakizumab (genetical recombination), "ILUMYA") in Japan

for the treatment of plaque psoriasis in adult patients who have an inadequate response to conventional therapies.

ILUMYA is a humanized IgG1/k monoclonal antibody designed to selectively bind to the p19 subunit of IL-23 and inhibit its interaction with the IL-23 receptor, leading to inhibition of the release of pro-inflammatory cytokines and chemokines

ILUMYA® product outline

Product name	ILUMYA subcutaneous 100mg syringe
Nonproprietary name	Tildrakizumab (genetical recombination)
Dosage form	Injection (prefilled syringe)
Effect / efficiency	Plaque psoriasis, which does not respond adequately to conventional therapies
Dosage and administration	Normal administration: 100mg of subcutaneous administration to adults as tildrakizumab (genetical recombination) in the first dose, followed by doses 4 weeks later and every 12 weeks thereafter.
National Health Insurance listed price	ILUMYA subcutaneous injection: 100mg syringe 1 cylinder: 487,413 yen
Marketing authorization date	June 29, 2020
Date of listing in the National Health Insurance drug list	August 26, 2020
Launch date	September 23, 2020
Manufacturing Approval holder	Sun Pharma Japan Limited

Hester acquires technology from ICAR - IVRI to develop a new generation Brucella Abortus S19 Delta Per Vaccine

Hester has signed the agreement towards receiving the indigenously developed technology from ICAR-IVRI (Indian Council of Agriculture Research – Indian Veterinary Research Institute), for developing the Brucella Abortus S19 Delta Per vaccine. The agreement was signed through video

conferencing on 22 September 2020.

While Hester is currently manufacturing the conventional Brucella Abortus S19 vaccine and supplying to all the states in India, the S19 Delta Per new generation vaccine technology developed by IVRI will be a step forward towards developing a Brucella vaccine with enhanced safety, immunogenicity, as well as assuring lifelong immunity with a single shot in calf-hood.

The Government of India has planned to immunize 4 crore female calves in India in the first phase against Brucella through vaccination. Hester has been and commits to remain a part of the Government of India's immunization program against Brucella in cattle.

With this vaccine Hester hopes to reach new heights not only within India but also become a channel for immunizing cattle against Brucella, worldwide. The technology is developed by Dr. Pallab Chaudhari and his team from ICAR-IVRI through their relentless efforts as well as support from Biotech Consortium India Limited and The Department of Biotechnology (DBT), Government of India.

Brucella is a disease of economic importance worldwide. Not only does it impact cattle, sheep, goat and swine, but it also gets transmitted to human beings. Incidentally there is no vaccine available to protect humans against Brucella. The animals need to be protected to protect mankind.

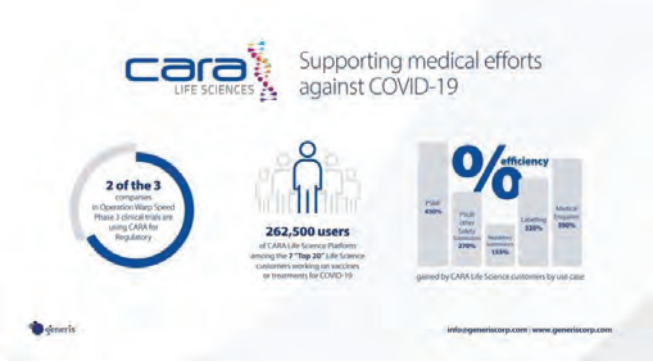
Immunization with Brucella vaccine also helps cattle to remain healthy, thereby improving their milk production. Hester hopes to launch the Brucella Abortus S19 Delta Per vaccine in 18 months.

HCG - Strand Life Sciences Launch StrandAdvantage500

Envisioned to drive a new standard of cancer care, HealthCare Global Enterprises Limited (HCG Cancer Hospital Bengaluru) and Strand Life Sciences launched comprehensive genomic profiling (CGP), an approach to detect multiple actionable cancer biomarkers at 'one go' to optimize treatment for better clinical outcomes. HCG has joined hands with Strand to develop StrandAdvantage500, a simple and comprehensive Next Generation Sequencing (NGS) based assay that analyses cancer-relevant genetic alterations from DNA and RNA derived from a patient's tumor in one integrated workflow.

Comprehensive genomic profiling with StrandAdvantage500 will overcome the challenge of iterative testing with limited biopsy samples and enable us to consolidate the detection of biomarkers into a single assay, thus saving precious biopsy samples, reducing the need of rebiopsy and provides faster and comprehensive results. This innovative approach will help in managing the disease better and design treatment with best possible clinical outcomes.

Two out of three leading COVID-19 vaccine initiatives utilising Generis's Life Science Platform, CARA



Generis, the global leader in content information management systems, is proud to announce that two out of the three leading COVID-19 vaccine initiatives in Operation

Warp Speed are using the CARA Life Science Platform for Regulatory.

The US-driven international initiative to support the rapid development, manufacturing, and distribution of COVID-19 vaccines is progressing with many promising efforts to move towards Phase 3 clinical trials. The CARA Life Sciences Platform, provided by Generis, is helping these Life Science companies to greatly reduce their development and submission cycles while focusing on oversight and compliance with stringent health regulations.

The CARA Life Sciences Platform manages regulated business processes, managing content and data across the core functional areas of Life Science companies. Adoption of this platform has driven process efficiency improvements of up to 450%, greatly reducing time-to-market for regulated products.

Sygnature Discovery expands DMPK capabilities with acquisition of XenoGesis

Dr Richard Weaver, Founder & CEO of Xenogesis with Dr Simon Hirst, Founder & CEO of Sygnature Discovery.

Sygnature Discovery, a world-leading integrated discovery and pre-clinical solutions provider, has significantly expanded its DMPK capabilities and expertise with the acquisition of XenoGesis, the UK's largest independent laboratory-based CRO specialising in pre-clinical DMPK, quantitative bioanalysis, in vitro pharmacology and expert interpretation.

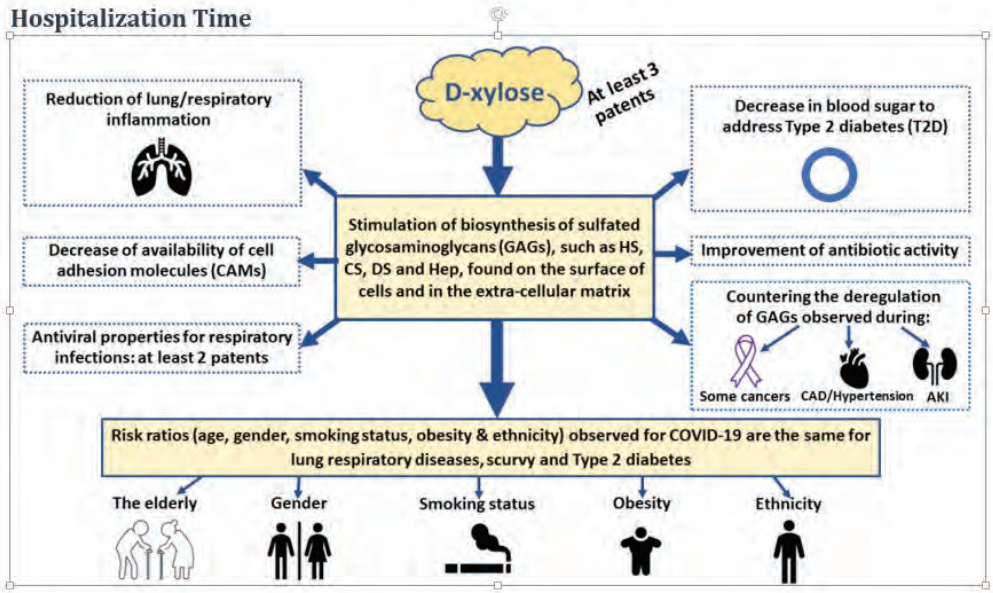
This latest acquisition by Sygnature – which has in recent years broadened its integrated drug discovery offering through the addition of in vivo pharmacology CROs RenaSci and Alderley Oncology – serves to meet both an increasing demand for its services and boost the company's reach into the pre-clinical space.

XenoGesis' novel consultative approach has achieved a strong track record of success since its inception in 2011 through its focus on high quality science and a forward-thinking methodology that always has clinical considerations in mind from the outset of a drug discovery project, resulting in the early prediction of PK and likely human dosage and enabling more successful candidate molecules.

This acquisition effectively doubles the size of Sygnature's DMPK department (established in 2015), broadening Sygnature's discovery and development expertise, complementing its existing service-offering and adding new skills and capabilities.

The companies are both located at BioCity in Nottingham, UK, fitting well with Sygnature's driving ethos of having co-located, multi-disciplinary teams of expert research scientists, working efficiently together, facilitating seamless drug discovery and creating innovative solutions for its partners

D-Xylose Can Potentiate the Antibiotic Treatment of COVID-19 and Reduce Hospitalization Time



An important breakthrough in COVID-19 treatment approaches has been described in a recent review, demonstrating for the first time the unique ability of D-xylose — a naturally occurring sugar and physiological metabolite of vitamin C — to enhance the efficacy of antibiotics, offering a novel therapeutic regimen for the disease. Notably, this new approach has the potential to drive new life-changing discoveries to significantly reduce the hospitalization and treatment duration for patients contracting COVID-19.

Titled "Correlation of D-xylose with Severity and Morbidity-Related Factors of COVID-19 and Possible Therapeutic Use of D-xylose and Antibiotics for COVID-19", the review unravels the pharmacological significance of D-xylose, highlighting its superior anti-inflammatory, antiviral, anti-hyperglycemic and anticancer properties. Furthermore, the review deduces that D-xylose provides a solid explanation for at least 21 symptoms, biomarkers, therapeutic pathways and risk ratios associated with severe COVID-19.

"Ever since the COVID-19 pandemic started, there has been a multi-thronged pursuit to discover antiviral therapies and vaccines to fight the disease," said Antony Cheudjeu, Independent Researcher and author of the review. "Patients are commonly treated with nonsteroidal anti-inflammatory drugs (NSAIDs), the prolonged use of which could cause health problems. It is, therefore, essential to develop alternative therapeutic approaches that are safe to use, while also drastically reducing hospitalization time for critically-ill patients. This review highlights the importance of ensuring D-xylose levels in blood remain at a high enough concentration to strengthen the immune defence against viral infections such as COVID-19 and the associated inflammation of the lungs. When used in combination with antibiotics, D-xylose holds great promise for safe and effective COVID-19 treatment."

The therapeutic properties of D-xylose are enabled as a result of its ability to stimulate the biosynthesis of chains of sulfated glycosaminoglycans (GAGs), especially heparan sulfate (HS). GAGs are present on the surface of cells and facilitate the binding of viral particles and subsequent entry into the cells. By stimulating the synthesis and secretion of HS, D-xylose helps to limit the attachment of viral particles to syndecan core proteins where HS is fixed and which also serve as attachment receptors of SARS-CoV-2 in addition to ACE2, thereby retarding the progress of viral pathogenesis. This role of D-xylose has not been recognized and brought to light before, marking a significant discovery.

Importantly, the review reveals that common risk ratios, including age, gender, smoking status, obesity and ethnicity, are not specific to COVID-19, but apply to several other pathologies, such as scurvy, lung diseases/ infections and Type 2 diabetes. Considering that GAGs play an important role in many of these pathologies, D-xylose likely has therapeutic effects for these diseases as well. "In addition to COVID-19 treatment, this review, published in the esteemed peer-reviewed journal "Life Sciences", opens new avenues for developing therapies for a wide range of life-threatening diseases," added Cheudjeu. "From Type 2 diabetes, cancer, hypertension, cardiovascular diseases and acute kidney injury, to bacterial and viral infections interacting with GAGs on the surface of cells, the possibilities are limitless."

Centaur Pharmaceuticals launches a New Chemical Entity (NCE) – 'WOXHeal®' in the treatment of Diabetic Foot Ulcer

Centaur Pharmaceuticals announced the launch of a New Chemical Entity (NCE) – WOXheal® – for the first time in the world. With its dual mechanism of action, WOXheal® is a unique product in the treatment of Diabetic Foot ulcers, and it will save millions of Diabetics who have to undergo foot amputation globally.

WHO predicts that there will be 10 crore Indians with Diabetes in the next 10 years. Amongst other complications of Diabetes; Diabetic foot ulcer is the most common complication seen in India. Apart from the fact that diabetic foot ulcers are non-healing, they not only hamper the Quality of life of the patient, but may also lead to complications such as wet gangrene, cellulitis, abscess and necrotizing fasciitis all leading to a total or partial foot amputation. Data indicates that 25% of people with Diabetes, will develop a Diabetic Foot Ulcer in their lifetime. 1 in 5 Diabetics who are hospitalised due to severe foot infection, undergo a foot amputation affecting the livelihood of the family.

Speaking on this occasion, Mr. S. D. Sawant, Chairman and MD of Centaur Pharmaceuticals, said, "We, at Centaur Pharmaceuticals were deeply concerned with the alarming rate of foot amputations in India, and wanted to discover a drug to prevent it. Fifteen years ago, we collaborated with CytoTools AG, Germany, who had this promising molecule for the treatment of Diabetic foot ulcer. We are very happy to offer this ray of hope to people with Diabetic foot ulcer in India."

A globally patented product, WOXheal® topical solution, is effective in treating Diabetic foot ulcers. WOXheal® contains the NCE, Diperoxochloric acid, also called as DPOCL. WOXheal® has dual mechanism of action, i.e. it has functional antibacterial action against Gram positive and Gram negative bacteria and it also promotes growth of fibroblast cells, thereby yielding complete wound closure.

Randomized clinical trials conducted across India in over 15 clinical trial centres on WOXheal® elucidated that over 90% patients with non-healing diabetic foot ulcer showed reduction in the size of the ulcer, and 75% out of these patients achieved complete healing within 6-8 weeks without any safety issue. The data and outcomes of the trial were submitted to the Indian Regulatory Authority and a manufacturing and marketing approval was granted to Centaur Pharmaceuticals for WOXheal®.

This pioneering effort by Centaur Pharmaceuticals, for an unmet medical need, enhances India's stature as a self-reliant nation and a Pharma super-power. WOXheal® will be readily available in the entire country by the end o

Digital Science's Dimensions has partnered with Google Cloud

Digital Science has partnered with Google Cloud to remove barriers to data access, analysis and visualization for organizations across the research and innovation ecosystem. With its new integration, the Dimensions database is now available to be analyzed on BigQuery, Google Cloud's server-less, highly scalable and secure multi-cloud data warehouse.

In today's environment, stakeholders in the research and innovation ecosystem are seeking to make better, evidence-based decisions. To do this, they need greater access to contextual information, while at the same time protecting the security of their own data. The combination of technologies like those of Dimensions and BigQuery directly addresses this fundamental need, and creates a new infrastructure for organizations across the full Research & Development lifecycle.

Dimensions provides a comprehensive view of the research and innovation landscape. Updated daily, it currently contains 112m publications linked to 1.3bn citations, 5.5m grants worth $1.7 trillion in funding, 41m patents, 600k clinical trials, over 120m Altmetric data points - and more.

BigQuery provides companies with a modern, server-less and highly scalable data warehouse. Through the integration with Dimensions, it gives these joint users an unprecedented flexibility to access the data in Dimensions, but also allows anyone in the research world to connect external datasets to Dimensions privately and securely. These datasets could be an organization's own private data, or important scientific databases such as ChEMBL.

Direct integration with business intelligence and data visualization tools, such as Tableau, Qlik and PowerBI, means that users can bring Dimensions data together with their own data, and use it for a broad set of use cases, from competitive intelligence through to the assessment of research's social and economic impact. With BigQuery, customers can gain insights with real-time and predictive analytics to support better business decisions, and enables users to create custom dashboards and reports that can be securely accessed and shared across their organization. ■

Analytical Instruments and Laboratory Equipment: Trends & Developments

Prof. Ashwini Nangia
Director, CSIR-National Chemical Laboratory, Pune

The elucidation of molecular structure is necessary to identify and confirm the structural identity of a chemical compound during research and product development. Unknown substances or trace impurities can be extremely difficult to identify. Products in a chemical reaction can arise due to unanticipated rearrangements and cross-reactivity making complete identification a formidable challenge. Chemical structural elucidation of impurities is necessary to support compound regulatory submissions for a number of industrial sectors such as agrochemicals, pharmaceuticals, fine and specialty chemicals, polymers, and new chemical entity registration with regulatory and government bodies.

Various non-destructive analytical techniques are available today which make possible the complete structure determination of a molecule using very small sample quantity and rapid analysis to confirm the structure. Hyphenated techniques such as GC-MS, LC-MS, MS-MS, etc. allow simultaneous compound

purification and spectral characterization in a single operation, thus minimizing any artefact interferences. Advances in instrumentation technologies, the integration of automated data gathering and simultaneous computer analysis have facilitated the structure elucidation of chemical, materials and biochemical. Most recent additions are the integration of experimental data with computer databases and virtual simulation to suggest/ predict probable answers for users.

Pharma Bio World's special focus on Analytical Instruments and Laboratory Equipment: Trends & Developments bring together experts in analytical instrumentation and Industry 4.0 sector to provide the current status and future of this very important segment of the pharma industry.

Mr. Ashutosh Parasnis of QLEAP Academy writes on the most contemporary topic of Industry 4.0 and how this platform will facilitate and stream line analytical instrumentation and manufacturing in pharmaceutical and chemical sectors. He recommends three steps that are critical to initiate Industry 4.0 journey with existing assets, before making larger investments. Dr. K. Srinivas of Ramky Enviro Engineers writes on the present day technology in instrumentation from micro gram to nano and pico gram level, and sample size / analyte going down to micro liter level. Auto sampling and self-calibration of instruments as well as clean background are essential for such high accuracy and precision, as explained for mass spectrometry. Dr Raju Tatituri of Virata Biochem Analytics & Assistant Professor of Medicine, Harvard Medical School, Boston writes about bioanalytical tools and techniques in discovery of biotherapies. The implementation of quadruple and time of flight mass spectrometry hyphenated to liquid chromatography–mass spectrometry instruments has enabled studies on molecular patterns, diagnostic markers, and quick quality checks. The guest column by Prof. P. Reddanna of University of Hyderabad presents a template model for drug discovery and pharmaceutical development research in India. It takes more than US$ 1 billion and a decade to bring a single drug molecule from concept to market. The inter-relationships between modern instrumentation and drug discovery are traced.

The articles are followed by interviews with Amit Chopra of Thermo Fisher Scientific, Dr. Jairam Varadaraj of ELGi Equipments, Rajiv Nath of Hindustan Syringes & Medical Devices, Balaji Sitharaman of Millennial Scientific, and Somesh Sharma of Discovery in GVK Biosciences.

The articles and interviews will update the readers to the latest in analytical instrumentation and R&D and manufacturing technologies. ■

Creating Analytical Instruments 4.0 for a Better World

This article reveals how Industry 4.0 can help Analytical Equipment Manufacturers and Pharma companies to improve their future financial performance, optimise investments and become globally competitive. The author then recommends 3 steps that are critical to initiate Industry 4.0 journey with existing assets, before making larger investments.

Analytical Instruments are used in multiple sectors for varied applications. According to one market research report[1], the global analytical instrument market is expected to grow at a rate of 8.4% CAGR. The analytical lab instruments market would grow at 7.3% and reach $124 billion by 2023. The demand is driven by increased investment in R&D and quality control, while having an emphasis on cost reduction and productivity optimisation. The instruments also help in ensuring that processes adhere to regulations.

Ashutosh Parasnis
Co-Founder - Qleap Academy

mpact on Pharma and Analytical Instruments Industry:

Let us take the example of new product development in Pharmaceutical Industry. The process is an intensive one, given that it impacts lives. Testing, Validation, QC and Compliance are of paramount importance.

At the same time, there is a constant endeavour to get pharma products to the market in shortest period at least cost, both for improving healthcare and business.

What is changing though is the rapid transitioning of Healthcare to a new world of personalisation, with a laser-like focus on outcomes and value. For that, healthcare systems now need to understand additional data of exogenous factors such as environmental influences, behaviour, genetics, treatment outcome etc. to create and deliver value.

Science, Technology and Engineering streams too are converging, creating new opportunities and opening new pathways for doing business.

These changes will continually push pharma companies to adapt to agile research and flexible manufacturing. The need for bringing together traditional and new data through automation creates new growth opportunities for Analytical Instruments sector.

Three paradigm shifts emerge from the above scenario:

- Shift in Patient Experience (Generic to Personalisation)
- Flexible and Fast Innovation (In-house versus Partnership)
- Increased role of Digitalisation (Portable/Wearable/In-house equipment, Automation, Real-time Analytics, Connected Systems)

And these trends are not futuristic. Partnerships are evolving to speed up trials and develop personalised treatment by leveraging digital technologies, with a mix of high/limited volumes. This is evident from the partnerships announced, a few being mentioned below

- Oxford University- Astra Zeneca-Serum Institute (for Covid -19 vaccine)

Figure 1 summarises the shift that is taking place:

Figure 1 : Market forces are compelling pharma companies to adopt an agile and flexible approach while maintaining high quality and rigorous compliance.

- Aravind Eye Clinic- Google[2] (for AI backed health monitoring, beyond eye care)
- Gilead Sciences- Dr. Reddys (For drug manufacturing)

These shifts are perfect candidates for the industry to adopt Industry 4.0[3] practices. At present, ISA-95 configuration of systems is well understood and adopted in the pharma sector.

While the ISA-95 and Industry 4.0 system configurations may appear similar, Industry 4.0 builds next level advantages through automated data aggregation and analytics that create additional insights. For a lab, such enhanced insights can strengthen Real Word Evidence, minimising trial costs and delays. For manufacturing, it can create cost and response advantage where automation is supported by analytics. Importantly, it also addresses how our people can truly add value with their creativity and innovation.

Financial Perspective:

It is but natural for companies to closely monitor its financial health, especially in stressed times. The focus is not on investments, but on revenues, profit and cashflow. But once business stabilises, Industry 4.0 offers opportunities for future financial benefits.

Those companies which have started the journey are focussed on one or more of the following:

- Reducing costs related to transactions, maintenance, energy and waste through automation for improved outcome, process quality, and experience.
- Improve revenue forecast and cashflow management by using data analytics and cloud technology.
- Broaden the revenue generating product mix by designing smart digital solutions.
- Develop technology leveraged business models for revenue and sustained cashflow.

Understanding the Role of Industry 4.0 in your Value Chain:

Industry 4.0 has been initially presented as a technology focussed solution. As a result, the true benefit to process industry was not clear.

In reality, Industry 4.0 is about establishing an active collaborative network, connecting people and integrating processes. The approach enables information exchange that supports industry standards, both within organizations and throughout their value chain.

Figure 2 represents a simplistic version of what the future Industry 4.0 system would look like. It shows the multifunction involvement across the value chain. It also includes partners (CRO, CMO, CSO,

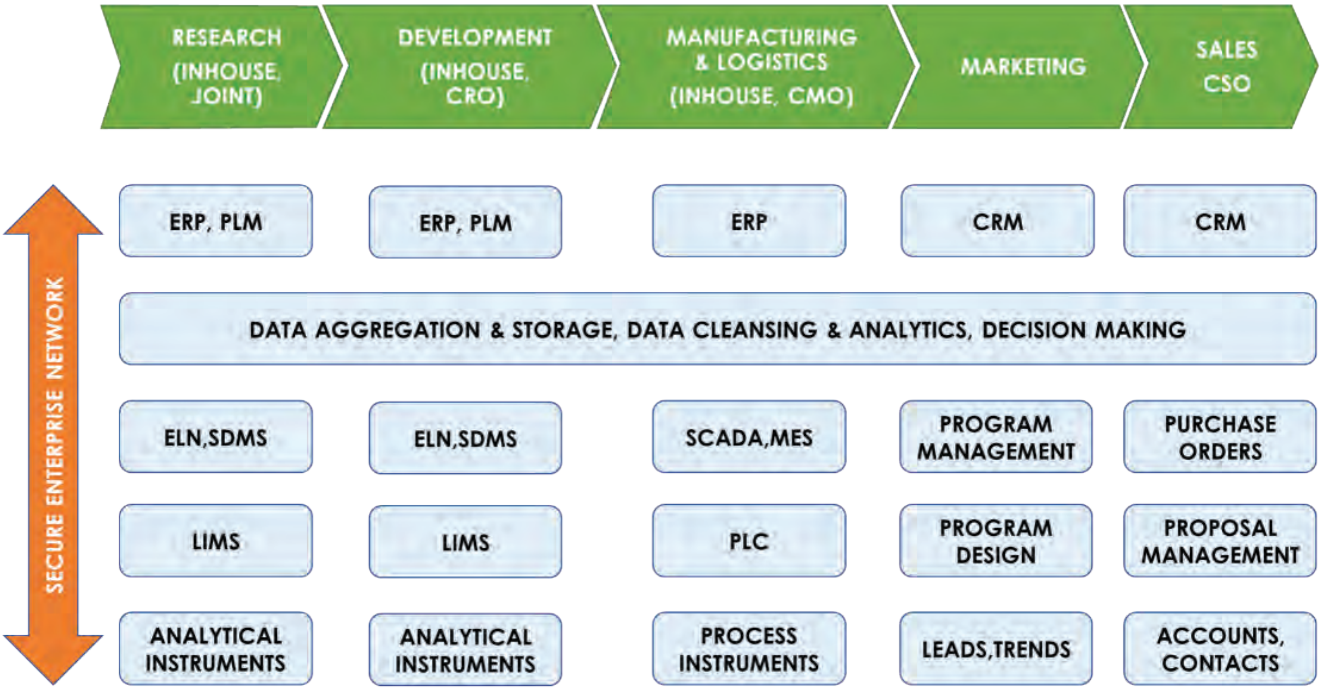


Figure 2 : The "Smart and Connected" approach of Industry 4.0 offers opportunities to meet the demands of market forces and create business advantage.

material and equipment suppliers). If an organisation must compete globally and create a profitable business, rapid innovation and flexible manufacturing is necessary. This is where digitalisation provides speed across the value chain, while maintaining accuracy, quality, security and compliance.

3 important steps to unlock opportunities in Analytical Instrumentation 4.0

In a smart and connected economy, Analytical Instruments and smart sensors are already reshaping the way they function for labs and manufacturing activities. Convergence of science, technology and engineering has created sensors that are small, non-invasive and can sample data more frequently. Embedded computing enables in-situ analysis. Results and data can be transported quickly via internet and 4G/5G technologies, for performing advanced analytics on aggregated data from multiple sources. Certain analytical instruments may thus move out of the lab. These scenarios create new possibilities and an important role for Analytical Instruments, in the Industry 4.0 world.

Manufacturers and users of analytical instruments should consider the following 3 steps.

Enhancing Existing Capabilities – Understand what Industry 4.0 is

Industry 4.0, when looked at in isolation,

can sound overwhelming to many. This feeling itself may stop you from taking the next step. However, once you understand the concept in its componential form (Figure 2), you shall more likely see how Industry 4.0 can help you to become future ready. But for that, Industry 4.0 skilling is needed at all levels. This helps in defining a thought-out strategy and roadmap. Companies should begin with small steps and experience quick wins, rather than a big initiative (not recommended).

The other important aspect is that Capability Development helps in building the right mindset and confidence amongst the staff. Rather than being concerned about the impact of digital technologies on job loss, it helps in stimulating creativity.

This componential implementation becomes the foundation for developing an adapting mindset and harnessing future business growth.

Embrace Big Data and Data Analytics:

Analysis of data is nothing new to pharma (or any other) industry. But when research, development and manufacturing are increasingly driven by collaboration and partnerships, then rapid multiple source data acquisition, management and sharing becomes extremely essential. Multiple sources include datasets such as clinical trial data, electronic medical records (EMRs), claims and billing data, product and disease registries, and data gathered by personal devices and health applications. This approach to link data is called a “digital thread” that provides limitless opportunities for rapid and singular view of information.

Innovation - Think Industry 4.0 Solutions, not just Products:

Pharma industry is no stranger to Innovation. It is based on a rock-solid foundation of research. As first touch point, Analytical Instruments and smart sensors become vital in “Smart, Connected and Autonomous” world. Enhancing existing products or building new products that are Industry 4.0 compatible thus presents an opportunity, which will soon become a need. Companies can consider a mix of portable and inhouse products, automation accessories, equipment health prediction, software applications and data interoperability with other equipment.

Similarly, various processes within an organisation, when digitally enabled can yield real business results. It can improve quality, prevent downtime, improve safety to save costs.

As an example, the lab automation equipment manufacturer Inpeco, manufactures equipment along with Robotic modules, interoperability with other analysers and Data Analytics Software. We also see that research is enabling sensors to become miniaturised, non-invasive and connected. When such

Image Source: https://www.apple.com/in/apple-events/september-2020/

technology matures, one can visualise emergence of "virtual" clinical trials and remote health management.

Apple's Series 6 Watch[4] announcement is a step in this direction. Its miniature sensors associated algorithms and app, monitor SpO2 levels, apart from other parameters. Such advancements get many researchers and innovators interested. Imagine the explosion in availability of rich, contextual data for deeper analysis and research.

Innovation is not just about creating new products or services. Delivering them in an efficient manner and managing their performance is equally important. If you do not leverage digitalisation for marketing, sales and performance management, you will lose a chance to secure valuable insight and revenue opportunities that may be unfolding outside the organisation.

Summary

Market growth forecasts provides a great opportunity for the Analytical Instruments industry. Health and Safety of Humans and Planet are focus areas of every industry. Analytical Instruments will continue to find newer applications in different sectors.

Industry 4.0 will not just create business advantages but also free people from repetitive tasks. We can then take advantage of human strengths like creativity and innovation to full effect.

Successful short-term results can be achieved using existing technology and data. However, the long-term results need innovation, patience and commitment to realise the full potential of Industry 4.0. This is primarily due to the time needed for devices, data analysis systems and re-designed processes to achieve maturity. All this is possible only if people are equipped with new skills and tools. The earlier you start, the earlier you can reconfigure people skills, business processes and business models.

When such systems are built, companies will create an immense competitive advantage on the global stage. ■

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Trends & Developments in Analytical Instruments and Laboratory Equipment

The analytical results produced from the laboratory is the lifeline for the pharmaceutical, bio-tech and life science industry as it deals with the lives of living beings. The important factors are the result that should be reliable, precise and accurate. The expected detection level of the results are going up to nano gram pico gram level and size of the sample / analyte is going down to micro liter level. In order to meet this, the two critical advancements required in the area are, automate the instrumentation to minimise manual interference (for precision and accuracy) and obtain a representative sample (for reliability and repeatability).

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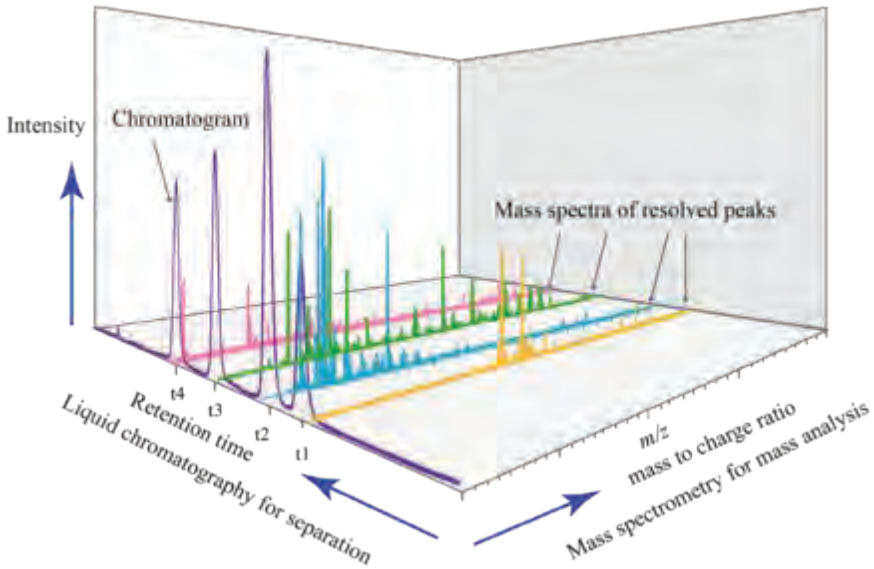
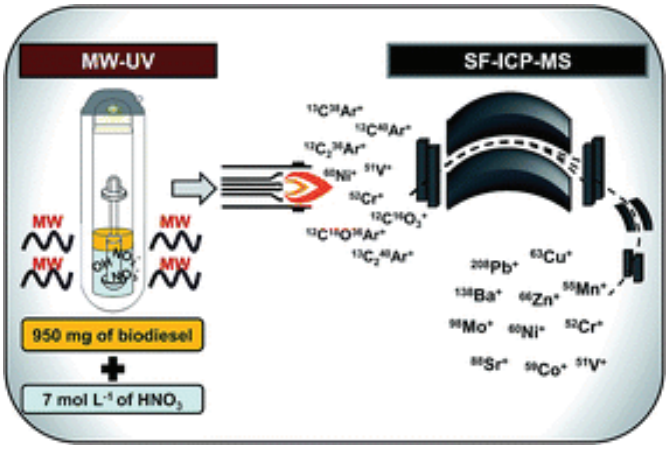
Techniques

Analytical instrumentation technology is mostly based on electro-analytical techniques like potentiometry, amperometry, optical techniques like spectrophotometry, fluorometry, separation techniques like chromatography etc., and can get results up to parts per billion level. However by integration with mass spectrometry it can be extended to parts per trillion level i.e., to detect at nano gram pico gram level. Emission method is advanced compared to absorption, graphite furnace is better than flame, inductively coupled plasma system will be able to scan the entire spectrum in a single run. Mass spectrometry is versatile for high resolution applications.

This can be further more improved when we use magnetic sector based technologies. High resolution GC, MRI etc., are some of the examples.



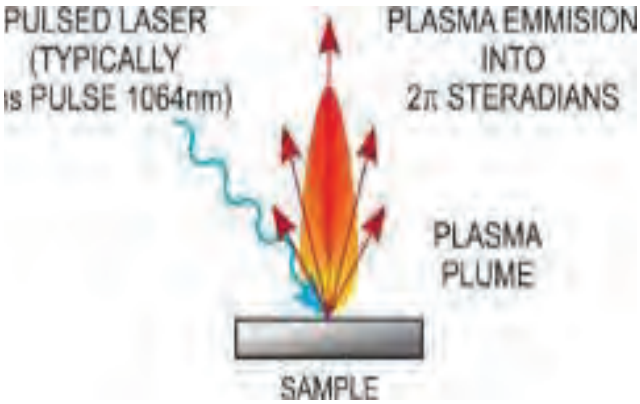
Representative Sample



Now the second part of the issue is representative sample. How best we can collect very small amount of sample / analyte that represents the large volume of source. Conventional analytical techniques used to bring down bigger sample (from the whole lot) to small size (to be able to fed the instrument) using various techniques like random, systematic, stratified, multistage and multiphase sampling techniques. Certain advanced techniques like fusion decomposition, microwave, microwave assisted UV, ultra sound etc., are used for heating / digestion / pre-concentration to bring the sample to desired volume without losing its integrity.

Time for Analysis

Then the most important part is time taken for analysis, how quickly we can get the result.



Conventional methods will take long time for analysis and provide results, whereas advanced analytical instruments can significantly reduce the time for analysis and at the same time provide results more precisely and accurately. We can see real advancement in this area by using laser ablation technique which will replace all manual handling and time required.

Validation

Lastly we need quality control and quality assurance. In the highly regulated pharmaceutical, medical, forensic areas of testing even minute variances can lead to serious issues, if proper qualification and validation protocols are not in place. The laboratory / analytical equipment have to have installation, operational and performance qualification (IQ, OQ, PQ) protocols in place.

Calibration and Certification

Calibration of the equipment is like giving life to the equipment, without which there is no credibility of the output. Calibration is to ensure that the equipment works properly and measured within the desired range of application. The equipment / device can be calibrated at the factory where it is manufactured (factory calibrated) or on site at user location, (field calibrated).

Manufactures will provided guidance has to how to properly calibrate a device in the field within the product's specifications and without damaging the device or voiding the warranty

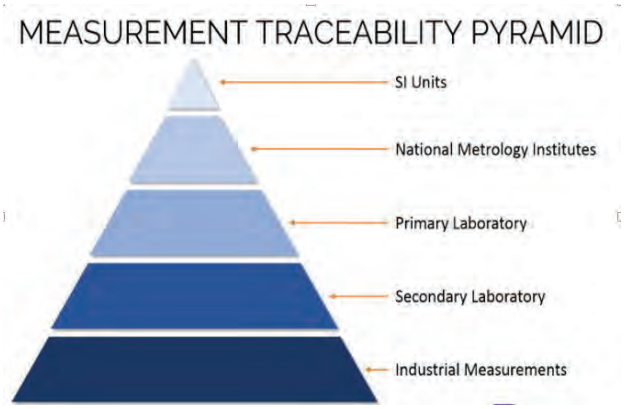
A common certification for measurement devices is a NIST (National Institute of Standards and Technology) calibration certificate. For NIST calibrations, the institute will supply standard reference material (SRM) for devices to be calibrated. A certificate of analysis and material safety data sheet are provided with every SRM sent out. The certification means that the device was tested against the SRM and met required specifications by the NIST. The NIST calibration certificates do come with expiration dates, so this means that for the device to keep its certification, it will have to be retested against a NIST SRM. When a device receives a Traceable NIST Certificate, that means the device was tested against another device with a paper trail leading back to a NIST SRM. A NIST Calibration Certificate proves that a product has been tested to ensure accuracy, and helps ensure a precision device is able to achieve the highest possible levels of measurement quality

and productivity. This is often required in validated or regulated applications, such as pharmaceutical, biotech and life sciences.

National Metrology Institute (NMI) of India is the CSIR-National Physical Laboratory, New Delhi which is the, member of the 'Metre Convention' and of the Asia-Pacific Metrology Programme (APMP). India is also a signatory of International Bureau of Weights & Measures (BIPM) and Mutual Recognition Arrangement (CIPM-MRA). CSIR-NPL has responsibility for maintaining the National Standards of Measurements, traceability of measurement through Bilateral/ International key comparisons and the Quality System as per ISO/IEC 17025. NPL offers a comprehensive range of high-quality calibration services, all of which are directly traceable to the internationally recognised primary measurement standards that maintain on behalf of the UK. Most of these services are independently accredited by the United Kingdom Accreditation Services (UKAS) to ISO 17025.

Traceability of Measurement

Measurement traceability is important because it gives confidence and assurance that the measurement results agree with national or international standards within the statement of uncertainty in measurement.



The measurement traceability and the calibration hierarchy from the realization of the SI Unit down to the measurements performed in the industrial environment.

All equipment used for tests and / or calibration have to be calibrated before put it into service. The laboratory shall have an established programme and procedure for calibration of its equipment. The programme should include a system for selecting using, calibrating, checking, controlling and maintaining measurement standards, reference materials. For calibration laboratories, the program for calibration of equipment shall be designed and operated to ensure that the calibrations and measurements made are traceable to International System of Units (SI). ■

Bioanalytical tools & techniques driving innovations in discovery and development of Bio-therapeutics: From Small molecules to Biologics

Medicine and how it is practiced is a dynamic field which brings in hope of fulfilling a long-lasting promise. The advent of robust and highly capable data generating machines to produce information generated by careful processing of samples is growing at an advanced pace. This rapid development has also laid the foundation for a wide variety of screen or untargeted based “omics” studies leading to genomics, proteomics, metabolomics, transcriptomics to name a few.

Dr. Raju Tatituri
Principal Consultant, Virata Biochem-Analytics Inc; Founder & Director of LC-MS, Brigham & Women’s Hospital; Assistant Professor of Medicine, Harvard Medical School, Boston

Many biochemical analyses using conventional approaches though they provide some solid data on a specific question but are less efficient when lot of samples have to be processed and studied. This has given the need to evolve in a global approach where high-throughput analytical methods are required for processing several samples and generating huge data, for example in terms of populations studies. The implementation of quadruple and time of flight mass spectrometry married to hybrid liquid chromatography–mass spectrometry instruments in the field of pharmaceuticals, food, environmental analysis and basic innovative bench sciences has enabled us to learn and explore several molecular patterns to help identify diagnostic markers may it be proteins, peptides, metabolites or lipids. This has also paved the way for several quick quality checks to be performed in pharmaceuticals starting from drug precursors to end product monitoring.

Omics and Terminologies:

The term Omics generally refers to a procedural screening - high resolution in-depth study of an entire set of molecular entities in a class. Omics has been functionally integrated into various fields of biochemical, clinical and pharmaceutical explorations: For example, in pharmaceuticals it is coined as pharmacogenomics, pharmacotranscriptomics, pharmacometabolomics, and pharmacoproteomics.

Briefly, Genomics is a genome wide study subclassified into structural and functional genomics and furthermore the subclassified study tracking the global gene expression and heritable modification is epigenomics. Transcriptomics is the study of all RNA molecules in a cell (including mRNA, rRNA, tRNA, and other non-coding RNAs) which investigates the changes that occur in the whole transcriptome under a variety of biological conditions.

Proteomics is a complementary study to genomics and aims at the identification, functional and structural modifications of proteins of a certain type extracted from cells, tissue and body fluid. These studies could be further performed in a high throughput manner using high resolution approaches in a systematic level to learn at post translational modifications like phosphorylation (Phosphoproteomics) and carbohydrate architecture and modifications (Glycoproteomics). Metabolomics studies deal with a complete set of extractable small molecules (i.e., metabolites) identified in a given biological sample and Lipidomics is the unbiased study of extractable lipids

which are the structural components of cell membranes, serving as energy storage sources and participating in many important cellular functions.

Omics and Instrument Advances:

There are several mass spectrometric technologies that exist namely Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography-Mass Spectrometry (LC-MS), and Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) which are widely used in basic research up until drug development. For the purpose of this article, we will discuss LC-MS technologies (Table 1).

With the continuing technological improvements and robustness in LC-MS Instrumentation, there are many advantages of performing qualitative and quantitative analyses. The scope of applications from basic science all the way to product development has accelerated immensely for the good. A variety of LC-MS technical strategies have been designed and continue to evolve to aid in the study of biochemical pathways, population studies, downstream purifications and drug development.

There are two types of mass specs: Accurate MS and Nominal MS. Accurate MS is done using Time of Flight MS (TOF-MS): This is generally used for discovery approaches and to get an accurate mass information of compounds

General Electrospray MS Instrumentation	General Workflow	Data Type Achievable
Triple Quadrupole	Direct Infusion, LC-MS and LC-MS/MS (normal and reverse phase, HILIC and Ion-Pair etc.,).	Full scan molecular weight - nominal mass, method development (Quantitative) screening, targeted, sensitive trace element/impurity quantitation with high dynamic range. Neutral and precursor ions scans can be done.
Time of Flight (TOF)	Direct Infusion, LC-MS and LC-MS/MS (normal and reverse phase, HILIC and Ion-Pair etc.,).	Full scan molecular formulae, high resolution, method development (Qualitative), accurate mass screening for omic studies.
Hybrid TOF, QTOF's, Ion-Traps, ICP-MS.	Direct Infusion, LC-MS and LC-MS/MS (normal and reverse phase, HILIC and Ion-Pair etc.,).	Full scan molecular formulae - structural characterization, high resolution, accurate mass, method development (qualitative and quantitative), for screening and targeted, quantitation with good dynamic range.
MS with Ion mobility	Direct Infusion, LC-MS and LC-MS/MS (normal and reverse phase, HILIC and Ion-Pair etc.,).	Ion mobility is very targeted separation of isomeric and isobaric species.

Table 1: Brief outline of electrospray ionization MS instrumentation and data achievable after sample clean up.

of interest with greater confidence. This has many uses from screening of samples for unbiased study of potential biomarkers to studying purity of synthetic drugs. In this TOF-MS approach proteomics, metabolomics, lipidomic screens using databases (protein pilot, simlipid, lipid view etc.,) is all done. Internal standards (deuterated synthetic compounds) also aid as technical controls for runs. Once such example of unbiased study is in clinical sciences where in TOF-MS (coupled to LC for separation and also as direct injection into MS) is used to screen samples in a high-through put way to see some potential diagnostic biomarkers hits. Here the raw data is blasted against known molecular specific databases for identification and confirmation. The diagnostic targets that are identified and confirmed across various samples related to a disease state pave the way to a routine targeted LC-MS approach analyses in clinical labs for sample testing of patients using triple quadrupole mass spectrometers as stated below.

Triple Quadrupole MS with Traps (Targeted): In the targeted approach, all identified and confirmed molecules are quantified on a regular basis. The Triple Quadrupole MS has greater dynamic range and allow the user to quantify all the way to femtograms if the sample is clean and molecule is able ionize well in the given MS conditions. Here, very similar and/or if available the same synthetic molecule is used to quantify the target molecule and also internal standards acts as technical controls to estimate recoveries and losses (for quality control purposes). Targeted approach leads to more confidence in absolute identification and confidence in quantification.

In drug manufacturing and QC studies, LC-MS methods provide a technical solution for tracking down impurities and synthetic byproducts from various lots of Active Pharmaceutical Ingredients (API). These LC-MS methods serve in the lot testing of first toxicology studies, followed by current Good Manufacturing Practices (cGMP) based on molecular mass of constituents along with LC retention time and UV spectrum if possible. The major limitations encountered with UV or diode array detection (DAD) is due to similar absorption characteristics of closely related impurities in drug product manufacturing and in some cases compounds lack sufficient chromophore for low-level sensitivity. These hindrances can often be answered by utilizing LC-MS in various assays related product development where both selectivity and sensitivity can be achieved.

Limitations due to sample preparation and LC-MS Instrument Sensitivities and Possible Solutions:

Sample Preparation: Despite the convenience of robotic arms for sample preparation, an optimal solvent sample preparation step to isolate the compound/s and natural metabolites of interest from the matrix remains an absolute necessity in many cases. A sub optimal sample preparation results in poor resolution analyses due the noise level at the detector. This is termed as matrix effects (MEs) which is a response caused by a modified/effected ionization patterns for compounds of interest due to co-eluting analytes (impurities in the same matrix). ME's generally cause an increase (ion enhancement) or loss (ion suppression) of ion patterns which severely limits confident quantitative data analysis and finally affects the accuracy, linearity and reproducibility. One possible solution to counter ME is pre cleanup / pretreatment methods using various optimized procedures like liquid–liquid extraction (LLE), solid phase extraction (SPE), solid-phase microextraction (SMPE) and supported liquid extraction (SLE).

Instrument Insensitivities: First, the problem with the confident identification of isomeric compounds even with the utilization of high-resolution mass spectrometry. Isomeric compounds are termed as compounds with a similar molecular formula but exhibit a different molecular structure. For example, in a complex sample, the inability to isolate and identify isomeric species of phosphatidylglycerol (PG), a phospholipid, has at least four known isomers related to head group (i.e., RR-PG, RS-PG, SS-PG and SR-PG) which will therefore makes it very challenging for the biologist to estimate the PG isomer responsible for biological activity. One possible solution is fusion of Ion Mobility (IM) to MS wherein the the ions resulting from compound of interest experience a drag force when moving through a charged electrical field in the drift cell while parallelly undergoing gas collisions typically nitrogen or helium gas in the cell. Different forms of IM exist based on this principle utilized such as Drift-Tube ion mobility (DT-IM), Trapped ion mobility (TIM) and Travelling-Wave ion mobility (TW-IM) all of which can be modularly integrated into LC-MS instrumentation as needed to separate isomeric and isobaric compounds.

Secondly, shotgun MS injection of a complex sample containing multiple compounds related to various architectures and backbone chemistries can enormously influence the ionization efficiency of the compound/product of interest. This will lead to an inaccurate

quantitation, but also affect the accuracy of the mass measurements. One such possible solution is to use optimal LC chemistries and much better is to use two-dimensional separations (LC-LC or LC × LC) mode. These techniques surely require mobile phases that are compatible with MS (containing ion-pairing reagents or non-volatile salts) to separate compounds of interest from its impurities. Under such online cutting-edge high-resolution LC separation, the impurities though may have the same mass (isomeric/isobaric) and may not be detected by UV due to the lack of UV-absorbance can still be separated and yields can be improved. This technique can be potentially employed within assay and product development in the area of purifications chemistries with weaker to medium ionic interactions and confident characterization of pharmaceutical materials particularly with respect to identification of counterfeit drugs in the field of therapeutic drug monitoring (TDM) and pharmacokinetics/ pharmacodynamics (PK/PD) studies.

Thirdly, the need for additional bioinformatic tools is crucial for a confident identification of compounds considering an accurate mass measurement, even at a mass error of a < 1ppm which generally results in the generation of several potential elemental formulae.

Omics and Data Mining

Omics research has become the key integral part of scientific research – be it pharmacokinetics, clinical research, basic sciences to systems biology and network biology. One of the main omics functionalities is full global analyses which is a study requirement of the most complicated research subjects. This makes it possible to fully understand the pathology of diseases, giving insights into biochemical mechanistic pathways necessary for pharmaceutical research and drug treatment which allows for safety assessments one of the key components of personalized medicine.

Omics, though a powerful player has some practical limitations in its applications: for example: massive omics data analysis may produce false positive or false negative results and or cannot completely identify some very important functional molecules in trace level compounds due to inconsistencies in sample preparation, various instrumentation usages and procedural inconsistencies across various labs, accuracy and sensitivity of analytical methods and moreover lack of enough specificity.

However, it still attracts a growing number of research interests worldwide. Currently, the production of large omics

data sets has become routine, and thus basic and pharmaceutical research has entered the new era of omics. High throughput omic studies and deep data mining bioinformatic capacities has paved the way for delineation of biochemical pathways, study of molecular interactions between drugs and biologically functional molecules, and also in huge population studies related to the pandemic like COVID-19.

For example, single experimental data obtained from drug-protein interactions is not just enough to explain complex phenotypes and question the integrity of data produced and understanding the drug responses at the level of entire system instead of one particular target organ. By means of bioinformatics and computer modeling, omics is expected to provide many more additional insights and clues to the mechanisms of biological processes and functions, and thus may build up a theoretical framework of modern life science.

Future Directions and Summary

LC-MS based Omics techniques are widely employed in various areas of precision medicine, clinical and biological science, agriculture and basic research fields. However, there are many potential challenges in omics based research, including sample preparations and separations, MS ionization procedures and data acquisition, multi-omics data analysis and modeling. But, numerous recent advances in robust instrumentation which helped to identify and quantitate trace level impurities (0.1% or less) using Trap technologies and obtaining qualitative and quantitative information on a single instrument platform like Triple TOF (TTOF) without compromising performance cannot be ignored.

Needless to say, no matter how much technologies improve, the way to successful progression and wellbeing of human find has always been through humble beings who are experts in the field but are students at heart and modest enough to submit to advanced training when needed. By keeping such an open mind about challenges and implementing the ever-continuous rapid development of high throughput technologies and informatics discussed all that remains in end is a future promise of positive hope for mankind. ■

COVID detection bringing in new opportunities

The COVID-19 pandemic has brought unprecedented challenges for the communities and economies worldwide, causing a profound effect on the lives of billions of people. Analytical techniques for drug testing and vaccine research, production and testing of sanitizers and personal protective equipment and analysis of medical sewage waste are playing a vital role. These comprehensive and effective solutions aid in the fight against the novel coronavirus. Dr Shyam Vasudeva Rao, Founder & Director of Forus Health Pvt Ltd as well as RenalyX health systems in his article writes about various methods of analysis available currently as well as questions various challenges that are still unanswered.

Dr. Shyam Vasudeva Rao
Founder & Director
RenalyX Health Systems Pvt. Ltd

By now every kid in this world knows COVID, but the ambiguity of how to detect this infection is debatable. What instrumentation is best for this purpose, what are its cost benefit analysis is still unclear. Detecting early stage of COVID is definitely good but then we need expensive quantitative polymerase chain reaction (qPCR)–based technique. This can lead to lot of false negative and risk of those who escaped the test not getting quarantined is very high. To get this more accurate humoral response to antibody IgA, IgM and IgG tests have proven more accurate. But this will need multiple ELISA tests for these antibodies. Similarly, just doing an Antigen test is also not proven accurate. Screening tests are never 100% sensitive and will always need multiple tests or combination of more than one test results to improve accuracy.

In these situations, we have an emergency on one end and uncertainties on other. How will regulators work on these uncertainties, what is the gold standard for such uncertain procedures? This leaves a big gap in the system.

Going further on mass screening, thermography using NIR imaging is a good standard. We will soon see several such cameras and handheld devices all over the place, offices, schools, public places and even hospitals. I have been mentoring a company who has made a good autonomous system which measures elevated temperature and using AI/ ML does a face recognition and mask detection. Do we call such a device as a medical device? If yes, what standards to be followed, which is a predicate device to compare? Do we call this a screening or diagnostic device? All these questions are yet to be answered, but before that we might have spread the COVID to the entire masses and several lives lost.

Once a person gets infected with COVID we have seen more then 90% of them have mild or asymptotic infection and in 3-7 days they are back to normal. The remaining 10 % could get serious and 3% may need ICU and go on 02 therapy and ventilators. Ventilators are of different complexity and there is no clarity on what kind of ventilators are required for COVID patients. People started to make very low-end ventilators like a transport ventilator made of Ambo bag while some of the serious MedTech companies already had medical ventilators and they made ICU grade ventilators. The price difference between these two categories is at least 3-4 times. Lack of understanding and no strict regulatory complaisance, several startups and companies started to make the easy low-cost ventilators. This led to a disaster as the clinicals and govt decided to only purchase the one which had some certification, so leaving only those companies who were already in this business of medical ventilators. More than 50 companies/ startups which have spent their valuable time and money on these low-end ventilators have to now shutdown. Eventually the need for ventilators have also come down with a late realization

that o2 therapy is just enough for serious COVID patients as per WHO.

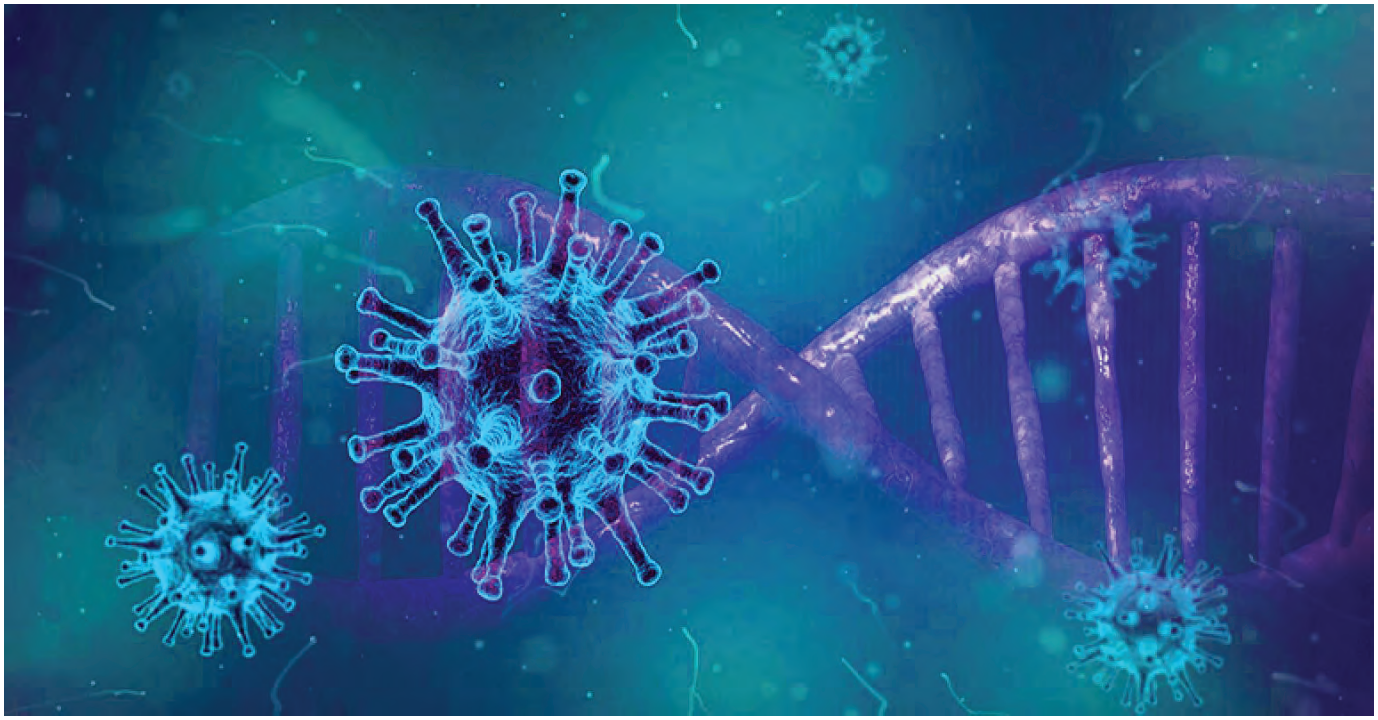
Physical bio markers find good application in mass screening of COVID case in 2-3 levels of narrowing down to the infected candidates as follows:

- Level 1: pick those who have elevated temperature (> 100.4 Degree F / 38 Degree C) and then perform next level tests like Oxygen saturation etc.
- Level 2: Perform O2 saturation tests on the 95 % or above indicates healthy anything less than 92% suggest that the person is seriously ill and may need supplementary oxygen, basically need immediate medical attention/ admission to hospital
- Level 3: detailed lab tests like antibody/ RT PCR etc. to confirm if the illness is COVID 19 or any other type of infections

The elevated temperature measurement becomes a key factor to select possible candidates in a mass of individually and this can be done in different ways, unfortunately thermometers, which is gold standard cannot be used in this case of infectious diseases like COVID and hence a non-contact temperature measurement is recommended. Non-contact thermometer could be using IR Laser based or near IR imaging device. IR Laser based devices cost less but the problem is that again they have to be held much closer(5-6 cms) to the forehead or palm, this is normally hand held and someone keeps measuring this with a hand-held gun, not only that this has to be done one at a time and locks up a human resource, it can also serve dangerous to the individual doing this as he / she can become the point of contact for all the people who got tested as individual is getting quite close to the people.

The next better option is the NIR Sensors which can read the temperature from a larger distance (4-6 ft and beyond). These sensors are a bit expensive but quite proven for various industrial applications and night vision surveillance cameras etc. These sensors can also measure the relative temperature from a larger distance and calibrated to give the absolute temperature to the accuracy of 0.1 Deg C. As there are atmospheric temperature variances in between the sensor and the person, there can be some errors in the measurement. This needs to be regulated or more smart features put in such a way that this variation are compensated.

The challenge in all these systems is how we certify these devices, what type of regulatory system need to be in place, these devices fall under the non-contact / noninvasive devices and hence exempt from serious regulatory process are questions to be answered. Even though these may not need serous regulatory process the outcome of these as used for decision making to pick the abnormal, there should not be any false negatives, so calibration is very important and needs a very strict calibration procedure.

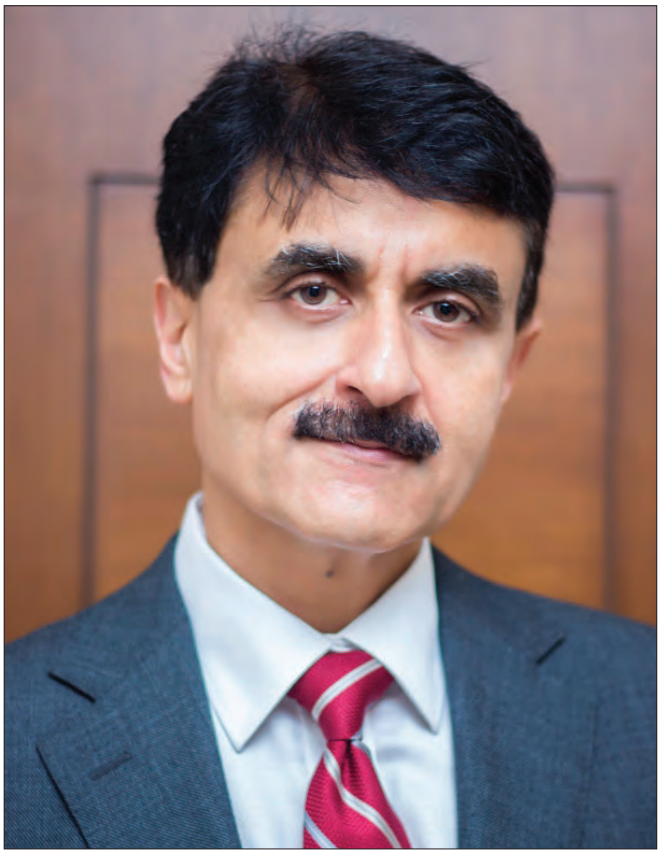


This three-step approach also helps in reducing the cost of screening as there is no consumables required in the first and second levels where the numbers are high and easy and fast operations. This can also be done autonomously on the go. The biggest risk in all these is how do we catch those who are asymptomatic COVID cases?

The answer to this is people doing a self-test like saliva test where samples are collected by the individuals and then these samples undergo RT -LAMP (loop mediated isothermal amplification) test which costs far less than RT-PCT test. RT-LAMP testing could provide easy. Non-invasive, quick and relatively accurate results, with minimal risk of viral transmission to healthcare workers. Typically for these LAMP tests is a colorimetric test and the reader costs less or can be done easily by mobile phone cameras. The only disadvantage of this technique is that it is voluntary and people have to go for screening unlike the Thermal cameras which are more autonomous.

In Europe and US for those who have developed breathing issues, they do a CT scan and detect inflammation in the lungs due to COVID infection at an early stage. This is an expensive test when it comes to Indian context and also several countries do not have the needed infrastructure to cater to a large population. These tests are now being done by simple X-RAY imaging, which costs much less and available in most of the hospitals. However, there is a need for digitization and lot of post processing to be done for enhancement and correlations to these X-RAY images but definitely an affordable option. ■

"Our mission to enable our customers to make the world healthier, cleaner, and safer has never been more relevant."



Amit Chopra
Managing Director, India and the Middle East, Thermo Fisher Scientific

Thermo Fisher Scientific Inc, world leader in serving science is well known for their services in life sciences research, solving complex analytical challenges, improving patient diagnostics and therapies or increasing productivity in their laboratories by delivering an unrivaled combination of innovative technologies and pharmaceutical services.

During this pandemic, Thermo Fisher Scientific expanded it testing capabilities with new High Throughput Automated testing Solution, real PCR designed to analyze over 6,000 samples in a single day. The modular solution delivers test results in a four-step process requiring minimal hands-on time, laboratory space and staffing resources. The Thermo Fisher Scientific Amplitude Solution is a molecular diagnostic testing system that leverages the company's Applied Biosystems QuantStudio 7 Flex Real-time PCR instruments along with liquid handling products from Tecan Group, a global leader in laboratory automation and liquid handling. The modular solution delivers test results in a four-step process requiring minimal hands-on time, laboratory space and staffing resources.

Mr. Amit Chopra, Managing Director, India and the Middle East, Thermo Fisher Scientific *said, "Ramping up testing capacity is the most critical aspect of dealing with COVID-19 and perhaps the only solution to bring the world back to normal. While each state conducts testing on different capacities, a new approach for scaling the testing volume is essential to safeguard human life. Thermo Fisher's high-yielding, automated solution will empower laboratories worldwide to drastically improve the testing volumes and bring the world back to normal."*

In an exclusive interview with Pharma Bio World, Mr Chopra gives the readers an insight into Thermo Fisher's Applied Biosystems TaqPath COVID-19 Combo Kit -- a fast, highly sensitive multiplex diagnostic test that contains the assays and controls needed for the qualitative detection of nucleic acid from SARS-CoV-2, the virus that causes COVID-19. Mr Chopra also talks about vaccine for COVID-19, and about how instrumentation can play a crucial role to managing pandemics.

Thermo Fisher Scientific has worked rapidly to develop a new multiplex real-time RT-PCR diagnostic kit to quickly diagnose COVID-19 caused by SARS-CoV-2 infection. Exceptionally, it was in response to an extremely critical need. How did Thermo Fisher's create the kit and how was the diagnostic designed?

TaqPath COVID-19 Combo Kits were one of the first tests to receive Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and are being extensively used across the world. The TaqPath COVID-19 Combo kits are highly sensitive and target specific regions of the COVID-19 genome. The assay has undergone rigorous analytical validation and clinical performance studies prior to launch. Thermo Fisher now distributes its diagnostic test to more than 50 countries, including India, and now has the capacity to produce more than 10 million COVID-19 tests per week globally to meet the rising demand. In addition to testing, the company is also rapidly scaling production of sample collection products to meet rising demands and supporting more than 200 vaccine and therapy development and manufacturing projects around the world.

Thermo Fisher Scientific has in collaboration with WuXi Diagnostics and Mayo Clinic developed a total antibodies test. Please explain how these two tests are different.

Once approved, Thermo Fisher Scientific's OmniPath COVID-19 Total Antibody ELISA test will detect immunoglobulin M (IgM) and immunoglobulin G (IgG) to help clinicians determine if a patient has been exposed to SARS-CoV-2. The test is designed to run on an open instrument platform, and the determination of antibody status will aid in the diagnosis of the disease during the acute and recovery stages of infection.

The global call to ramp up testing requires a combination of both PCR-based molecular tests and serological tests. Molecular tests, such as Thermo Fisher's Applied Biosystems TaqPath Combo Kit, are considered the gold standard for determining if a patient has an active infection. Serological tests determine if a person has antibodies to SARS-CoV-2, indicating whether they have had – or still have – the virus and if they have built up an immune response. When used in combination, these tests provide greater clinical efficacy, support contact tracing, and enhance epidemiological efforts to stop the spread of the virus.

It would be grueling, complying with exhaustive regulations simultaneously. How was this achieved?

Given the unprecedented nature of the situation and the global demand, we are providing additional support to customers, both private and government labs, to

ensure they have the necessary testing infrastructure to get India back to normal. Furthermore, we have been very proactive in aligning all our stakeholders to ensure all our sites are current with changing regulatory standards and guidelines applicable to the respective regions. As the world leader in serving science, we recognize the significant role we play in helping our customers respond to the pandemic and ultimately win the battle against the virus.

What workflow at Thermo Fisher enables faster and superior product deliveries, all while being consistent?

At Thermo Fisher, our mission to enable our customers to make the world healthier, cleaner, and safer has never been more relevant. Being a global manufacturer and supplier of COVID-19 testing kits, our teams are working around the clock to ramp up production and ensure continuous availability of products with consistent quality. We are also leveraging our large distribution infrastructure and network to enable faster deliveries of these kits and continue supporting our customers with products and services they rely on to address this rapidly evolving public health crisis.

Is Thermo Fisher Scientific developing a vaccine for COVID-19?

Our wide portfolio of technologies and products are used by many companies at both the upstream and downstream stages of vaccine research and bio-production. To support these efforts, Thermo Fisher continues to expand its global capacity and capabilities across its leading pharma services network to support customers in government, industry, and academia as they accelerate development and production of COVID-19 vaccines, therapies, and other treatments. These approaches enable researchers to discover, develop, test, and potentially produce new vaccines. For instance, in upstream process we have our single use technologies (SUTs) that include the bioreactors, the single-use bags and cell- culture media and cell lines. Additionally, we also offer chromatography purification media used extensively in the downstream process. We also offer instruments for critical in-depth analytical characterization, quality assurance (QA), and quality control (QC) and more. Overall, our comprehensive solutions significantly contribute to accelerate research and development to scale therapy and vaccine development.

What accuracy are the tests designed to deliver?

Thermo Fisher Scientific's TaqPath COVID-19 Combo Kit is designed to detect the presence of the virus at very low levels when used by a qualified lab according the strict requirements of the most current

regulatory approvals. The test kit includes detailed instructions for use, including an updated interpretive software package that laboratories must implement to ensure the accuracy of results.

Often Instrumentation is relatively ignored. This pandemic has shown that's perilous. Why is instrumentation crucial to managing pandemics?

Testing plays an important role in gaining confidence while reopening economies and to contain the spread of the virus. In India, the government has taken several initiatives by setting-up virology laboratories within states, districts and zones and authorizing private labs to accelerate the testing infrastructure and capabilities in the country. Build a robust testing infrastructure for COVID-19 is crucial and there is an immense need for laboratories to quickly upgrade their existing facilities for sample extraction, PCR set-up and analysis, apart from safe and efficient handling of samples. Thermo Fisher has significantly ramped up production and distribution of instruments like our Kingfisher series automated RNA extraction and QuantStudio series qPCR systems that have been deployed in thousands of labs across the globe to provide reliable and consistent sample preparation and pathogen detection. In addition, the COVID-19 laboratories and testing facilities require skilled handling of the samples, adequate knowledge of operating various instruments and accessories, and usage of software for accurate reporting of test results. There is immense need to train staff to efficiently handle samples and operate instruments in multiple shifts to expand the testing capability. At Thermo Fisher, our service and support teams are working round the clock to ensure these instruments are installed and users are trained on our workflow solutions to build capabilities and rapidly respond to the pandemic.

Many epidemiologists warn of more pandemics. What is Thermo Fisher doing to prepare for the next one?

Epidemiological surveillance is conducted to ensure viral diseases match the reference strain and to monitor possible mutations, since any changes in the viral genome can impact public health policies and options, how the illness spreads in the population, potential study of treatment options, and vaccine development research. Thermo Fisher offers complete solutions to support these efforts including virus typing, virus monitoring, and sample preparation to assist scientists conducting epidemiological studies. ■

"India needs to create Quality Testing infrastructure and incentivize Indian certification of medical devices."

Hindustan Syringes & Medical Devices Ltd (HMD), one of the largest manufacturers of Disposable Syringes in the World and the largest for Auto Disable syringes with annual capacity of around 700 million auto-disable syringes for vaccination is scaling up production to a billion in the first half of 2021 as India gets ready for COVID-19 Vaccine. They have recently received order from UNICEF to increase its supply of immunization AD syringes to the organization to around 300 million to build up a stockpile of around 140 million syringes for Covid-19 by the end of the year.

Mr. Rajiv Nath, Managing Director who is spearheading Hindustan Syringes & Medical Devices Ltd to set a benchmark when it comes to manufacturing medical consumable in his discussion with Pharma Bio World talks about how HMD is scaling up production to 1 billion auto disable immunization syringes to help in Covid-19 Vaccination and about how Aatmanirbhar Bharat should play the role of a launch pad for fostering entrepreneurship, promoting local products, nurturing innovation and creation of an ecosystem for rural-urban symbiotic development.

Rajiv Nath
Managing Director, Hindustan Syringes & Medical Devices Ltd

HMD has scaled up production to1 billion auto disable immunization syringes to help in Covid-19 vaccination. How is HMD preparing for this request from UNICEF?

Hindustan Syringes & Medical Devices Ltd (HMD), one of the largest manufacturers of Disposable Syringes in the World and the largest for Auto Disable syringes with over 9 plants and current annual capacity from 550 million AD Immunization Syringes in June to around 700 million auto-disable syringes for vaccination by debottlenecking and is further scaling up production to a billion in the first half of 2021 as India gets ready for COVID-19 Vaccine.

HMD has ordered multi cavity molds, high speed assembly & packaging lines and expects to achieve 800 million capacity p.a. in Qtr1 and 1000 million by end of Qtr 2 of 2021.

HMD has received order from UNICEF to increase its supply of immunization AD syringes to the organization to around 300 million for this year under amendment of its Long Term agreement to enable COVAX a WHO - GAVI- CEPI initiative to build up a stockpile of around 140 million Kojak AD syringes for Covid-19 by the end of the year.

HMD is one of the largest suppliers to UNICEF for Auto Disable Syringes for immunization and is the first Company in India to manufacture Auto Disable Syringes for Curative Segment.

As India gets ready for COVID-19 vaccine, the Govt. should be well equipped with secured stock of syringes in advance to administer a vaccine when it is approved and ready. At least 60 to 70% of 1.3 Billion people in India will need 800 – 900 million AD syringes and similarly 60-70% of 7.8 Billion people Worldwide will need disposable and auto disable syringes for Covid-19 vaccination drive.

HMD's commitment to produce billions of immunization AD syringes for the global COVID-19 vaccination reinforces the company's vision to contribute to better healthcare in the country and internationally in areas of injection safety, patients safety, affordable access and stand with the country to fight the deadly virus.

What are the other biggest company milestones expected this year for HMD?

Kindly HMD is also ramping up its capacity of other medical disposables – I.V. Cannulas, ScalpVein Sets, evacuated blood collection tubes. These expansion plans were already initiated when Covid struck and delayed execution by our suppliers by a Quarter.

Companies in the pharma and healthcare sector view Covid-19 as once-in-a-lifetime business opportunity. How do you view this situation and what have been your top priorities?

In this large black cloud of Coronavirus

the only silver lining was the major boost provided to Make in India of certain Covid related Medical Devices which has been a neglected sector with import friendly policies in past with negligible duties. Many businessmen in auto sector, garments, hospitality, tourism industry diversified into medical devices considering depressing times for their own businesses and saw opportunity and growth in devices.

HMD's top priorities had been in ensuring continuity of supply chain and its manufacturing plants to ensure no shortages for its critically needed disposable devices during the total lockdown period.

What impacts and / or transformations do you see digitization and digitalization making in the healthcare industry?

Covid-19 has changed the scenario of doing business. It has opened massive opportunities for healthcare sector in tele- consultation, AI-based diagnostics and remote healthcare management. India has shown its capability of rapid product development during the #COVID19 pandemic and it has a strong hold in the IT domain, we can build sophisticated software products in the healthcare domain.

Hindustan Syringes & Medical Devices Ltd. has been a very traditional company since it's inception with high technology being only present at our manufacturing stage but not our corporate level platform. However, the wave of pandemic has taught us to re- think some of our policies & thus have initiated the digitalization of our Marketing function. We are also focusing& taking use of virtual communications like Video Calls &WhatsApp messaging as safer alternatives from Face-to-Face meetings. As a 63- year-old manufacturing business, it would be difficult for us to completely digitalize our operations but however, we are making our best efforts to digitalize whatever is possible.

Make in India is a major new national program of the Government of India designed to gain momentum for investment, innovation and enhance skill development and build best in class manufacturing in the country. What is the impact of this program on Medical Devices sector?

If we talk about the new campaign of Govt. we should talk about Atmanirbhar Bharat Abhiyan. Aatmanirbhar Bharatis a launch pad for fostering entrepreneurship, promoting local products, nurturing innovation and creation of an ecosystem for rural-urban symbiotic development.

In a move to make the country self-reliant through a "AatmaNirbhar Bharat" campaign & promote 'Make in India', the government modified public procurement norms to give maximum preference to local companies whose goods and

services have 50 per cent or more local content. The India Medical Devices industry is happy that now domestic is preferred over foreign origin goods wherever possible.

The Aatmanirbhar Bharat Abhiyaan is definitely a 'Make in India' enabler. The domestic industries should be supported, so that they can compete locally as well as globally & help India emerge as a Medical Devices Manufacturing Superpower. The Dept. of Pharma has launched a medical devices park promotion scheme and Production linked incentive scheme under this Abhiyan, however we have yet to see any immediate impact as these schemes will take time and meanwhile we hope Govt. will act on our requests for policy support needed.

With the world under siege and a country wide lockdown due to COVID-19, the lives & economies are going through tough time. What are the new opportunities you see for boosting Healthcare Sector to emerge through this tough time?

The Covid-19 pandemic situation was initially dreadfully challenging in India with a huge population and exposed its unpreparedness to handle this crisis and healthcare insecurity due its overly 85% import dependence and weak healthcare infrastructure leading to lockdown to give time for building ammunition to fight this war.

Medical Device Industry is an area on which India's vulnerability on healthcare insecurity stands exposed and on shaky ground with respect to Import Dependency on over Rs. 42000 crore Medical Devices Import Bill. Therefore this industry needs to be rescued from this dependency, from the cash flow challenges, poor financing viability and the will to compete with cheap imports. These challenges need to be converted into opportunities .India needs to invest heavily in Public Health. The MSME Companies needs to be rehabilitated and revived with supporting policies like nominal duty protection of 10 to 15% that nurture them back to health so that they can take care of the health of the Nation. India needs to create Quality Testing infrastructure and incentivize Indian certification of medical devices.

There is a strong need for addressing various policies issues in various sectors which can support domestic industry and reduce dependence on import.

The Government of India through its flagship "Make in India" initiative relied heavily on the Indian manufacturers to meet the rising demand of essential healthcare equipment for the country, and brought a focused need forpushing the Indian medical devices sector to become self-reliant or Atmanirbhar Bharat. ■

A journey to excellence for the industry

Compressed air is vital to many processes when manufacturing pharmaceuticals. If contaminated, this compressed air can lead to reduced performance, product spoilage and damaged production equipment, resulting in additional costs and unexpected downtime for site owners and operators. Compressed air often referred to as the "fourth utility," underlines its huge importance to the pharmaceutical manufacturing industry. The sector requires reliable, high-quality compressed air to power manufacturing processes and in vast quantities. The risk of contamination and its consequences should not be understated. Even the smallest possible risk of contamination can impair processes.

ELGi - a pioneer in cutting edge compressed air technology with presence across 120 countries, offers customers across the world a complete range of compressed air solutions from oil-lubricated and oil-free rotary screw compressors, oil-lubricated and oil-free reciprocating compressors and centrifugal compressors to dryers, filters, and downstream accessories. With state-of-the-art manufacturing units and a product portfolio of 400+ compressed air systems, ELGi redefines reliability, efficiency, and cost-effectiveness across 2+ million installations globally.

Dr. Jairam Varadaraj, Managing Director of ELGi Equipments Ltd talks to Pharma Bio World about ELGi's journey and future plans.

Dr. Jairam Varadaraj
Managing Director, ELGi Equipments Ltd

Video Link: https://youtu.be/V01XmWQvj3k

Importance of Oil Free Air in the World of Pharmaceuticals

In the world of pharmaceuticals, oil-free air is vital to the manufacturing of medicine and related products. Oil-free compressors are used in a variety of pharmaceutical applications, from conveying capsules and packaging to providing factories with a steady supply of clean, breathable air. The reason is simple: the air must meet the highest purity levels possible to ensure that no contamination of the end-product occurs.

ELGi AB Series oil free screw air compressor delivers certified Class '0', 100% oil free compressed air with low cost of ownership. With high reliability, consistent air quality, better return on investment, lower cost of ownership, and fast, efficient service support for sensitive applications with moisture content between +3°C, to -20°C PDP; the AB series range of air compressors meets the ISO 8573–1 compliance requirements. The sheer performance of the ELGi AB Series, coupled with its compelling value proposition has resulted in India's leading pharmaceutical companies replacing existing machines with the AB series, while successful installations, have prompted pharmaceutical companies, across the country, to revisit their entire fleet of air compressors.

ELGi AB Series

The ELGi AB Series delivers Class '0' quality air, while the water in the closed circuit is insulated with proprietary material to ensure zero contamination due to corrosion. It has a unique air cooling system which ensures ample condensation of water from air particles, aiding the self-replenishment of water in the closed loop. This eliminates the need for external water top-up and also reduces the load on the driers and the water management system. The in-built microbial inhibition system prevents microbial growth, across all scenarios of operation, thereby ensuring microbe free air.

The ELGi AB Series operates with a single airend, as opposed to conventional oil free machines that operate with dual airends. This results in lower foot print, fewer rotating components and lower maintenance costs. Fitted with stainless steel rotors for better performance, every ELGi AB series air compressor comes with standard bearings for ease of maintenance. Additionally, the AB series range operates at a lower RPM, resulting in less wear and tear of rotating parts, low noise levels and reduced power consumption. Additionally, the low noise levels ensure the AB series does not require a dedicated compressor room and can be placed right next to the application area, thereby reducing costs involved with the build-up of additional infrastructure and compressed air supply systems. ■

"The pandemic has challenged the bioprocessing companies to conform to an aggressive timeline at a lower cost without sacrificing quality"

Dr. Balaji Sitharaman, Founder & President, Millennial Scientific *is an inventor and is internationally recognized for nanotechnology R&D with over 20 years of experience and expertise in carbon nanotechnology. He has published over 80 peer-reviewed scientific articles and over 10 full or provisional patents. Dr Sitharaman, in his interview with PBW talks about tomorrow's laboratories and the advances that have impacted the analytical instrumentation. He will be speaking at Purify'20, the annual conference dedicated to Chromatography Purification at Hyderabad.*

Balaji Sitharaman
Founder & President
Millennial Scientific

The success of tomorrow's laboratories will hinge on how well the various pieces of equipment perform in digitally transformed, connected scenarios. Your thoughts on the phenomenal advances in Analytical instrumentation over the last decade that have impacted the conventional techniques like chromatography and spectroscopy.

Several innovations in materials, manufacturing, instrumentation, and software development have fostered next-generation analytical products and solutions. Nowhere is this better illustrated than in the field of healthcare. Novel silica, polymeric, and carbon particles approaching nanoscopic sizes, additive and lithographic manufacturing techniques that allow unconventional shapes, instrumentation capable of higher pressures, and very low analyte volumes have driven down analysis time, costs, and improved efficiency in separations. Further, artificial intelligence-based data processing and analytics and automated systems ease workflows, optimize method development, allow self-diagnosis and remote monitoring, and analyze big chromatography data.

The scientific instrument industry plays a vital role in the bioprocessing market. Companies offer analytical techniques and products that can help the market adapt to changing demands. One such change has been the COVID-19 pandemic, which has caused bioprocessing businesses to shift their priorities to be able to manufacture treatments and vaccines related to the virus once a vaccine is approved. Your observation.

The COVID 19 pandemic has challenged the bioprocessing companies to conform to an aggressive timeline at a lower cost without sacrificing quality. These challenges have driven the adoption of innovative bioprocessing technologies. For example, companies are embracing flexible automation integration to ensure continuity in work during lockdowns and reduce manual errors. Additionally, companies are also employing leading-edge analytical technologies such as next-generation sequencing to accelerate understanding of their products and processes.

Impact of Make in India program to gain momentum for investment, innovation and enhance skill development in Pharma sector.

The India pharmaceutical market has grown in leaps and bounds during the

last decade. It is currently facing flux due to COVID 19 due to significant disruptions in the supply chain. The Make in India initiative, if successfully implemented, will strengthen the ecosystem concept. It will move the focus from established supply chain models to a dynamic, thriving ecosystem concept.

New opportunities you see for boosting Healthcare Sector to emerge through this tough time.

The socioeconomic burden attributable to COVID 19 has been tremendous. A few new opportunities on the horizon include automation to enhance productivity within the healthcare system, and virtual care of patients. Additionally, the introduction of novel testing technologies offers rapid, low cost, not reagent intensive, accurate, and sensitive alternatives to existing testing methods suitable for use in the clinic, field, or at home. These opportunities also allow more flexibility for low-resource or limited-resource settings. ■

"The focus of interest lies in faster innovation, data management and AI learning tools to facilitate faster development."

Mr. Somesh Sharma, SVP and Business head *for Discovery Chemistry at GVK Biosciences Pvt. Ltd with more than 20years of experience in Drug Discovery field in his interaction with PBW talks about advances in Analytical instrumentation and about the impact of COVID-19 on bioprocessing businesses. He will be speaking at Purify'20, the annual conference dedicated to Chromatography Purification at Hyderabad.*

Somesh Sharma
SVP and Business Head for Discovery Chemistry at GVK Biosciences Pvt. Ltd

The success of tomorrow's laboratories will hinge on how well the various pieces of equipment perform in digitally transformed, connected scenarios. Your thoughts on the phenomenal advances in Analytical instrumentation over the last decade that have impacted the conventional techniques like chromatography and spectroscopy.

Pharmaceutical industry has realized the significance of laboratory and manufacturing digitization to accelerate the development of new medicines for unmet medical needs. The focus of interest lies in faster innovation, data management and artificial intelligence learning tools to facilitate faster chemical development. Historically, laboratory equipment's were accustomed for manual interventions with limited application range and cumbersome data recording and retrieval process.

Advanced and innovative tools ascertain the ease and safe operational control from remote locations, assure experimental reproducibility, data interpretation and traceability. Drug development process generally demands robust and accurate analytical tools to cater three requirements – drug discovery (identification & elucidation), development (development & validation) and manufacturing (repeatability & robustness).

There is a tremendous improvement in technologies over the time – high performance liquid chromatography (HPLC) has changed to Ultra-high performance liquid chromatography (UPLC), CAD, Arc and 2D HPLC. Orbitrap GC-MS/MS, evolution of bench top mass spectrometry and nuclear magnetic resonance (NMR) instrument with high precision and accuracy, vibrational spectroscopies (infra-red and Raman), X-ray fluorescence spectrometry, elemental analysis & identifications (ICP-MS) and imaging techniques for identification for any substance.

New platforms in circular dichroism, super fluid chromatography (SFC) and simulated moving bed (SMB) helps in defining chirality and purification of racemic drug substance. There is also a steady progression observed in preparative HPLC, ion-exchange chromatography and dynamic axial compression (DAC) technology for parallel screening and purification of complex drug substances, where, there is shrinkage of column size noticed due to development of high-pressure system.

Besides these platforms, sampling is a critical factor in the analysis of any

sample – poor sampling procedures lead to variable results and data integrity. However, smart work-stations with fully laboratory digitization helps to address this issue, wherein, real time instrument data recording with consistent & well defined structural formats, data storage, back-up, retrieval mechanism and integration with electronic laboratory notebooks (eLN), makes the process seamless and informative for knowledge sharing.

The scientific instrument industry plays a vital role in the bioprocessing market, with companies offering analytical techniques and products that can help the market adapt to changing demands. One such change has been the COVID-19 pandemic, which has caused bioprocessing businesses to shift their priorities to be able to manufacture treatments and vaccines related to the virus once a vaccine is approved. Your observation.

Covid-19 pandemic has nearly impacted all global industries and institutions, including bioprocessing and biopharmaceutical industry. Undeniably challenging time has pushed industry to be more resilient, flexible and adaptive for new normal. Bioprocessing industry being part of 'essential' services kept their operations running with minimal disruptions, however, with remote site of any medication in short time, and to support business growth and expansion, industry requires calibration and realignment in following areas:

1. **Staffing:** Categorization of human resources – essential and non-essential staffs to implement enough social distancing norm at workplace. Flexible shift modules with cluster identification to avoid any disruptions and ensuring safe operations. Implementation of work from home policy will become a usual pattern in accordance to IT firms. More emphasis on talent build up will be initiated for forthcoming business opportunities.
2. **Supply chain:** More control and integration of supply chain will happen – backward or forward, to meet business demands. Long term contract, dependency on single suppliers and localization of sourcing will always be deliberated.
3. **Inventory management:** The need of hour is the implementation of smart inventory management system along with business strategy to circumvent delay in critical assignments.

4. **Logistics:** Movements of goods will be adversely affected due to delays in shipment and requires proactive planning, monitoring and execution.
5. **Facilities:** In order to address pandemic related bioprocessing, the modular facilities with single use systems will be preferred. Big companies might go for regionalization or decentralization of manufacturing sites as part of their disaster or contingency policies to avoid any disturbance in supply and demand.
6. **Automation:** In case of staffing challenge and desire to reduce onsite staff, industry will bring for more investment in automation for process improvement and cost control.
7. **Information and technology:** Organization might encourage employees to work from home during pandemic like situations, which in turn, requires improvement in IT infrastructure and cybersecurity controls. New platforms such as cloud based services, industrial internet of things (IIoT), artificial intelligence and machine based learning will become accessible as innovation driver.

Bioprocessing industry will strive for opportunity in faster and customized R&D activities, and push for streamlining approval considerations from regulatory bodies to speed-up product development. More, collaborative and interactive communication will be witnessed between academia and industry. Outsourcing business will keep on flourishing as a risk mitigation for large supplies and faster R&D activities.

Your comments on the Make in India initiative of Government of India and its impact on Pharma sector?

India is one of the fastest growing economic in the world and Government's push to "Make in India' campaign a reality has resulted in fundamental structural changes in pharmaceutical sector. The Government of India has planned to incentivize bulk drug manufacturers and reduce dependency on China for active pharmaceutical ingredients. The department of pharmaceutical has set up a venture capital fund to facilitate start-ups ecosystem in the research and development in the pharmaceutical industry. For smooth functioning, an inter-ministerial co-ordination committee is formed for periodic review and address any issues. Moreover,

Government of India unveiled "Pharma Vision 2020", with prime objective of making India a drug discovery and innovation centre in 'end to end' manufacturing.

The success of all these initiatives will rely on contemporary technologies and talent availability. With such a huge young population available in country, it becomes imperative to provide relevant training and development, and make them ready for job opportunities. Life Sciences Sector Skill Development Council (LSSSDC) is one the best initiative undertaken under National Skill Development program, where focus is majorly on talent development for Pharmaceutical, Bio-pharma and Contract research organizations.

In this pursuit, industry-relevant skill training programs (based on job roles) have mapped with training centers and assessment bodies. Beyond this, training of trainers (ToT) program help selected trainers to understand new training requirement and make modifications in existing modules. LSSSDS also works in close association with industry to provide 'training on demand' program to meet immediate business requirement. To address training for high capex sensitive job roles, Virtual Reality Simulation (VRS) modules have been implemented. The other important activity is on assessment and certification of already employed workforce under 'Recognition of Prior Learning' (RPL) program, to make sure talent is always compliant as per business requirement. During Covid time, on-line training modules have become quite important in upskilling the work force – LSSSDC is working closely with Department of Biotechnology (DBT) to provide gamut of trainings for biotech industry.

However, in order to keep the supply engine robust and sustainable, it is critical to nurture quality and excellence in pharmaceutical education and research, develop a cross-functional mutli-disciplinary culture and ecosystem for academic and industry interactions. Finishing school concept for students is a stepping stone to meet shortage of skilled human resources requirement for industry.

New opportunities you see for boosting Healthcare Sector to emerge through this tough time?

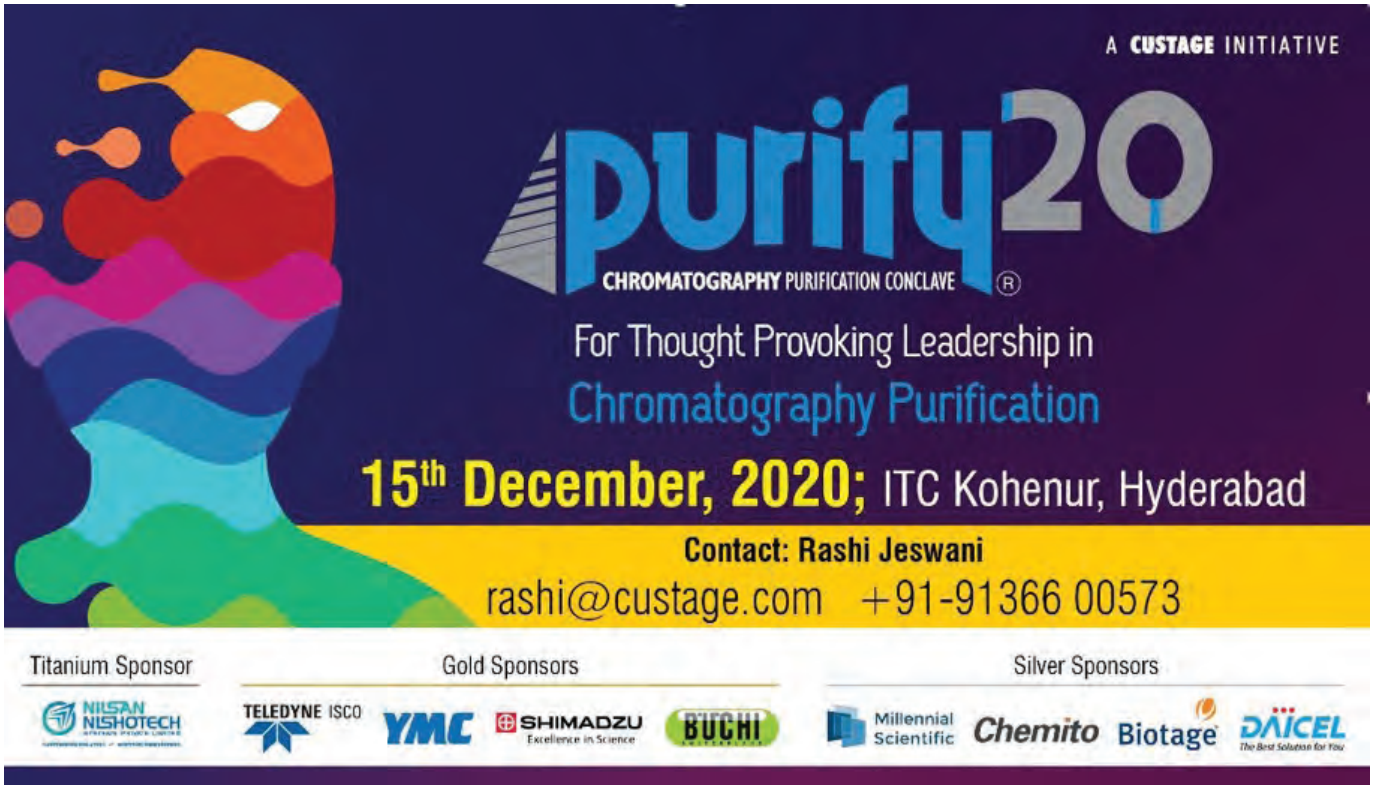
Covid-19 pandemic has put global economy in doldrums, amongst all sectors, healthcare sector has been challenged mostly, and ramifications

of this will change the dynamics of healthcare industry. It has put biopharmaceutical industry under tremendous stress in bringing and in developing vaccines as soon as possible and created new growth opportunities in healthcare, including:

1. **Behavioral healthcare:** The pandemic has resulted in unprecedented levels of social isolation and financial pain, there is an increased demand of behavioral healthcare.
2. **Modular facilities:** Great attention is drawn towards infection control facilities and segregation of intensive or critical care units in hospital layout to address pandemic like situation. More thoughts on scalability of operations and integration of multifaceted resources.
3. **Virtual care services:** Online, phone-based consultancy or home based care will be attractive opportunity as patients will show reluctance in visiting hospitals. Remote patient engagements like virtual rehabilitation and assistants will be a common precedence in future. Artificial intelligence and data management tools will play a crucial role in patient management for nonacute cares.
4. **Ambulatory care:** As patients will choose to avoid hospitals, an increase in ambulatory care or day care services will be noticed.
5. **Diagnostic:** The demand of in-vitro testing platforms will see a surge in their services to manage disease spread in new normal post pandemic.
6. **Digital healthcare:** More funding in data analytics will be required to support Onclick assessment of patient outcome data. This will lead to a conducive ecosystem for start-ups in digitization of easily scalable, readily deployable and tractable solutions.
7. **Regulatory environment:** Digitization of regulatory operations can be disruptive in bringing life saving medicines fast to market, and lead to end of paper-based document management.

As healthcare industry will begin new journey post-Covid, resurgence of value-based care services, digitization and integration of medical services, with tailored made delivery systems will transform the future of this industry. ■

PURIFY'20 – High-Profile Event on Chromatography Purification



PURIFY, the annual conference dedicated to Chromatography Purification is getting ready to showcase its next edition – PURIFY'20.

PURIFY'19 exceeded the industry expectations with some of the finest content that was shared with over 113 fellow chromatographers across 19 cities representing 51 companies. On the dais we had 14 industry experts addressing the gathering with their phenomenal experience in Chromatography Purification. With this successful edition, Custage Marketing Solutions LLP, Mumbai is now busy getting its act together to raise the bar still further with PURIFY'20. So here is this curtain raiser to the bigger and still better PURIFY'20!

PURIFY'20 is going to be on a much grander scale on 15th December, 2020 at ITC Kohenur, Hyderabad. The entire ballroom at ITC Kohenur has been booked to ensure utmost comfort and space for the growing number of attendees expected as well as for our galaxy of speakers.

The event has been carefully crafted to cover a myriad of topics with high-power quality sessions to empower you for the Chromatography Purification of tomorrow, including a breakout session dedicated to bio-molecules.

With the last edition, being the maiden one, touched upon a horizontal spectrum of content covering a lot of lateral topics, this edition is positioned to provide penetrative insight into the various relevant facets that are a part and parcel of every day routine of a day of a purification chromatographer! The attendee will find answers to improve productivity, know of newer technologies, better comprehend the market and regulatory requirements, get updated on the latest in technologies - current and forthcoming, get to know of the best global practices, with lots of practical tips on finally getting that additional gram of pure product at the lowest possible price!

With a never-before-experienced networking opportunity, a number of sponsors of PURIFY'19 quickly decided on their participation at PURIFY'20. What attendees appreciated the most was the networking opportunity with senior management who otherwise aren't accessible easily. As the time of this print, the sponsor list for PURIFY'20 include renowned brands who have well empowered this industry to deliver - Nilsan Nishotech, Teledyne, YMC, Shimadzu, Buchi, Millennial Scientific, Chemito, Biotage and Daicel.

Another first from PURIFY being its post-event coverage. The industry saw a very elaborate compilation of all that happened at PURIFY'19. The industry was in fact agog with the quality of content, quality of delegates, choice of speakers and their topics, expansive venue, luck draws etc.

Putting wind under the wings of PURIFY are also its esteemed advisory board members comprising of Katkam Srinivas, Vice President - Business Head, Maithri, MSN Group of Companies, Hyderabad; S. Damodharan, Executive Vice President - Operational Excellence & New Technologies, Sai Life Sciences Ltd., Hyderabad; Somesh Sharma, Sr. Vice President - Discovery & Development Solutions, GVK Biosciences Pvt. Ltd., Hyderabad; Y. S. Lakshmi Narasimham, General Manager - Analytical, Novel Drug Discovery and Development, Lupin Ltd. (Research Park), Pune and Manish Chawla, Managing Partner, Custage Marketing Solutions LLP, Mumbai. They together bring an unparalleled experience to PURIFY'20 and create a knowledge platform that will provide significant business opportunities to stakeholders in chromatography purification.

One of the best ways to know all about PURIFY'19 and stay updated with the latest updates about PURIFY'20 is to follow the PURIFY LinkedIn page, a fast-growing virtual platform for all stakeholder in chromatography purification. PURIFY'20 is definitely going to be a mammoth of an event. We have strengthened our strengths and weakened our weaknesses to deliver to you the near-perfect event .■

Time for Indian Pharma R&D to shift its gears to match with the global players

The Indian Pharmaceutical Industry (IPI) is ranked third globally in terms of volume and thirteenth in terms of value. The lower market share in terms of value can be attributed to the predominance of IPI in generic medicines which command lower prices. As per estimates, the industry size is expected to grow at a compound annual growth rate (CAGR) of about 7-8% from around USD 42.78 billion in 2020 to about USD 80 to 90 billion by 2030 given the huge export potential coupled with steady growth in the domestic formulation market. Growth in the domestic Pharma market is expected to be driven by increase in the penetration of health insurance, improving access to healthcare facilities, rising prevalence of chronic diseases and rising per capita income. The export growth is expected to be led by increasing generic penetration in the regulated markets on the back of enhanced focus on the niche and complex product segments, patent expiries, medicine patent pool announcing licensing agreement with pharmaceutical companies and growing demand from semi-regulated Pharma markets. In the long term, growth in the export market will be sustained by emerging markets such as Russia, Brazil, and South Africa, etc.

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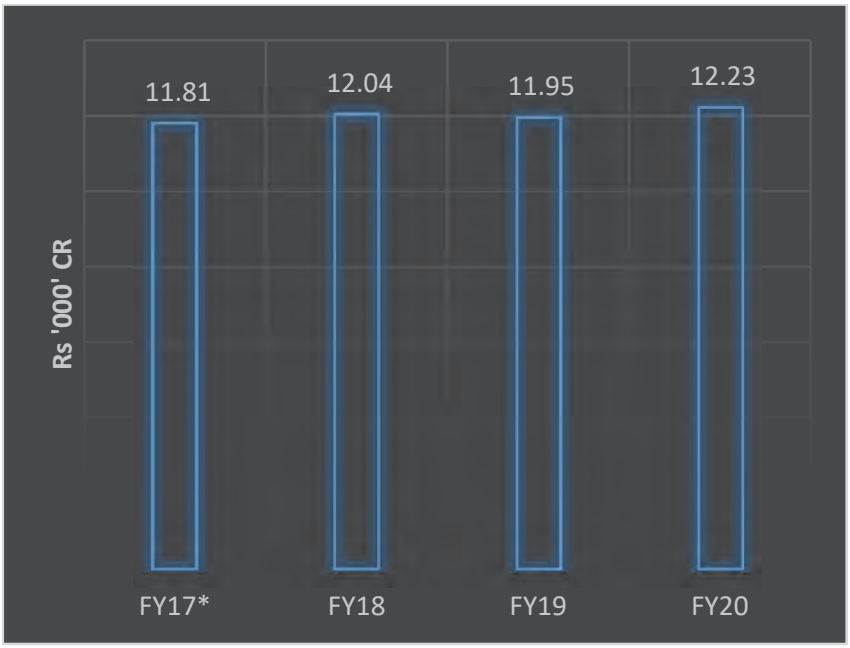
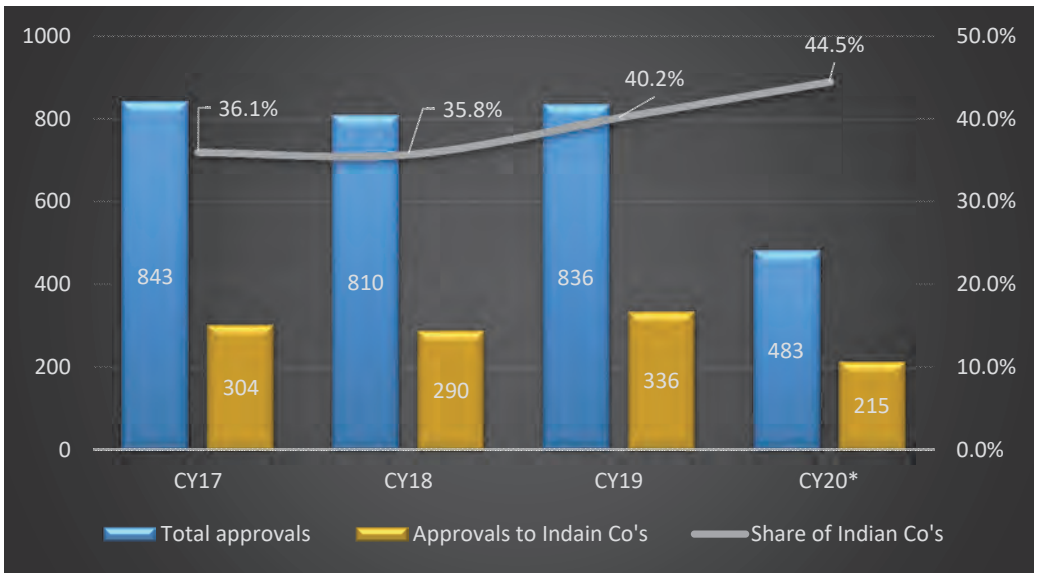
R&D Scenario of IPI

In order to maintain the current growth rate and gain strong foothold in export market, it demands that the Pharma industry build a strong product pipeline through continuous investment in R&D. Opportunities arising from patent expiries, medicine patent pool announcing licensing agreement with pharmaceutical companies and growth of stiff competition in the international market has necessitated and accentuated the Indian Pharma companies to step-up their R&D expenditure. There exists strong correlation between the company's current/proposed spending on R&D and the future growth rate. The top 25 Indian Pharma companies' investment in R&D muted at CAGR of around 1% over the period of period of four years from Rs.11.52 bn (excluding one-time Rs 2.75 bn in R&D by Pfizer) during FY17 to Rs.12.23 bn during FY20. With continuously investing in R&D, the Indian companies were able to bag the lion share of approvals from highly regulated authorities such as United States Food & Drug



R&D investment by Top 25 Pharma Cos, *Pfizer Ltd Rs 2.75 bn excluded in FY17,

Source: Compiled by CARE



ANDA Approvals granted by USFDA, *CY20 till August, *Source: USFDA*

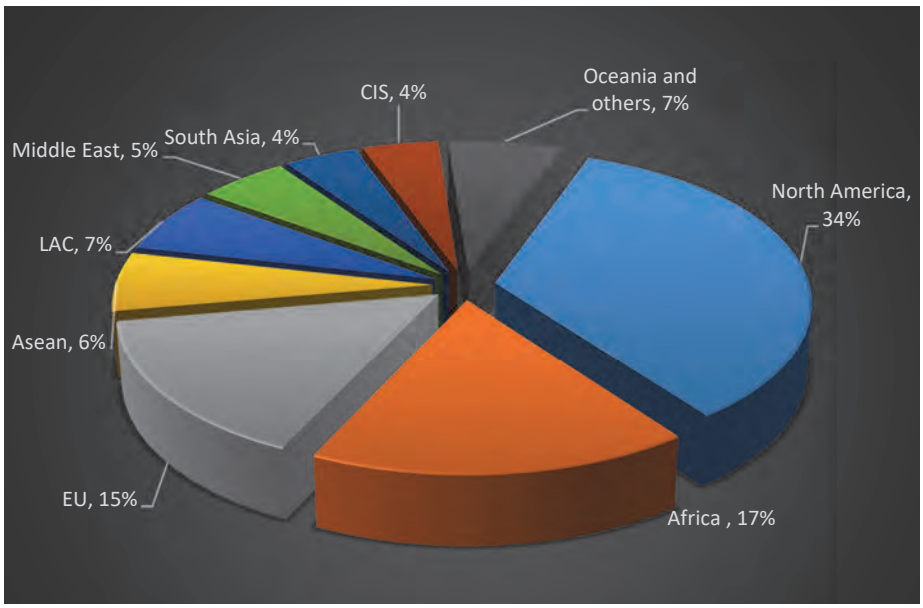
Administration (USFDA). During CY2019, the Indian Pharma companies were able to grab about 40% of total Abbreviated New Drug Applications (ANDA) approvals granted by USFDA and the companies are now focusing on difficult to manufacture and the products where legal and regulated challenges are present.

Export scenario of IPI

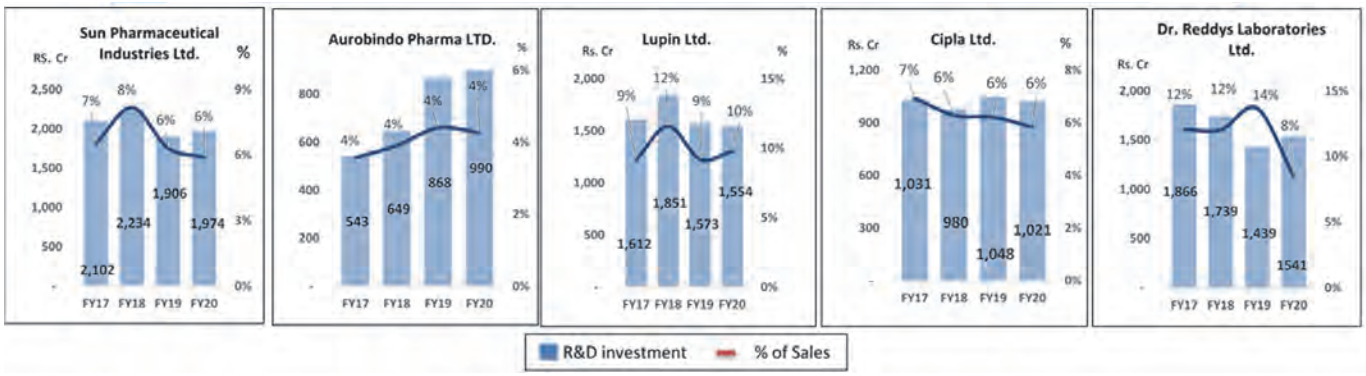
India's export market grew year-on-year by 8% during FY20 to US $20.59 bn from US $ 19.13 bn during FY19. North America continues to be the largest market contributing about 32.74% of the total Indian Export market during FY20 as against 30.4% during FY19, followed by U.K (2.71%) and South Africa (2.97%). Over the last three years on an average Indian Pharma cos have bagged over one third of the total ANDA approvals. During CY2019 Indian Pharma companies have managed to secure US FDA final approval for 336 ANDAs out the total 836 approvals granted by the health regulator of the country. Despite the increasing competition in the U.S. generic market and the increased due-diligence by the health regulator, Indian Pharma Inc. has managed to secure the dominant position on the back of the R&D investment.

The share of the exports from India towards the highly regulated markets (Include USA and UK) has increased to 35.45% during FY2020 (FY19: 33.37%) which shows the competency of the Indian Pharma cos and the improving compliance aspects with highly regulated markets.

The R&D investment by the Indian Pharma cos primarily pertains to development of generic drugs to regulated markets. The R&D investment by the top 25 companies muted year-on-year by 1% to Rs.12.23 bn during FY20 from Rs.11.95 bn during FY19. Average R&D investment of Indian Pharma Inc. (Top25 companies' revenue wise) as a percentage of total sales decreased to 5.95% for FY20 form 6.2% and



Export share of various regions, *Source: Pharmexcil*



Export share of various regions, *Source: Pharmexcil*

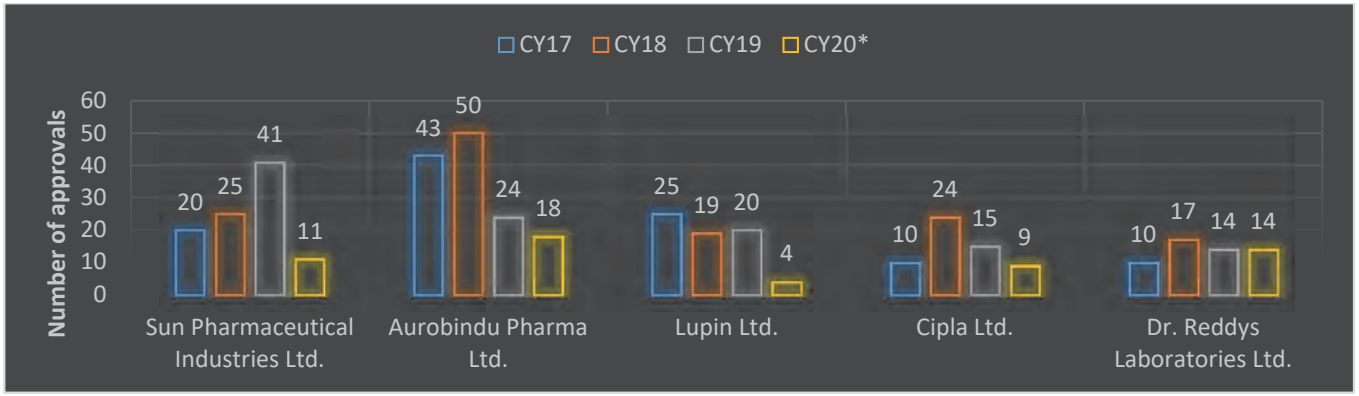
7.1% during FY19 and FY18 respectively.

Notwithstanding the decreasing trend of R&D investment, Indian Pharma Inc. has still a long way if they have to venture into developing a New Molecular entity (NME). The global players in regulated markets spend on an average of 18-21% of the total sales towards developing New Molecule. Further the gestation period for developing and commercializing a generic product may vary from 2-4 years but in order to develop a NME, it takes about 12-15 years before it could get commercialized.

Out of the total 336 Final ANDA Approvals secured by the Indian companies during 2019, Aurobindo Pharma loses its dominant position - got only 24 approvals, While Sun Pharmaceuticals got.

The following are the inherent factors that propel the increasing R&D investment:

- The increasing competition from the Chinese and Latin American countries and the faster ANDA approvals by the U.S. health regulator has started exerting pricing pressure on generic drugs. The effect of the same can be observed in the phenomena wherein the generic drug prices were trimmed from the prevailing market prices despite of generic drug price inflation of about 6% during the past three years.
- The consolidation of the generic drug distribution network in U.S., distribution players can now exert stronger price negotiation power on the generic drugs manufacturers.
- The delay in conduct of inspections by the regulatory authorities on account of prevailing Covid-19 pandemic situation both for the new units and also for the units which have implemented remediation measures as suggested by regulatory authorities post to issue of warning letters or imports alerts could significantly delay the launch of new products. These developments are likely



Receipt of ANDA approvals by the top Indian Pharmaceutical companies during CY17-CY20, *CY20 till August - *Source: USFDA*

to put price pressure on the margins of industry.

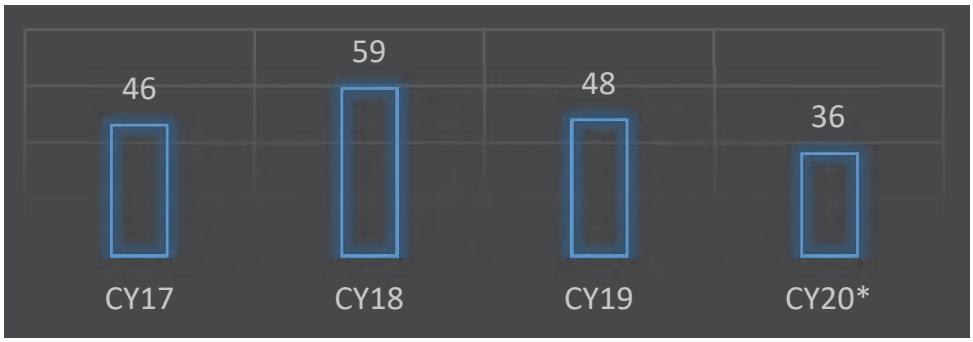
- With the US President insisting on changing the procedures for bidding and encouraging the local US based Pharma manufacturers in order to reduce the cost of medicines would increase the focus of US based Pharma on generics, which in turn would intensify the competition for and between Indian Pharma companies.

Spot light on development of NMEs by regulated markets vis-à-vis India

As per USFDA, NME is a drug that contains an active moiety (part of a molecule) that has never been approved by the FDA or marketed in the US or to mention in simpler terms is totally an innovative drug. The challenge for the industry in developing NME comes in the context of amount of expenditure and long gestation time period. As per industry data, it takes about 12-15 years for a drug before it gets approved by USFDA.

After going through drug discovery process and several phases of clinical trials and then gets commercialized. Successfully developing a molecule is a not only a time consuming process but also a costly affair, with zero revenue generation during the development period (about 12-15 years) and high risk of failure (about 90% of the failure). To develop an NME a company spends about $ 5-7 billion during the said gestation period. The side graph depicts the number of NMEs approved by USFDA during CY17-CY20*. Of the total number of NMEs approved by USFDA, more than 40% belong to US Pharma players. Further, India Pharma companies hardly have any NME approved till date. Therefore it becomes imperative that

Indian Pharma companies to start veering at developing the NME while leveraging their inherent capabilities. India has



Receipt of ANDA approvals by the top Indian Pharmaceutical companies during CY17-CY20, *CY20 till August, *Source: USFDA*

advantage of R&D and clinical trials cost being abysmally low at about 12.50% and 10% respectively compared to that of regulated markets.

Conclusion

Till now Indian Pharma Inc., through lower R&D investment had primarily aimed at maintaining their dominance over the generic space with sustainable earnings. Yearly R&D investment has resulted in bagging of larger share of generic approvals from highly regulated and emerging markets. Through high R&D expense, companies are trying to pace up the rate of ANDA Approvals, along with increasing the share of difficult to formulate complex drugs, thereby creating high entry barrier, which results to lower competition and higher margins. With the change in operational dynamics especially of global Pharma industry, the Indian Pharma companies which hitherto were concentrating on their R&D investment on development of complex generics, now have to shift on developing new molecular entities (NME). Further in view of decreasing number of drugs going off-patent and increasing competition in generic segment, it is imperative on Indian Pharma companies to focus on developing NMEs instead of mere copycatting the drugs developed by the counterparts from developed nations. Although development of NME may have longer gestation period along with high cost involvement, nonetheless the industry has to shift its gears by focusing on development of Innovative drugs even at the cost of narrowing margins, for it has to be inferred that the revenues generated from generics are circumstantial and would fade away with transformation of industry dynamics whereas revenues from patented innovative drugs is substantial and gives long term revenue visibility. ■

Pharmaceutical Research in India:
New Models of Drug Discovery

The Indian Pharmaceutical Industry today is a highly organized sector with a growth rate of about 14 to 15 percent annually. It is technologically strong, totally self-reliant and the low costs of production with innovative scientific manpower will help it grow further. India has a very good track record for development of alternative processes for various drug molecules with improved yield and low costs. Many of these developments were based mainly on expertise and experience gained through integration of technologies/products developed elsewhere. Though many Pharma companies have initiated drug discovery research, none of them are anywhere close to releasing block-buster drugs. A variety of reasons contribute to this dismal performance of Indian Pharma companies. Globally also the drug discovery industry is in a critical condition with increasing R&D spending and high attrition rates, making drug discovery a risky business. Recent estimates indicate that it takes more than US$ 1 billion and a decade long year to bring a single drug molecule from concept to commercialization. This review highlights some of the recent developments in analytical instrumentation and presents new models of drug discovery that may overcome the present crisis in the drug discovery industry.

Dr. Pallu Reddanna

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I. Analytical and bioanalytical instrumentation in drug discovery

Drug discovery involves research carried by a multidisciplinary team composed of chemists, biologists, pharmacologists and clinicians. The drugs developed so far have been targeted not more than 500 disease linked genes or proteins. As a result of various analytical and bioanalytical technological breakthroughs in genomics and proteomics, it is anticipated that around 5000 relevant new targets will possibly be identified over the next 10 years. The automated sequencers and genome analyzers have brought the costs down more than 2X per year, making the entire human genome sequence affordable. The development in the microarray technology and proteomics tools have made it easy for the studies on gene/ protein expression profiles of the whole genome. Rapid advances in technologies such as mass spectrometry(MS), nuclear magnetic resonance (NMR) spectroscopy, fluorescence spectroscopy, dual polarisation interferometry and computational methods played key role in the field of metabolomics. These tools played critical role in the identification of novel targets, not only for known diseases but also for emerging diseases.

Similarly, rapid developments in molecular separation platforms, coupled with variety of detectors have revolutionized the separation and identification of not only small molecules but also large molecular proteins. Some of these include capillary electrophoresis (CE), gas chromatography (GC), HPLC, UPLC, LC-MS, LC-MS/ MS, MALDI-TOF and MALDI-TOF/MS. These separation platforms, however, rely on conventional particle-based technologies optimally designed for small molecule separation. Recent technologies involving renaissance of membrane and introduction of continuous bed or monolithic separation stationary phases overcome these problems. As a result, the separation of extremely large molecules like proteins, viruses or DNA can be achieved within seconds to a few minutes. High resolution-mass spectrometry (HR-MS) technology has made several breakthrough improvements in the past 5-7 years, including developments of new HR-MS instruments, data-mining tools and data-acquisition techniques. As a result, HR-MS has become the LC/MS platform of choice for drug metabolite profiling and identification in discovery and development.

Combinatorial chemistry and auto purification systems, along with separation platforms are immensely useful in developing compound libraries, of both

natural and synthetic, which are critical for drug discovery.

Instrumentation Driving Omics

- Genomics :Automated Sequencers, Genome analyzers
- Microarrays: Array Platforms
- Proteomics: Separation Platforms, MALDI-TOF-MS
- Metabolomics: Separation Platforms, MS, NMR spectroscopy, fluorescence spectroscopy, dual polarisation interferometry, MALDI-TOF-MS

Separation Platforms

- Chromatography: GC, HPLC, UPLC
- Combination Techniques : GC-MS, LC/MS/MS, CE-MS, SPE-LC-MS-MS

Rapid developments also have taken place in drug screening, cutting down the costs and time. From the manual screening of few hundreds of compounds per day, we have now reached towards screening of more than 2 million compounds in a day with robotic high throughput screening (HTS). HTS helps in reducing the time of screening, repetitive works and cost effectiveness.

Computer Aided Drug Design (in silico) approaches have been widely employed in Lead Identification and Lead Optimization stages of drug development against various targets over the years (Buchan et al., 2011). Molecular Modeling and Drug Design would be an important stream in the development of potential drug candidates for the pharma industry. In comparison to traditional drug discovery methods rational drug design methods bring down the time and cost involved in drug development process. It can be used to identify/design new inhibitors de novo or for the optimization of identified molecules from various sources. The development of more effective binding affinity prediction methods has made the application of CADD approaches in drug development process more invincible.

II. New models for drug discovery

Academia as the front-end player

The drug discovery industry globally is facing a considerable challenge due to increasing costs, decreasing productivity, and high rates of attrition of projects as they progress through the development process. These challenges can be overcome by developing novel models of drug discovery. One such approach would be to refocus the pharmaceutical industry research to involve academia as a 'front end' player. Universities/institutes with specialized core facilities, expert faculty, and talented young scientists should nurture innovation and provide

a pipeline of inventions and product ideas for licensing to industries for further development. This model should shorten the duration of drug discovery, enable the translation of publicly funded research, and lead the development of novel therapies at affordable prices. More importantly, this should promote innovative research in academic institutions.

The University-industry partnership models must be flexible and adequately funded by industry and/or Govt. agencies. Some of the recent initiatives of Govt. agencies to promote academia-industry tie-ups are:

- Drugs & Pharmaceutical Research program of Department of Science and Technology-DST (www.dst.gov.in/scientific.programme/td-drugs.htm),
- Technology Development Board (TDB, www.tdbindia.org),
- The National Science & Technology Entrepreneurship Development Board (NSTEDB, www.nstedb.com) of Department of Science and Technology (DST, www.dst.gov.in),
- "Promoting Innovations in Individuals Start-ups and MSME" (PRISM) is the erstwhile "Technopreneur Promotion Programme" (TePP) (https://step-iit.org/tepp.html), Technology Development and Demonstration Program (TDDP) and Industrial R&D Promotion Programme (IRDPP) of Department of Scientific and Industrial Research (DSIR, www.dsir.nic.in),
- Biotechnology Industry Research Assistance Council (BIRAC) set up by Department of Biotechnology, Government of India (https://www.birac.nic.in/), empowers the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs through programs like e-YUVA, BIG, PACE, SBIRI, BIPP, CRS etc.,
- New Millennium Indian Technology Leadership Initiative (NMITLI) grants by Council of Scientific and Industrial Research (CSIR, www.csir.res.in),
- Biotechnology Industry Research Assistance Program by DBT in partnership with ABLE and BCIL (BIRAP, www.birapdbt.nic.in),
- Seeding Drug Discovery Initiative by Wellcome Trust (www.wellcome.ac.uk),
- Medical Research Council Development Pathway Funding Scheme set up by the MRC (www.mrc.ac.uk),
- The National Biopharma Mission (NBM) is an industry-academia collaborative mission for accelerating biopharmaceutical development launched in 2017 (https://www.birac.nic.in/nbm/).

Academia and industry should exploit the above incentives and work towards novel drug discovery processes.

Push and Pull models

Push and Pull models have to be created where 'push' from the owners of the IP and 'pull' from the pharma/biotech companies will help in more effective drug development processes. Many leading organizations have initiated programs to commercialize the outputs of their parent organization or funded components. These models would bring together key research and commercial players to identify and execute joint research activities more efficiently and more strategically.

Promoting & Nurturing Innovation

In addition to University-Industry tie-ups, there is a need to develop strategies for promoting innovation, protecting and enforcing intellectual property (IPR) and fostering entrepreneurship among scientists. This will be possible by promoting scientist- based enterprises across the country, which will focus on innovative translational research leading to IPR generation and commercialization of technologies. Even though Union Government had permitted the Faculty members to involve with such Science and Engineering driven Scientific Enterprises (vide a notification no. 3/3/2009-TU/ Knowledge to Equity dated May 25, 2009 by Department of Scientific and Industrial Research (DSIR), Ministry of Science and Technology, Govt. of India), it is not being implemented in most of the universities and institutes. Hence there is need to give wide publicity of the scheme and encourage for setting up of the faculty led enterprises so that innovations in academic institutions are taken up for further development.

The major constraint for budding entrepreneurs is the lack of mechanisms for venture capital (VC) support. Most VCs are interested in investments in companies with assured returns, and are not ready to finance drug discovery enterprises, especially in the early stages. In this connection, the announcement of the Rs. 100 crore "NASSCOM- ICICI Knowledge park Innovation Fund" for seed-stage investments to startups with a focus on creating intellectual property, and to academicians and researchers looking to commercialize inventions is a welcome trend. Such enterprises, set up with support from the Government/ Private agencies in University/Institute incubation centres, will become the centres of innovative discoveries to be exploited by big pharma companies. This will channelize the young pool of researchers in the country, who are otherwise unemployed or underemployed,

towards innovative drug discovery and nation-building.

Setting up of Biotech-Pharma Entrepreneur (BPE) Fund

A number of Government agencies (CSIR/ UGC/ICMR/DBT) have been offering fellowships for conducting doctoral/ postdoctoral research in publicly funded institutions. However, there is no agency that promotes young entrepreneurs from Universities/IITs/IIMs, coming up with innovative ideas. These are exclusively for students graduating from the Universities/ Institutes. Hence, there is need to setup 'BPE Fund' to support about 100 young scientists with innovative ideas every year, who are selected through a nation-wide competitive selection process. These BPE awardees may be given priority to locate their ventures in the Technology Business Incubators (TBIs)/BioNEST/TIDE incubation centers established by various Government agencies across the country. Those who are successful in this scheme may compete along with others for second round support through BIG/SBIRI/ BIPP/ CRS/TDB schemes of Govt. agencies.

This BPE Fund will form a channel to nurture innovation among the young scientists emerging from Universities/ IITs/IIMs. The leads coming from these innovators will feed established biotech/pharma companies for further development. If we promote about 100 BPEs every year, within a period of 10 years, there will be 1000 startup companies engaged in drug discovery and development.

III. Traditional systems of medicine

Natural products have provided important leads in traditional medicine. India has a rich legacy of traditional medicine such as Ayurveda, Unani and Siddha. These systems have given leads on important medicinal plants and formulations that are effective in treating several complex diseases, often with fewer side effects. Historically, natural products provide the oldest sources for new medicines. Natural selection during evolution provided every species with powerful biologically active natural products for self-defense, which can serve as leads to be refined by chemists as more effective drugs.

According to recent reports, phytochemicals as herbal drugs have an annual market of 100 billion USD all over the world. The herbal drug business dominated by the Northern Block, comprising of Germany, Sweden, Switzerland, UK and US accounts for 47 billion USD worth. Of the balance of 53 billion USD, China commands 57 percent of the market. India's share of this market

is only 2.3 percent and remains on the fringes. There is a need to focus on our age-old Ayurvedic system and develop herbal drugs in focused areas for global market. Towards this direction Council of Scientific & Industrial Research (CSIR) has initiated steps to first document the traditional leads and take up systematic studies to scientifically validate the claims in Ayurveda, Siddha & Unani systems of Medicine. Once validated, the products can be developed further as per international norms and marketed globally. This approach would provide India the advantage to emerge as global leader and contribute to the world with natural product based pharmaceutical products.

IV. The Road Ahead

Indian pharma and biotech companies have to quickly graduate from reverse engineering to innovative research leading to new drug discovery. The strong IT base and large pool of scientific manpower has to be exploited for the design and development of innovative drugs. There is need to refocus pharmaceutical research away from early discovery activities by involving academia and focus on later stages of drug development. This shift in the focus of the industry from early to late drug discovery will enable the translation of publicly funded research and lead to the cost-effective development of drugs. Moreover, they can overcome the challenges in drug discovery like increasing costs, decreasing productivity and attrition of projects. To make these novel partnership models successful, sustainable funding strategies are needed to create specialized core facilities within the academic institutions and driving them towards innovative research. In addition, there is need to create an ideal environment for scientist-based enterprises focusing on innovation and creativity. On the same lines nurturing the young graduates with innovative ideas with the BPE fund will help in channelizing the youth towards innovation and entrepreneurship along with the faculty. These efforts not only creates job opportunities for young graduates coming out of Universities and Institutes, but also channelizes them towards innovative translational research and nation building. ■

Yokogawa Survey Finds Two-Thirds of Process Industry Companies Are Anticipating Fully Autonomous Operations by 2030

Yokogawa Electric Corporation revealed the results of a global end-user survey on the outlook for industrial autonomy*, which shows that 64% of respondents from companies in process industries are anticipating fully autonomous operations by 2030. The survey provides an in-depth view of future trends in automation and autonomy, business priorities, and technologies being deployed in key process industries including oil and gas, pharmaceuticals, chemicals, petrochemicals, and power generation.

Key Insights

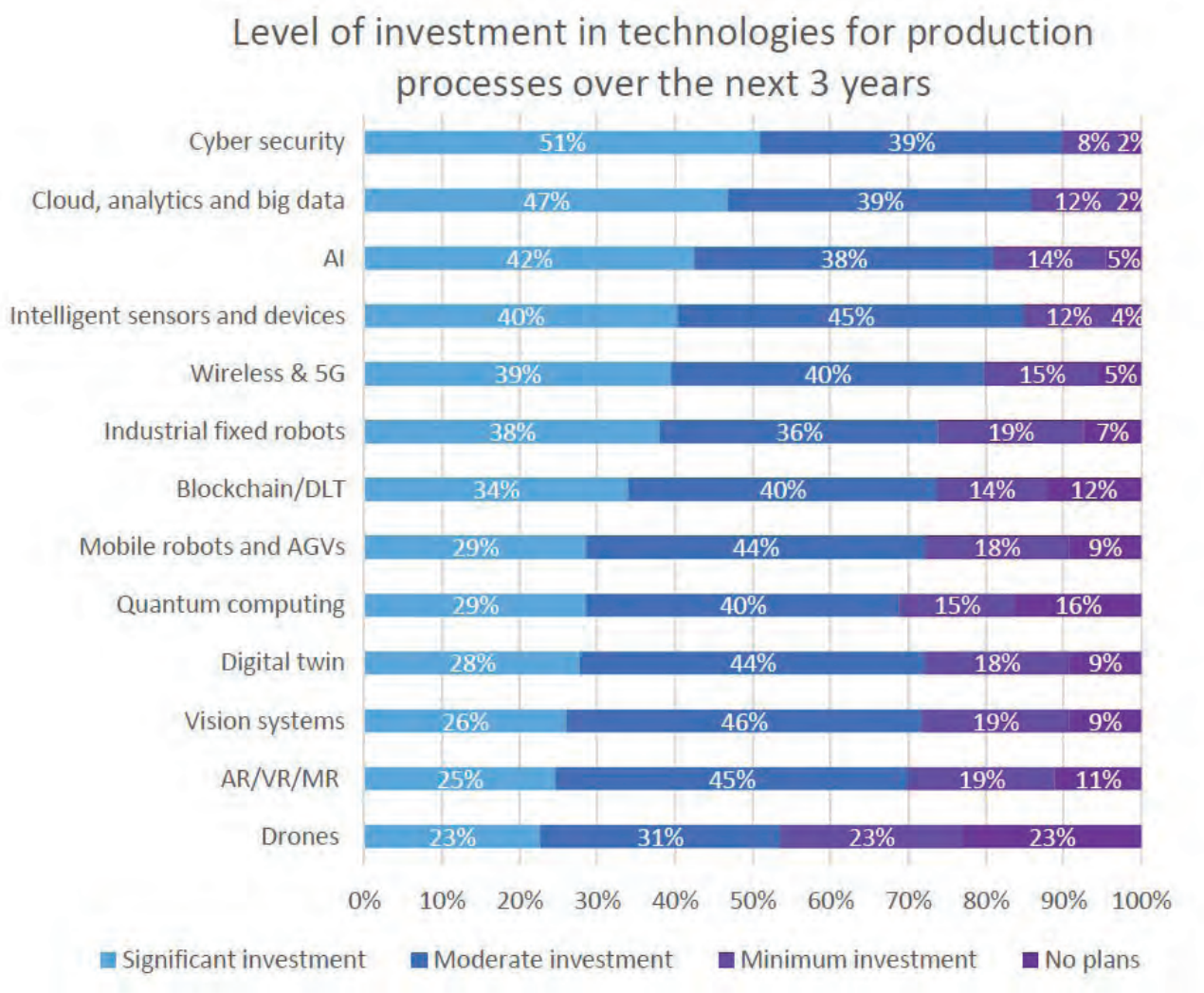
Companies are moving to fully autonomous operations by 2030, and will invest in technologies that aid decision-making

Sixty-four percent of respondents stated that they expect to reach autonomous operations in their primary operations by 2030. Eighty-nine percent said their companies currently have plans to increase the level of autonomy in their operations. Regarding their current status, 64% said that they are conducting or are piloting semi-autonomous or autonomous operations, while 67% expect significant automation of most decision-making processes in plant operations by 2023.

Cyber security (51%), cloud, analytics, and big data (47%), and artificial intelligence (42%) are three key areas in which companies are planning significant investment over the next three years. These will enable organizations to make better decisions across a greater span of control.

COVID-19 has put the brakes on economic growth in 2020 but will be a catalyst for the medium- to long-term growth of industrial autonomy

COVID-19 has arguably presented a great impetus for industrial autonomy moving forward. A higher priority is now being placed on the ability to continue running operations without workers needing to be present. A majority of respondents are expecting to increase their investment in autonomous operations as a direct result of COVID-19.

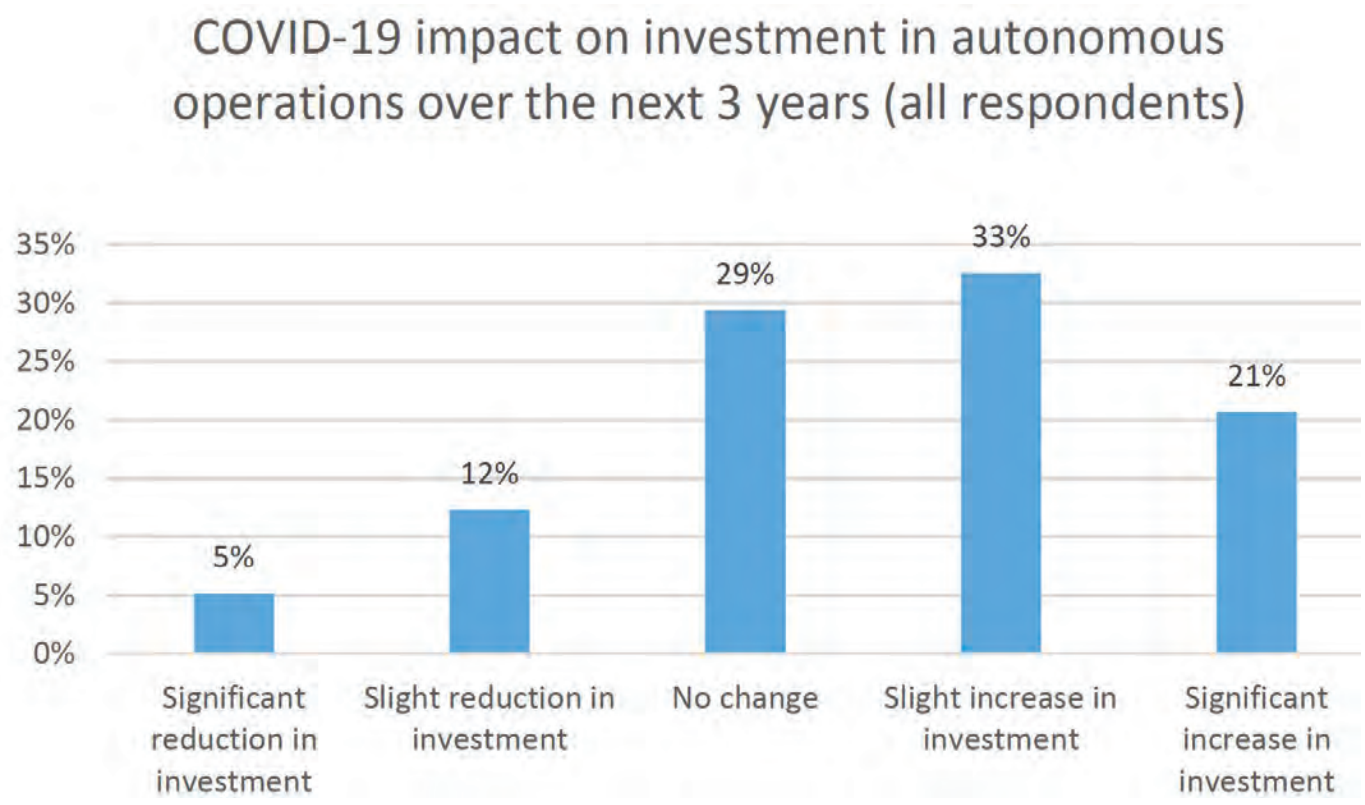


Respondents were also asked to rank the top four applications in which they were directing investment as a result of the COVID-19 pandemic. Unsurprisingly, remote operations and remote servicing came out as two of the key applications for which priorities have increased, with a respective 36% and 30% of participants selecting them. The ability to conduct work without the need for workers to be present in a hazardous environment provides significant safety and cost benefits.

The survey also uncovered significant differences across industries in post-COVID-19 investment priorities. For example, compared with other industries, conventional power generation and chemical/petrochemical participants placed a greater focus on investments in worker safety.

Regional trends

The survey revealed regional differences in investment in new technologies and the push to industrial autonomy. Relative to other regions, Asia-Pacific is the most engaged in the shift to industrial autonomy. The survey found



that the proportion of companies in Asia-Pacific that are prioritizing investment in autonomous systems for operations is 18% to 27% higher than other regions. This is a key statistic and shows that funding is being directed into autonomous operations in the region. Seventy-one percent of respondents in Asia-Pacific felt that they would attain fully autonomous operations in ten years' time, compared with just 58% in North America and 56% in Western Europe.

"From this research study, we have confirmed our perception that the shift from industrial automation to industrial autonomy, which we call IA2IA, is going to gain momentum over the next decade. As COVID-19 will accelerate this trend, and companies' interest in introducing related technologies continues to be strong, Yokogawa can support customers in strengthening their competitiveness step by step based upon our roadmap to autonomous operations," said Tsuyoshi Abe, senior vice president and head of the Marketing Headquarters at Yokogawa.

Yokogawa believes the digital transformation of companies' manufacturing and production operations will lead towards autonomous operations; the results of the survey demonstrate that companies are prioritizing and investing in the technologies of tomorrow in order to make this a reality.

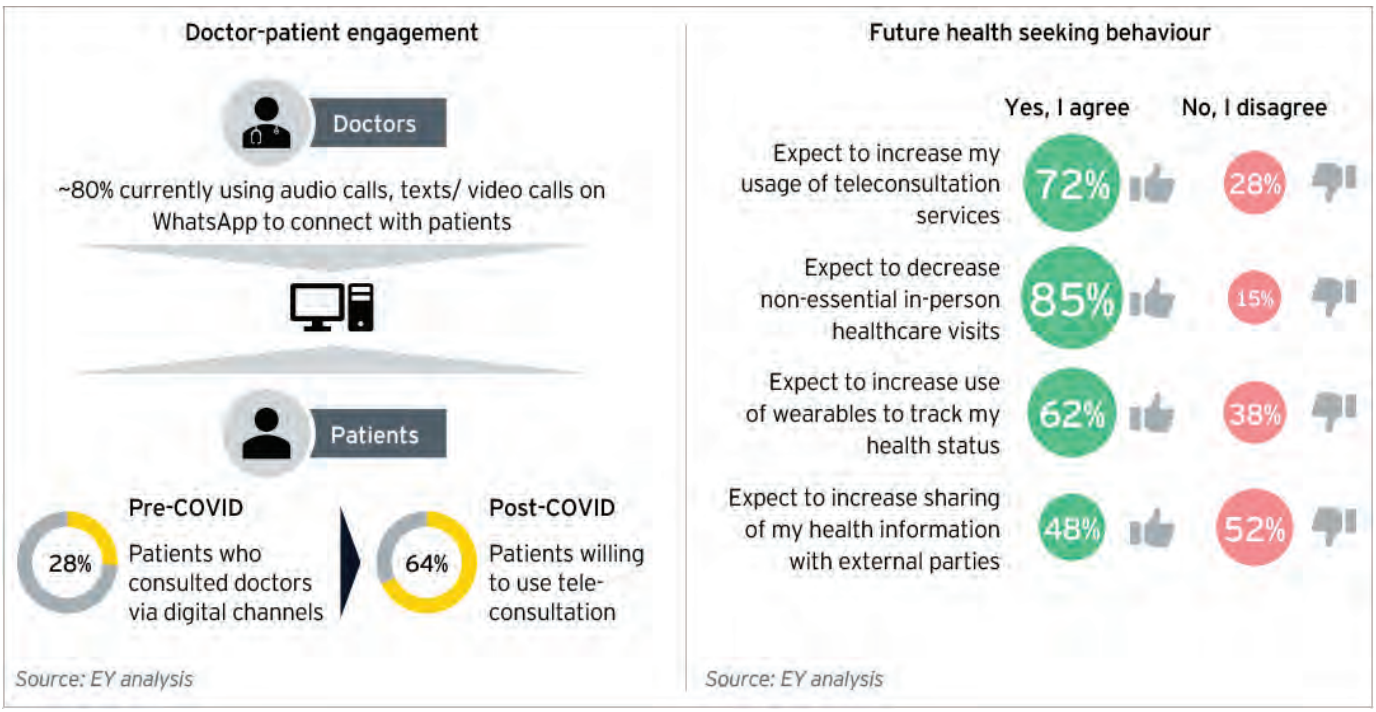
The survey highlight report can be downloaded from the following website. *https://www.yokogawa.com/special/ia2ia/outlook/*. ■

Telemedicine market to reach US$5.5 billion by 2025 with teleconsultation and e-pharmacy making up 90%

The Indian healthcare industry needs to shift from traditional in-person doctor patient interaction to digitally enabled remote consultations, states the recently released study by EY titled, "Healthcare goes mobile: Evolution of teleconsultation and e-pharmacy in new Normal." The study, conducted in collaboration with the Indian Pharmaceutical Alliance (IPA), is based on results collated by surveying consumers, doctors, stakeholders from leading Indian pharma companies and Global EY research. The study aims to understand the transition of the Indian healthcare system due to technology disruptions, opportunities and challenges.

As COVID-19 defines a new normal, the patient—doctor interactions via digital channels are expected to increase. According to the survey results, 64% of consumers showed an increased willingness to adopt teleconsultation post—COVID-19. On the other hand, doctors are also trying to reduce the non-essential visits of the patients with approximately 80% of them being consulted using informal means of consultation such as audio, video and texts messages through various apps. 15%-20% of the healthcare ecosystem is expected to shift to virtual care, across triaging, consults, remote monitoring, home health, etc. However, the rapid growth driven by increased digitization will raise challenges related to patient's data privacy and prescription substitution.

- 5%-20% of healthcare is expected to shift to virtual care, across triaging, consults, remote monitoring and home health
- 64% of surveyed consumers are willing to adopt teleconsultation post COVID-19
- 80% of surveyed doctors are being consulted using informal means of communication such as audio, video, texts on various messaging apps.



Thus, there is an immediate need for a strong regulatory framework in the interest of patients /consumers. As per the study, India's e-pharmacy market is projected to reach 10%-12% of overall pharmaceutical sales in the next five years driven by strong regulations, increased funding and creation of digital infrastructure.

Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliance expressed, "As the COVID-19 pandemic throws unprecedented challenges, consumer behaviour and patterns are changing dramatically. With the new norms of "social distancing", traditional ways of in-person doctor-patient interaction are being digitally enabled by remote consultations. While the technology will be a great enabler, evolving regulation should guard areas of patient privacy which is fundamental in relation to healthcare. The industry is experiencing a technology revolution and customer expectations have huge demands on what is possible."

Virtual care constitutes of tele–consult, telepathology, teleradiology and e–pharmacy. It is experiencing an encouraging stimulus in India due to the pandemic. This stimulus has the potential to make teleconsultation and e-pharmacy account for ~95% of the telemedicine market by 2025, which amounts to US$5.2b. Sriram Shrinivasan, Partner & Leader – Life Sciences, EY India, says, "With the current levels of adoption by the patients and doctors along with emerging technologies and ecosystem, India is well poised to grow the digital health ecosystem. For the wider acceptance and usage, there is a need for robust regulatory

and governance framework that provides the right support for growth"

The pandemic has highlighted the need to build a simplified and holistic teleconsultation platform, guided by the robust regulatory and policy framework, encompassing all key stakeholders. The teleconsultation healthcare ecosystem will connect the three stakeholders, namely, (i) providers – doctors and paramedics, (ii) payers – patients and insurance companies, and (iii) fulfilment centers – pharmacies and diagnostic labs, through platform providers. The platform providers can be hospitals, pharmaceutical companies, NGOs and government or private bodies.

Teleconsultation's market size in India is expected to grow from US$100m to US$700m in next five years at a CAGR of 48% as per the EY-IPA report. The recently released regulatory guidelines by Medical Council of India (MCI) provide necessary impetus to teleconsulting. Moreover, the spend on medical infrastructure is also likely to increase to US$200b by 2024.

Pramod Sudhindra, Digital Leader – Life Sciences, EY India, said, "The next nine months will see a rapid evolution and transformation in the healthcare industry with the adoption of e-pharma and tele-medicine services. Integrated ecosystem is the largest factor driving adoption of these services."

Having said that, there are challenges towards the adoption of teleconsulting as well. While 54% patients questioned the reliability of the online diagnosis, 30% are not comfortable with the use of technology and the virtual sphere. Data privacy also remains a key area of concern.

The pandemic has accelerated the need for change in the form of immediate adoption of widespread telehealth services. Teleconsultation has the potential to add value to the patient-provider experience. It may become the next frontier to handle public health crisis and be one of key pillar of patient care in the post COVID world.

The government is taking necessary steps through active policy making to develop the teleconsultation ecosystem and increase its adoption. Digital policies including National Digital Health Mission have given a boost to private entities to participate in the creation of collaborative digital platforms. A technology-enabled ecosystem with strategic partnerships with relevant stakeholders will be key to a thriving/sustained virtual healthcare journey.

Key factors to make teleconsultation a success:

- Patient experience emerged as a key determinant for continued use of teleconsultation services. Addressing

certain perception barriers may enable teleconsultation to transcend and extend beyond the current crisis

- Healthcare providers are also demonstrating an increased propensity towards finding a comprehensive virtual solution to enable seamless patient care in a secure environment. There is a need to support doctors to deliver care across the continuum by using the right technology enablers and focused specialties for teleconsultation for value and volume debottlenecking
- Interventions by relevant government stakeholders to build patient confidence and authenticity in remote consultations with transparent SOPs, compliance and strict data privacy and security laws

The change in healthcare delivery is imminent. An ecosystem-based approach can foster quicker development and adoption of teleconsultation platforms. Navigating the emerging collaborative platforms may be challenging for the stakeholders. But the actions accomplished today have the potential of transforming the healthcare system. ■

Source: EY-IPA study

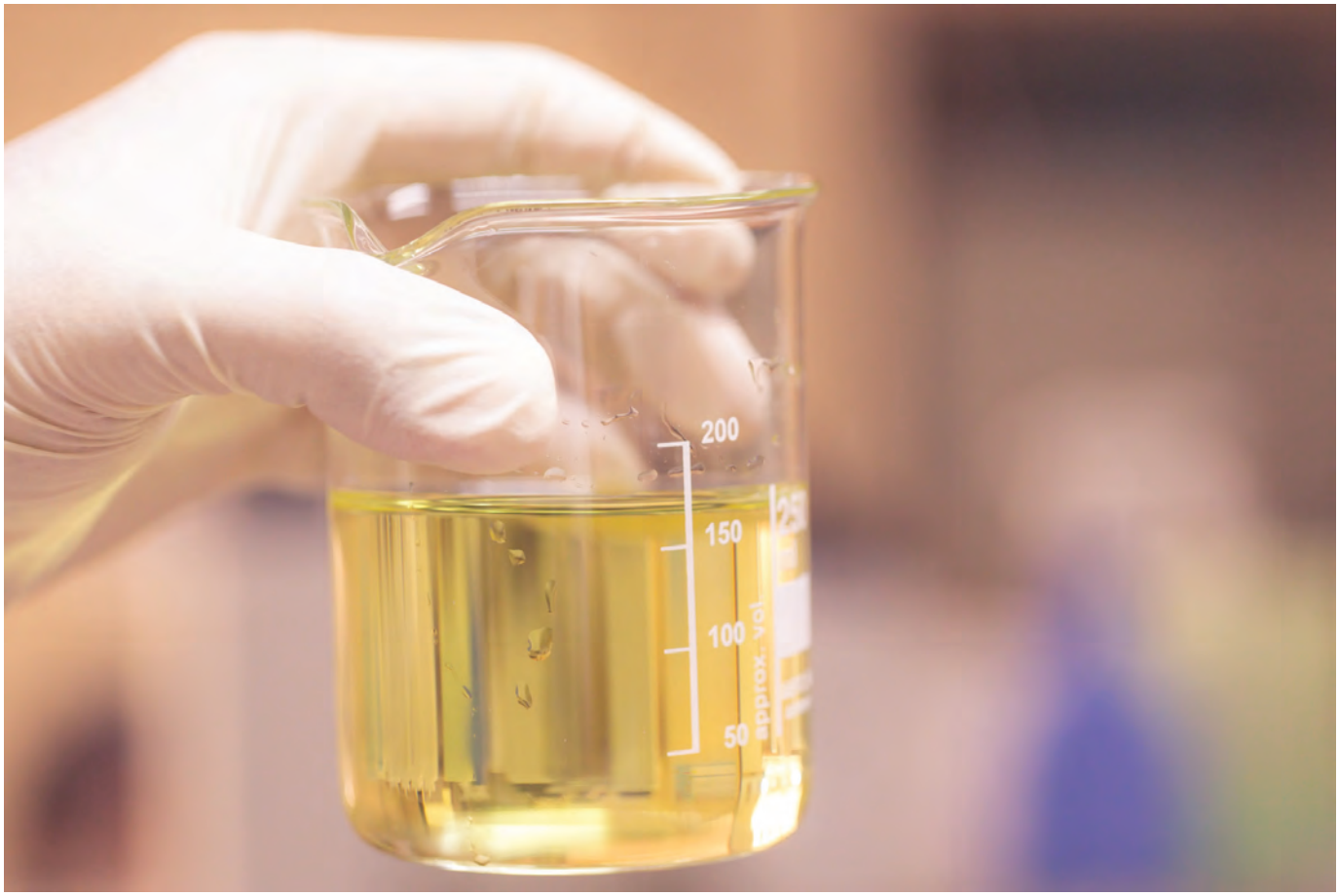
Ultra-High Solids Polyurethane Adhesives with up to 80% Biomass Content

Toyochem, a wholly owned subsidiary of the Toyo Ink Group, oversees the Group's Polymers and Coatings-related business segment as a core operating company. Headquartered in Tokyo, the company using the Group's polymer design technologies that have been cultivated for over a century, manufactures polymers, adhesive tapes, marking films and coatings for a wide array of industrial applications. The company's slogan "Something New, Close to You" embodies its commitment to continuously bring new value to everyday lives by delivering new solutions that use Toyochem polymers as their core material.

Toyochem has developed new Cyabine™ and Oribain™ pressure-sensitive adhesive (PSA) with high bio-based content for use in packaging, labels and tapes. The bio-based content for the company's Cyabine™ series of polyurethane adhesives recorded values up to 80 percent, while the Oribain™ series for acrylic adhesives up to 75 percent.

Toyochem Co., Ltd., a member of the Toyo Ink Group of Japan, has developed a new Cyabine™ series of polyurethane pressure-sensitive adhesives (PSAs) with ultra-high solids content of 99% or more. The new adhesive composition achieves the same performance levels as conventional solvent-based PSAs, while reducing solvent and volatile content to minimal levels. They are suitable for use in a wide range of industrial applications such as protective films.

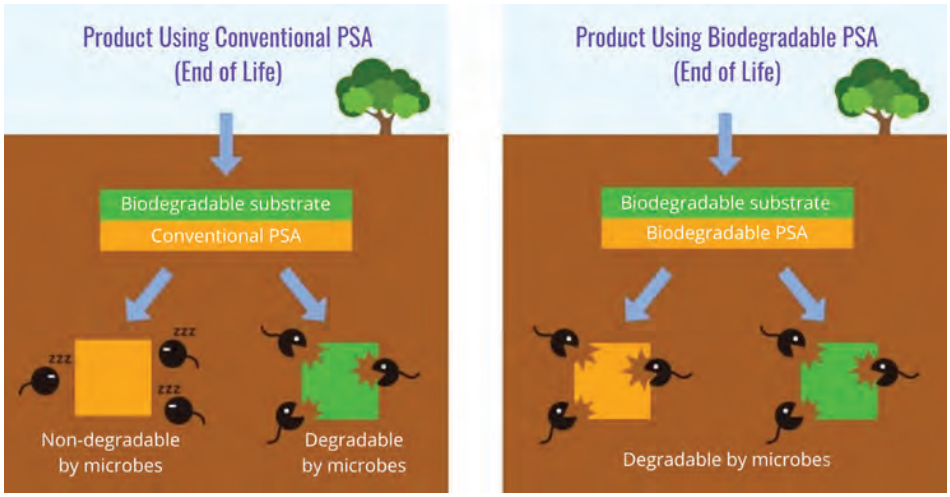
In recent years, countries around the world have been taking urgent action to mitigate climate change and its impact. This is also true in the field of adhesives, where much research is being conducted in the area of renewable materials derived from bio-based polymers. While petroleum solvents had been extensively used in adhesive systems of the past, there has been a growing call to reduce or eliminate the solvent content as a countermeasure to address environmental concerns.



There has been growing interest in reducing plastic waste, in particular with regard to the development of biodegradable materials that reduce the use of petroleum and its negative impact on the environment. In many countries, industrial waste generated from fields such as civil engineering, forestry and agriculture need to be recovered or decomposed naturally without imposing a burden on the environment. While the base paper or film substrates used in recovered products are biodegradable, the additives such as adhesives traditionally used to coat or treat them are not, resulting in disposal issues.

To meet the demand for lower VOC-emitting products, Toyochem has been gradually building on its lineup of high-solids content adhesive compositions with high levels of non-volatile content. The new PSA product is the outcome of new technological developments in synthesis and crosslinking methods developed by Toyochem. These advances allowed the company to engineer a new high solids system that contributes to reduced CO2 gases during coating and drying processes, for a safer, more environmentally sound work environment.

Typically, the more solids that an adhesive mixture contains, the higher its viscosity is, making it more difficult to coat. To resolve this issue, Toyochem researchers applied



its original polymer and crosslink design technology to control chemical reactivity in the development of a new formulation with low viscosity and high solids content while maintaining performance standards. In addition, a unique synthesis method was introduced, making it possible to keep solvent content down to very low levels. These new developments enabled Toyochem to achieve near-100% solids formulations that exhibit excellent transparency, reworkability and air release properties on a par with conventional pressure-sensitive adhesives.

Cyabine ultra-high solids polyurethane PSAs are currently available in Japan with a worldwide release to follow in the next few years. With an ever-growing portfolio of biodegradable, bio-based and water-based adhesive products, Toyochem will continually work to create innovative solutions that help to reduce the environmental load on society.

In addition, by using plant-derived raw materials, the new Cyabine adhesive achieves a biomass content on a dry weight basis of up to 45%. This means the product can reduce CO2 emissions throughout the lifecycle of the newly developed product, without compromising on adhesive performance.

After use, the adhesive waste can be digested by soil microorganisms and converted over time into substances, such as carbon dioxide, water, nitrogen and methane gas, thus helping to reduce landfilling and further close the circular loop on plastic waste.

Moreover, the new PSA system demonstrates biodegradation rates of 60% or higher after 60 days. When combined with other biodegradable materials used in a wide range of products, it helps to improve the overall biodegradability of these products (see illustration).

The biodegradability of the new Cyabine PSAs has been confirmed under controlled composting conditions as prescribed by the Japanese Standards Association's JIS K 6953-1, the equivalent of the international standard ISO 14855-1.■

The Evolution of Law and Ethics in Pharma Sector: Tracing the Indian Context - Part II

*In the previous editions the author **Mr R. S. Raveendhren, Advocate** at the High Court of Madras & Legal Expert in the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre has traced the evolution of international norms pertaining to clinical trials and the legal ethics in the Indian pharma sector. Part II of the series on legal ethics in India chalks out the role of the various institutions and functions.*

The Indian Council for Medical Research (ICMR) is the apex body in India not just for formulation of biomedical research but also for its promotion. It is directly funded by the Government of India and promotes both intramural and extramural biomedical research in the country.

Mr R. S. Raveendhren
Advocate, High Court of Madras & Legal Expert in the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre.

What is Intramural Research?

Research that takes place within the precincts of the institution is called intramural research. At present, there are 21 national and permanent research institutes that are located in different parts of India. They carry out research on areas such as Tuberculosis, Leprosy, Cholera and Diarrhoeal diseases, viral diseases including AIDS, Malaria, Kala-azar, vector control, nutrition, food & drug toxicology, reproduction, Immune-haematology, Oncology, Medical statistics, etc.

There are also six other regional medical research centres addressing regional health problems.

Extramural Research:

The extramural research centers are centers that are promoted by the ICMR through

- Setting up centres for advanced research in areas of research already existing;
- Lending of expertise and infrastructure in select departments of Medical Colleges, Universities and other non-ICMR Research Institutes;
- Commissioning task force studies emphasising time-bound and a goal-oriented approach.
- Conducting open-ended research on the basis of applications for grants-in-aid received from scientists in the non-ICMR Research Institutes.

Central Drugs Standards Control Organisation (CDSCO)

The CDSCO or the Central Drugs Standard Control Organisation is the central drug authority in India. It discharges all the functions assigned to the Central Government under the Drugs and Cosmetics Act of 1940. The CDSCO has all together six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories. It is headed by the Drugs Controller General (India) [DCGI] under the Directorate General of Health Services which is directly under the Ministry of Health and Family Welfare.

Functions of CDSCO

- It exercises regulatory control over import of drugs
- It approved new drugs and clinical trials
- It convenes meetings of Drugs Consultative Committee & Drugs Technical Advisory Board (DTB).
- Also approves certain drug licences

The development relating to clinical trials in India

With the surge in clinical trials in India,

the lacunae in regulatory structure began coming to light. It was obvious that the legal framework was acutely insufficient.

Several thousands were dying or were dead because of unethical clinical trials. In 2004, a Public Interest Litigation suit was filed before the Supreme Court of India by a NGO named 'Adar Destitute and Old People Home' (ADOPH).

It questioned the veracity of the clinical trials that were carried out without any explicit approval and the resultant deaths of patients during the trial of genetically engineered (GE) drugs by two specific pharma companies. According to the statistics collected by Swasthya Adhikar Manch (SAM), a non-profit organisation, a total of 4967 patients died during the course of drug trials and research and another 20,000 plus suffered irreversible adverse reaction for the same reason.

The Apex Court prompted CDSCO to introduce remedial measures which was not very good news for the domestic and international pharma companies.

The positive outcome of the judgement

Per the Supreme Court's observation, any advancement in biomedical and health

research required that regular revision of existing rules and guidelines was made. More and more areas were brought within the ambit of expanded framework:

- Responsible conduct of research,
- Due importance be given to public health and socio-behavioural research
- conduct of research during emergent situations
- Use of stored biological material and datasets.
- Concerted effort made to consult various stakeholders ranging from members of various government departments/agencies, public and private institutions.
- Consultation programmes to be held including the two programmes supported by World Health Organisation (WHO) - Country India Office by partnering with ICMR Bioethics Unit.

The 59th report of the Parliamentary Standing Committee on Health Family Welfare

The 59th Report of the Parliamentary Standing Committee on Health and Family Welfare tabled a report before the Parliament in the year 2012 on the functioning of CDSCO. The report made scathing observations about functioning of CDSCO and its governance of clinical trial in India. It indicted CDSCO thus:

(Sic) most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of CDSCO. For decades together, it has been according primacy to the propagation and facilitation of the drugs industry, due to which, unfortunately, the interest of the biggest stakeholder i.e. the consumer has never been ensured. Taking strong exception to this continued neglect of the poor and hapless patient, the Committee recommends that the Mission Statement of CDSCO be formulated forthwith to convey in very unambiguous terms that the organization is solely meant for public health.

The report decried about lack of transparency and conflict of interest and recommended the immediate restructuring of drug regulation mechanism in India.

Ranjit Roy Chaudhury Committee

As fallout of the 59th Report of the Parliamentary Standing Committee on Health and Family Welfare on the functioning of CDSCO, the Ministry of Health and Family Welfare constituted an Expert Committee in July 2013 that was headed by Professor Ranjit

Roy Chaudhury. It was done to review the existing system and make recommendations to improve and strengthen it.

The Ranjit Roy Committee (RRC) Report recommended the accreditation of the different stakeholders involved in clinical trials, including principal investigators, trial sites and Ethics Committees. The most important recommendations of RRC Report were as follows:

- Creation of a single Technical Review Committee (TRC)
- Accreditation of different stakeholders involved in clinical trials, including principal investigators, trial sites and Ethics Committees
- Safeguarding of the rights of participants through all the stages of a clinical trial, beginning with determining whether the trial needs to be conducted in the first place right up to ensuring that appropriate compensation is awarded or not for trial-related injuries or death.
- Ethnic differences can affect the efficacy, safety and dose regimen of a medicine. The committee recommended that certain factors such as the choice of control group and regional medical practice be taken into consideration when determining whether the available data regarding a drug is ethically sensitive or not.
- Only those drugs that fulfil a real medical need ought to be made available by taking into account the factors in relation to the new drug's risk/benefit assessment, the innovativeness of the new drug, the existing therapeutic option, and unmet medical need in the country.
- The decision making process must be transparent, time-bound and have clear-cut timelines.
- Compensation need not be paid for death or injury due to 'totally unproven unrelated causes'. In the event of an Adverse Event during the clinical trial, the sponsor must be held responsible for providing medical care and treatment to the patient at his cost till the resolution of the event.

(to be continued)

In the next edition the author proposes to deal with the role of revised guidelines, courts and statutes that influenced policy formulation in pharma sector. ■

Breakthroughs in Type 2 diabetes – The silent Indian Endemic

Dr. Uday Saxena
PhD, Reagene Biosciences Private Limited

Type 2 diabetes has become a global problem with India being the world's capital for this disease. Statistically most middle- and upper-class families in India will have at least one-member suffering from this disease. The future projections for the spread of type diabetes are colossal and dismal with no immediate cure in sight. Type 2 diabetes is distinct from Type 1 diabetes – Type 1 diabetes is caused by the inability of the body to make sufficient insulin whereas Type 2 diabetes has sufficient insulin production but the organs which take up glucose are insensitive to insulin induced uptake of glucose. In both cases hyperglycemia and related neuropathy, nephropathy and retinopathy etc. are apparent.

The journey of glucose in the body is largely initiated in the human intestine. Upon intake of dietary carbohydrate and glucose, these are absorbed and carbohydrates are broken down into glucose and released into the blood for transport to the other tissues. Most organs use glucose for generation of energy. The key organs in glucose metabolism are intestine, pancreas, liver, muscle and adipose tissues. Once pancreas releases insulin in response to blood glucose, uptake of glucose by organs is trigged. The muscle serves as the major utilizer of glucose and accounts for almost 80% of glucose uptake. Therefore, any defect in muscle glucose utilization results Type 2 diabetes and hyperglycemia. In fact, this disease can be called a muscle dysfunction problem more than anything else. Figure 1 shows the major organs involved in human glucose metabolism:

The consequences of uncontrolled high levels of blood glucose are debilitating – affecting the nervous system (neuropathy), eyes (retinopathy), nephropathy (kidney dysfunction) as well as the cardiovascular system. All of these when collectively manifested have significant impact on patients' healthy normal function and longevity.

Risk factors and causes of disease

The risk factors for Type 2 diabetes are mostly life style related – obesity, high stress levels, sedentary lifestyle and consumption of carbohydrate rich diet. Of course, age and family history have a role to play as well but these are not modifiable risk factors. In vast majority of cases, a major reduction of the life style induced factors can control or even reverse the disease in its early stages. This is something that is often overlooked and I believe that patients are being put too quickly on medications without giving lifestyle changes a chance to work.

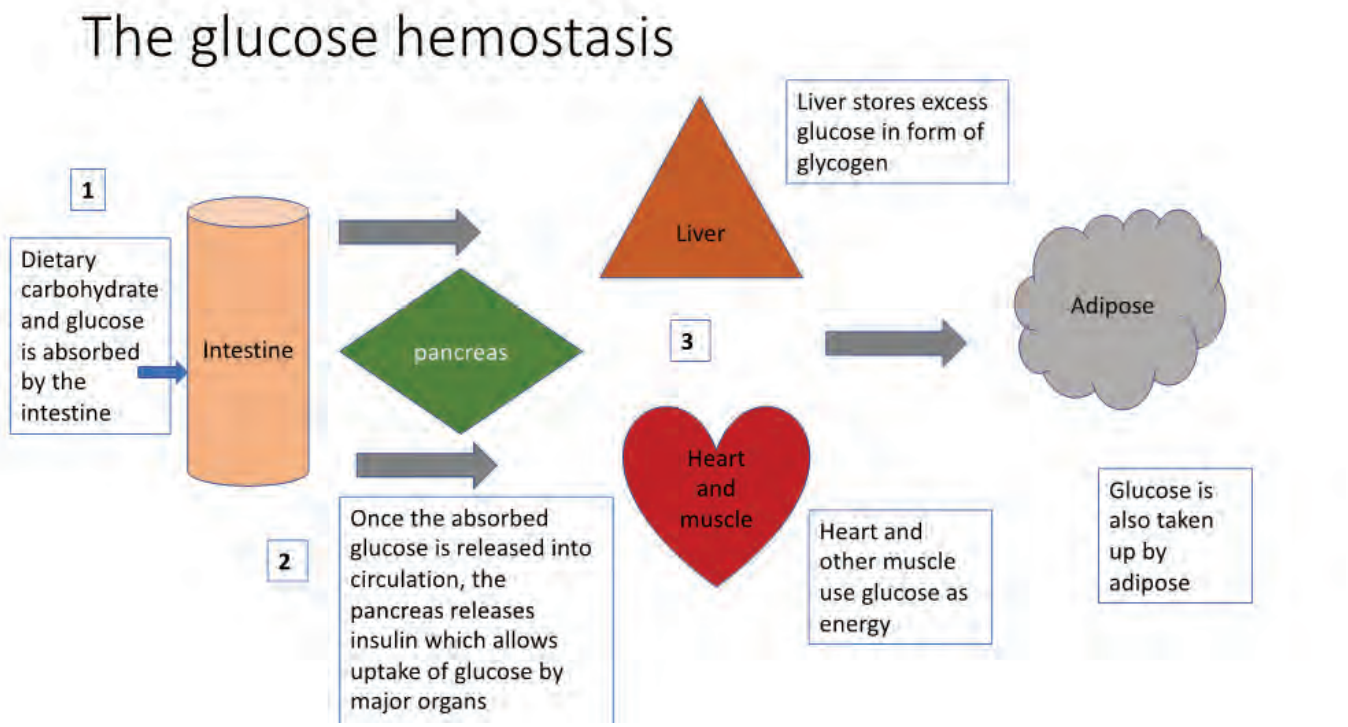
Type 2 diabetes is one of the few diseases which actually sends a signal before its onset called pre-diabetes during which the fasting blood glucose levels keep rising year on year to border line diabetic levels. By changing your risk factors, the pre-diabetes condition can be reversed to normal glucose levels.

Current treatments and gaps

Type 2 diabetes is no longer considered a disease with unmet needs, meaning there are enough medications available to control the disease. Without delving deep into the type of drugs available to treat diabetes, it is sufficient to mention that there are more than half a dozen oral and injectable drugs available on the market today starting with metformin used in early stages of the disease to insulin injections needed to control blood glucose in a highly diabetic condition. It is important to note that these drugs are symptomatic in nature, meaning that they can control blood glucose as long as the patient uses them but they cannot cure or reverse the disease.

Breakthroughs

One of the big challenges in any chronic disease is patient compliance. Patient compliance is often dependent on the convivence of how diagnosis is done or therapy is delivered. This is especially true in diabetes where there is frequent monitoring of blood glucose by finger pricks and also daily injections of insulin. When these activities have to be carried out day in and day out over several years, it can become a source of inconvenience and therefore lack of patient adherence. With this background I will now discuss two separate "breakthroughs" which have



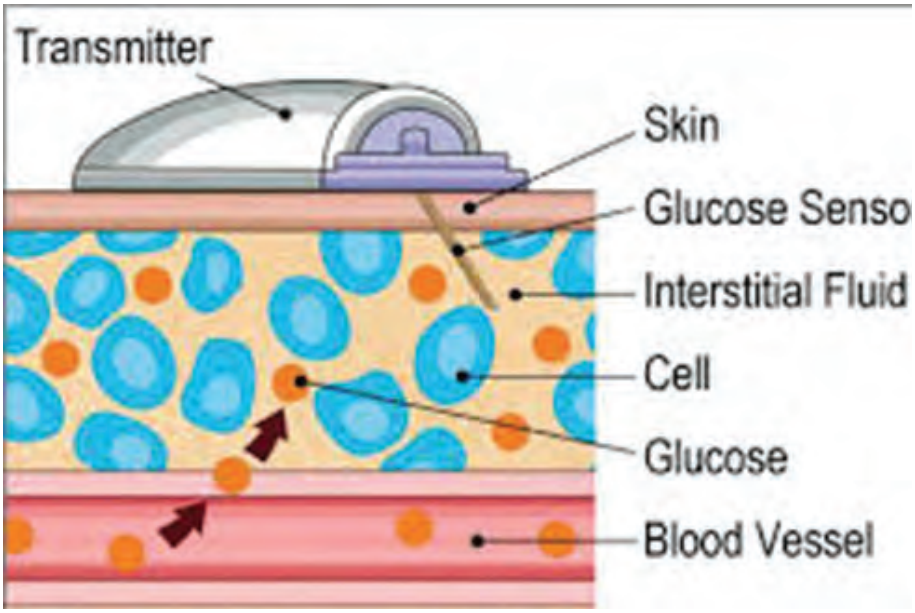
occurred in the diagnosis and treatment of diabetes.

1. Breakthrough in glucose monitoring

For decades, the standard way to monitor blood glucose has been to use a lancet to perform finger prick to draw a drop of blood and place it on a glucometer which uses an enzyme-based detection system to report glucose levels. This method while accurate is cumbersome and frequent pricks can also leave wounds, which is not desirable for a diabetic. The other issue with the finger prick method is that it only provides the glucose values of one time point. So, to be able to perform continuous monitoring which may allow better management of diabetes is not possible using the traditional glucometer.

The next generation breakthrough products are the "Continuous Monitoring" systems which allow for constant measurement of glucose. These work thru a "skin patch" which can be attached to the patient's body on the arm for example. The patch has a glucose sensing probe that penetrates the dermis and is able to sample the interstitial fluid which contains glucose. The glucose levels in the fluid mirror the blood glucose levels. The sensor transmits the glucose signal to a transmitter which then computes the blood glucose level. In this way the device offers several benefits to the patient:

1. Its non-invasive
2. Allows for continuous monitoring of



glucose levels which is very useful to track spikes of hyperglycemia or hypoglycemia

3. Appropriate drug therapy can be given to the patient based on this information
4. The information can be directly transmitted to the Physician

A typical design of such a device is shown below:

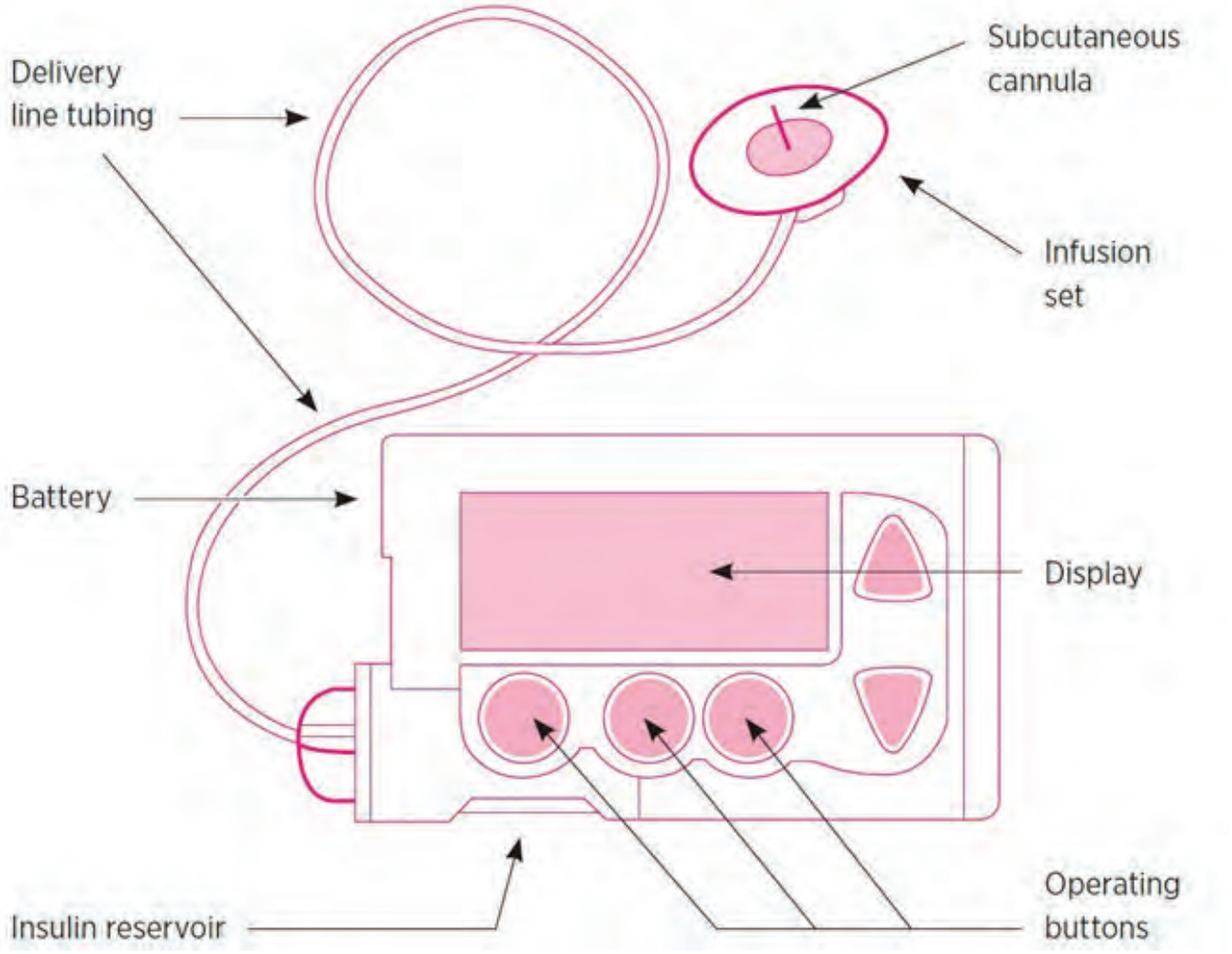
Reproduced from presentation on Continuous Glucose Monitoring [Internet]. National Institute of Diabetes and Digestive and Kidney Diseases. U.S. Department of Health and Human Service

2. Breakthrough in insulin delivery

The use of insulin injections is very common for Type 2 diabetes especially during advanced stages of the disease. The current dominant practice is to self-inject the required dose of insulin intraperitoneally at least twice a day. One can imagine how cumbersome this could be for a chronic patient.

In order to overcome the issue of self-injections, there are now devices available that deliver insulin to the body using an insulin pump. Basically, there is a skin patch that is attached to the patient which has a cannula that pierces the dermal layers and can reach the blood vessels. Attached to this patch is a delivery device which has a battery to keep the pump going, a display that tells how much insulin is available, a reservoir which contains the insulin carrying disposable cartridge. Once the setting of how much insulin to deliver is programed, then the pump can infuse insulin at the required rate and time. The basic elements of such a pump are shown below in the figure. The major advantages of such an automated insulin delivery pump are as follows

1. Calibrated infusion of insulin so as not to cause insulin spikes
2. Patient does not have to self-inject so compliance is high



Reproduced from : Insulin pumps in general practice, Barbora Paldus, Melissa H Lee, David N O'Neal, Aust Prescr 2018;41:186–90

3. Lowers likely hood of any infections that occur upon repeated injection

Conclusion

The breakthroughs described above will help in disease management enormously. They will improve patient compliance and add to convenience. While they may appear incremental, the improvement in quality of care to the patients will increase logarithmically. Additionally, both these devices can be used for Type 1 or 2 diabetes. In the absence of a cure, these innovations are godsent for diabetics globally. ■

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Ease of use, flexibility, reliable performance and quality of service has made AMETEK Brookfield Viscometers favourites all over the world. All AMETEK Brookfield Viscometers are accurate within ±1.0% of the range in use and have reproducibility within ±0.2%. Test results can be duplicated anywhere in the world when the same model instrument is used.

Viscosity – Physical measurement of product excellence:

The ability to gather data on a material's viscosity behaviour gives manufacturers an important "product dimension." The interrelation between rheology and other product dimensions often makes the measurement of viscosity the most sensitive or convenient way of detecting changes in colour, density, stability, solids content, and molecular weight.

AMETEK Brookfield offers widest ranges of viscometers to suit wide variety of application - Lab viscometers Gel time instruments and in-line process viscometers.

DVNext Rheometer: Next Generation Viscometer

The DVNext Rheometer is Brookfield's latest model that incorporates new advanced features that our customers have been asking for with the repeatability and reliability you expect from us. It is an easy-to-use, stand-alone instrument for

Standard Version	Complaint version
Digital Leveling	Hand-held Scanner for Bar Code Detection
Ethernet Connectivity	Magnetic Coupling Attachment (replaces EZ-Lock)
Start-up Wizard	Compliance to 21CFR Part 11 in Stand-alone and GAMP Compliant
Gel-Timer Functionality	LIMS Connectivity
Optional Magnetic Coupling Attachment (replaces EZ-lock)	Printing to non-editable PDF
Optional Bar Code Scanner	

measuring viscosity and yield stress. It's available in a Standard version and a 21 CFR Part 11 Compliant version.

Features & benefits of New Generation Viscometer Model DVnext

Each of the standard Laboratory Viscometers/ Rheometers is supplied with an internal spring which is used to calculate the viscosity of a material. These springs have different measuring capabilities and based on the Viscosity range Brookfield offers wide variety of viscometers to suit its application.

- **LV** is for low viscosity materials and can be used to measure the thinnest materials. Examples: inks, oils, and solvents.
- **RV** is for medium viscosity materials than those measured with an LV torque. Examples: creams, food, and paints.
- **HA** is for higher viscosity materials than those measured with an RV torque. Examples: gels, chocolate and epoxies.
- **HB** is for even higher viscosity materials than those measured with an HA torque spring. Examples: asphalt, caulking compounds, and molasses.

One can add additional springs as per request by the customer. Brookfield offers the customers comprehensive support in understanding the application and training in their own application lab.

Smart lab tech Application lab:

The lab with well trained technicians for CALIBRATION & REPAIR SERVICE offers guidance on the model selection process, spindle construction considerations and other useful information to help the customer make an informed decision on the best instrument for their application. Do visit the application lab at Hyderabad to get hands on experience and interact with our experienced scientist for all your quarries to zeroed-in on your requirements. ■

Contact Details

Smart Labtech Pvt Ltd
Contact: 9848444237

Italvacuum and India: Can't stop the feeling!

Italvacuum, with over 80 years of experience in the design and production of vacuum pumps and vacuum dryers for pharmaceutical and chemical companies, is a well-known company in Italy and Europe, but it also confirms its position as an important player in this sector on a global level. The presence of the company in the five continents, with a number of installations in continuous growth in both consolidated and emerging markets, is a tangible sign of Italvacuum's reliability. India, in particular, is one of the main markets for Italvacuum and for many years, some of the most important Indian pharmaceutical and chemical groups have relied on the Turin-based company for the drying of their products. Let's discover together why, thanks also to the precious contribution of Italvacuum Sales Area Manager Mr. Ennio Batissa.

The keys to Italvacuum's success in India

Present on the Indian market since the 1990s, Italvacuum, an Italian vacuum pump and vacuum dryer manufacturer, has steadily increased its market share and sales volumes in India year after year and is still growing. What are the main reasons that have led to this excellent collaboration over the years? Ennio Batissa, Italvacuum Sales Area Manager in India has told us some secrets...

"The success of Italvacuum in India," says Mr. Batissa, "has not been accidental, but is the result of a constant commitment over time and the creation of business relationships built in a stable and lasting way. If I had to summarize in few points the reason for the success of Italvacuum in India" continues the Area Manager, "I would use these four keywords:

Reliability; Italvacuum machines offer very long lasting levels of performance, precisely because of the high quality of the machinery. This is certainly an aspect that has been rewarded over the years by Indian companies, more inclined to purchase quality machinery and very demanding from the point of view of maintaining an high level of performance;

Service; as far as Service is concerned, we mean the whole part of commissioning and maintance operations. On this point, a decisive role is played by Vacuum Drying Technology India LLP, sole indian agent for Italvacuum since 2005. Over the years, Italvacuum has guaranteed the training of the Indian company's technicians, in all phases of service, from the moment of installation of the machinery to the moment of both ordinary and

extraordinary maintenance, thus guaranteeing complete and efficient on-site assistance to the customer.

Well-rooted presence; the collaboration with Vacuum Drying Technology India LLP, is not only fundamental as far as the provision of services is concerned, but it has allowed Italvacuum a well-rooted and widespread presence throughout the Indian territory.

Saurus939

References; last but not least, the number of strong and consolidated commercial relationships with the most important Indian Pharmaceutical and Chemical groups, of which Italvacuum is very proud".

Most appreciated products - Vacuum Pump Saurus 939

Designed to never stop - Vacuum pumps must above all work reliability for 24 hours a day and 7 days a week. However, due to the growing competitive pressure, the operators require economic operation and complete clarity of the final product. Specialists from Italy meet the challenge.

Be it vacuum drying, reaction procedure, distillation, crystallisation, filtration, vaporization or even polymerization - all these processes require vacuum.

Italvacuum has perfected, potentised and overhauled the vacuum pump Saurus939 over the years precisely for these processes in order to guarantee an optimum operation in all important chemical and pharmaceutical processes such as drying, distillation, reaction and crystallization processes.

For this, the vacuum pump should ensure the complete recovery of extracted solvent, even in particularly difficult operating conditions with durably constant throughput and high degree of vacuum.

In this way, the vacuum pump Saurus 939 can vacuum the steams of conventional solvents (methanol, ethyl alcohol, chloroform, acetone, acetic ether, methyl chloride, benzene, toluene, isopropyl alcohol, diethyl ether, heptane) as well as that of aggressive solvents (hydrochloric acid, acetic acid, chlorobenzene, dimethyl, acrylonitrile, dichloroethane, cyclohexane, pyridine, dimethyl sulfoxide).

Robust and Reliable - In order to guarantee this, the pump is developed and designed for continuous operation. The Italians also have an eye on the operating costs: Due to the energy-saving engines, the negligible oil consumption and simple, economic maintenance, the costs remain very low.

Cylinders, pistons, piston rings and cylinder head consist of “acid-free” special cast-iron. The other parts are produced from machine casting, special purpose steel and PTFE with filler material.

The pump is completely closed and compact and hence suitable to ren- der optimal performances over a long time period even in humid, dust-laden rooms.

The exhaust valves have an opening in the direction of flow and are available in various materials, including hastelloy.

Moreover, the pump is air-cooled. Saurus 939 has two completely separate and independent lubrication cycles: one for the process section with calibrated injection of fresh oil using the Lubri Zero system and one for the mechanics with oil circulation. The Lubri Zero system — mounted on the two-stage models— facilitates negligible oil consumption. It combines a calibrated oil injection with a kit made of new PTEE materials with special filler materials that are resistant to corrosion and practically do not require any lubrication. Thus, “FDA approved” synthetic oils can also be used. The equilibrated injection of few drops of fresh oil (ratio 10 g/h) guarantees an effective protection even against the aggressive solvents with the result that the operating performance of perfect cylinder-piston clearance and thus the service life of vacuum pump are increased considerably.

Uncontaminated vacuum - Besides a high-performance, durable and efficient operation, users particularly demand absolute safety in the pharmaceutical and fine-chemical production: With the vacuum pump, Italvacuum offers a device that facilitates maximum safety of entire process and complete clarity of the final product. In other words, an uncontaminated vacuum. Therefore, not a single oil molecule can reach the treated product during the entire operation cycle. This is also certified by the faculty for material science and chemical engineering at the Politecnico Institute of technology in Turin with a specific study that was carried out on the entire vacuum drying process.

Quality should not be considered as expenditure, but as investment. And an investment is measured on the basis of concrete results—and not just in terms of operating performance and operating duration. Low operating costs and production quality also pay at last.

Today Italvacuum’s production capacities include a wide range of original and patented products, in addition to vacuum pumps:

- Horizontal paddle vacuum dryers
- Rotary double cone vacuum dryers / powderers
- ray vacuum dryers

Production Plant in Borgaro T.se (Italy)

- Laboratory-scale tray vacuum ovens
- Rotary cylindrical vacuum systems.

The right partner for Indian market of yesterday, today and tomorrow

Although the Covid-19 health emergency has upset the world economy and despite the situation is still to be considered at least unstable and fluid, what is significant for Italvacuum lies in the continuation of relations and economic exchanges with India, which have not only maintained their solidity but have continued to grow even in this difficult period. During the Lockdown period in Italy, Italvacuum has always guaranteed service to its customers and also as far as India is concerned, thanks also to our sole agent, sales and after-sales service has always been guaranteed without renouncing the classic quality.

This allows us to look with extreme confidence towards the future and we are confident that this economic relationship that binds us can further improve and grow. ■

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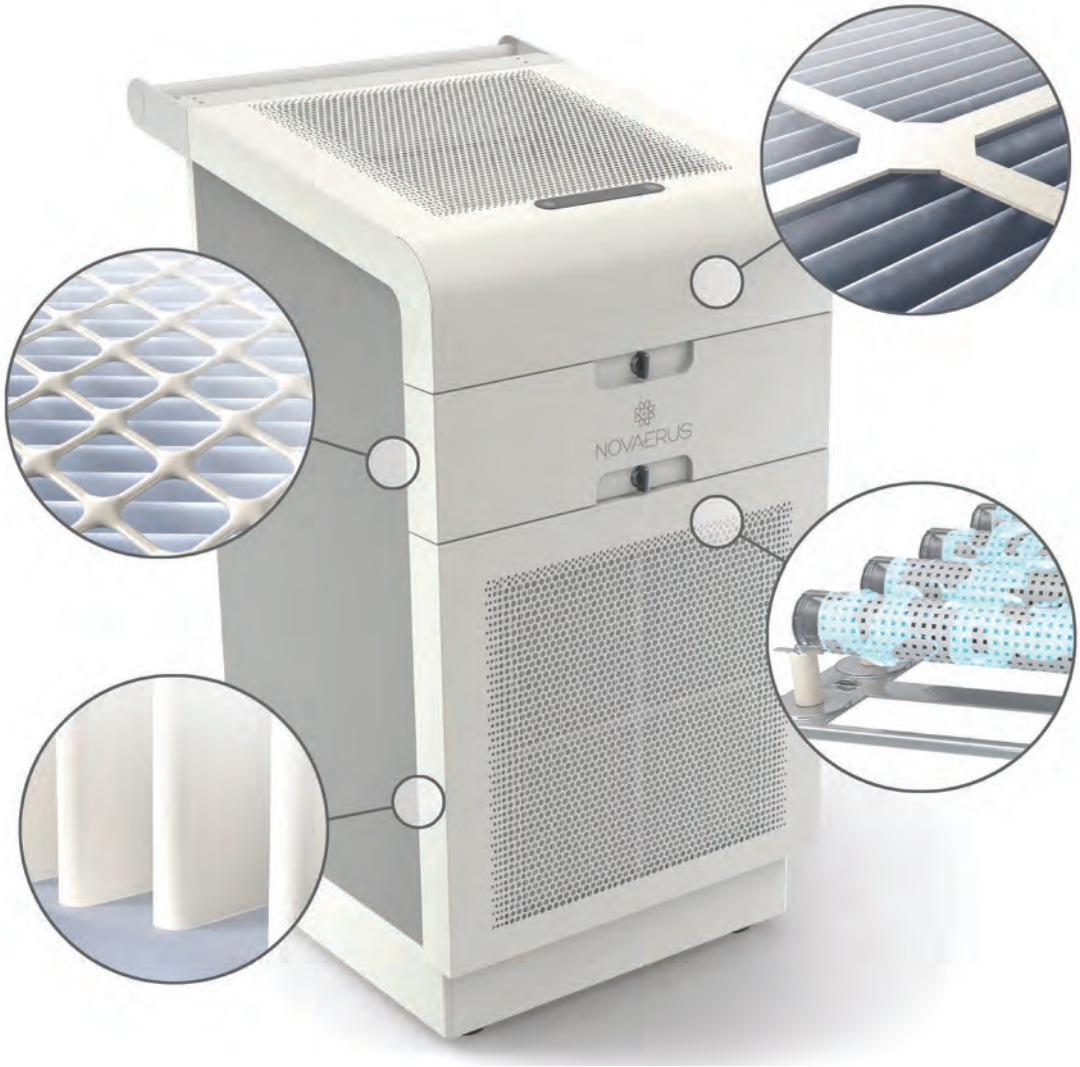
Novaerus air disinfectant with NanoStrike Technology for corona free air

Trivector Biomed LLP, one of the leading operators in the Indian infection control space has introduced Novaerus' Nano Strike Technology powered air disinfectant product line that assures corona free air. Whether at home or at a hospital, educational institution, offices, hotel etc., these products keep the atmosphere safe to breathe. With the ongoing fight against the novel coronavirus, people have become more conscious about cleanliness, hygiene and keeping themselves and their environment germ-free. In addition, the consensus among scientists that the virus is also transmitted through aerosols and droplets that are released into the air by a carrier, especially when the person coughs, sneezes, or even talks forcefully in a closed environment has increased the demand to have a proper air disinfectant system.

Trivector Biomed LLP and Novaerus, a global Irish company has introduced their new trademarked technology brand - NanoStrike Technology. This technology is the new trademarked name for the existing Novaerus Plasma Dielectric Barrier Discharge (DBD) technology and is the core, patented technology that powers all three Novaerus portable air disinfection devices. This plasma-based nanotechnology kills all airborne microorganisms on contact providing the first line of protection against viruses and bacteria. This technology utilizes plasma coils to provide a deadly strike to all harmful airborne pathogens – such as viruses, bacteria (including Tuberculosis) and fungi – as they pass through the plasma field, obliterating them at the DNA level.

Novaerus' team of scientists and engineers have developed this technology that utilizes an atmospheric plasma discharge — the same type of discharge found in lightning strikes — to kill and deactivate harmful airborne microorganisms. What makes the nano-strike technology unique is its ability to burst a pathogen cell; where other technologies simply deactivate them. All the concurrent deactivation processes as part of NanoStrike technology happen inside the machine within milliseconds and what comes out is the dis-infected air which is safe to be consumed by the occupants of the room. This has been independently tested and proven effective at killing and deactivating the smallest of airborne viruses, bacteria, mould spores and VOCs in dozens of independent laboratory tests.

Trivector Biomed LLP, known for launching the latest and innovative technologies in



the Indian healthcare sector introduced Novaerus in India in the year 2016 and have since installed several Novaerus air-disinfection units. With the worldwide spread of novel coronavirus, Novaerus has been relentlessly working towards bringing out effective solutions through its technological advancement to protect the front-line healthcare workers at prominent COVID hospitals in many parts of India.

The three Air-Disinfection models are helping various institutions and individuals lead a cleaner and healthier life. Depending on the size of an area, one can choose from the models i.e. Protect - 200, Protect - 800 and Defend - 1050 that covers an area of 80 - 100 sq. ft, 300 - 400 sq. ft, upt1,000 sq. ft. respectively within 8-10 ft height. These units are also available of rent on a convenient terms. ■

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AGILE and Whiz from Spectralab Instruments Pvt. Ltd

Spectralab Instruments Pvt. Ltd, are in the business of Analytical Instruments for the last three decades. We have more than 1000 satisfactory customers using one or many instruments, available from our broad product range.

One of the flagship Instruments is Potentiometric Titrator. The first model introduced was Titrator model AT- 38, which was most preferred by many users as an economical substitute for MNC brands. With time various developments occur in many sectors and as such, testing methods and instrumentation are also passing through these constant changes. Further, market segments like pharma, chemical, fertilizer, food, dairy and agro and oil industries require specific types of analysis. To cover these wide range of analytical methods of industry segments, in one single instrument is really a challenge for instrument designing and manufacturing.

Spectralab Research & Development team together with the manufacturing team is highly specialised in working on these challenges resulting in state-of-the-art-instruments, fulfilling the industry requirement with total satisfaction.

Keeping these objectives in mind Spectralab has come out with the new innovation in auto Titrator, with the introduction of the latest high-end model 'AGILE.' The new product has successfully passed through very stringent quality inspection followed by a performance test in Spectralab's own QC and Application lab.

AGILE is not only a state-of-the-art designed Titrator, but is also aesthetic and

loaded with many user friendly features. But the key focus remains on the performance with respect to accuracy, precision and reproducibility of test results in different locations.

The salient features of model AGILE are as follows:

- **Display:** 7 inch TFT, bright graphical display having touch screen
- **Live Status:** During titration live titration curve and also the Derivative curve is displayed for understanding the quality and progress of analysis
- **Burette Recognition :** 5ml/10 ml/25 ml burette recognition with the name of reagent
- **Wi-Fi Connectivity:** PC and Printer can be connected via Wi-Fi. Thus issues of cable connection is avoided.
- **Equivalent Points :** up to 12 EQs can be detected if present in the sample matrix
- **Electrodes :** Sturdy and long lasting electrodes for various application
- **Data Storage :** 50 Titration method and 100 results are automatically stored in Instrument. And also can be transferred to Pen drive / PC
- **USB Connectivity :** PC/Printer/ Mouse/Key board/ Pen drive connected via USB ports
- **21 CFR Part 11 :** Available in Stand-alone instrument and also via PC through operation
- **Performance:** Matches with leading brands
- **Add on KF facility:** Works as combo model for titration and KF
- **Price:** Most economical and affordable option for budget conscious Customers
- **Support:** In time application and Service Support across country
- **Spare Parts:** Immediate availability at reasonable price due to in-house production
- **Demonstration:** Free demo with customer's sample in at the application Lab in Thane
- **Installation:** More than 1000 installations of Auto Titrator in various industry segment.

WHIZ, is a high end KF-based Moisture Analyser manufactured as the extension of the same vision as of AGILE. With the above features, Titrator and KF moisture analyser are ready to use for carrying out testing as per International standards like ASTM, EP, USP, and Indian BIS Standards.

These quality Instruments from Spectralab, will always remain an appropriate choice of testing labs covering all applications pertaining to titration. ■

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Total Nitrogen measurement in waste water

Total Nitrogen is an essential nutrient for plants and animals. However, an excess amount of nitrogen in a waterway may lead to low levels of dissolved oxygen and negatively alter various plant life and organisms. Sources of nitrogen include: wastewater treatment plants, runoff from fertilized lawns and croplands, failing septic systems, runoff from animal manure and storage areas, and industrial discharges that contain corrosion inhibitors. Nitrogen in freshly polluted water is originally present in the form of organic nitrogen and ammonia.

Natural biochemical processes slowly convert the organic nitrogen into ammonia, which is the form of nitrogen best able to be utilized as a nutrient by microorganisms in the treatment process. (Some waste waters may be nitrogen deficient and require supplemental ammonia for adequate reproduction.) Under aerobic conditions the conversion of organic nitrogen into ammonia reaches a peak and, under the appropriate biological conditions, is biochemically oxidized first into nitrite, then into nitrate. When nitrite and ammonia nitrogen are at minimum concentration (at or near zero)

and nitrate is at a maximum value, the wastewater has been fully nitrified. A fully nitrified wastewater will have little or no organic nitrogen.

Nitrogen itself is not hazardous when present in water, and therefore does not cause any environmental damage. In seawater nitrates, nitrites and ammonia are dietary requirements for plankton, causing nitrogen concentrations to be lower at the surface than in the deep. At increasing nitrogen concentrations in surface layers, plankton production increases, leading to algal blooms. This may occur in any type of surface water. Large amounts of nitrate may cause eutrophication, which means an excess of nutrients resulting in oxygen deprivation and fish deaths . Nitrogen does not limit algal growth, because phosphorus is generally a limiting factor in water bodies. This means that phosphorus is the determining factor of algal spreading through surface waters. Oxygen deficits in surface water generally result in nitrate reduction to elementary nitrogen or nitrous oxide. This so-called denitrification process causes oxygen reserve releases, when oxygen supplies decrease to zero. In some cases nitrate may even be biologically reduced to ammonia. Ammonium compounds decrease the water oxygen concentration, because these are oxidized from nitrite to nitrate. Small concentrations of free ammonia may be toxic to fish.

In wastewater treatment plants the first two treatment steps may remove only 50% of nitrogen concentrations. For further treatment, lime and HOCl addition were attempted. This however turned out not to be very effective. Consequently, the third step of wastewater treatment includes biological nitrogen removal. This means a combination of nitrification and denitrification processes, carried out by various micro-organisms.

Hanna offers to measure Nitrogen right from 0 to 150 mg/L that employs 4500-N of Water and Waste water standard method. HI83399 supports Nitrogen measurement in water. We supply pre-dosed vials for easy Nitrogen measurement without any requirement of special skill set. HI83399 not only measure Total Nitrogen but also provides results for ammonia (NH^3) and nitrate (NO^3-). ■

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Water Electrolysis – An Alternative Way to Treat Cooling Tower Circulation Water to Reduce Blow Down Water Consumption

Water electrolysis is a known principle and many applications in water treatment & waste water treatment utilize this principle. Each application poses its own challenges. Field trials and actual implementation on the commercial scale have proven that water electrolysis can be a promising alternative to treat cooling tower circulation water effectively and reduce the blow down water consumption.

The Principle:

Water electrolysis system is a chemical free treatment system to treat water for the cooling towers. Such systems are typically installed in the side stream of cooling tower so that it works effectively because of the higher conductivity levels. The main circulation water flow is not disturbed.

The system would consist of Electrolytic Reactor comprising of Anode and Cathode - anode is an electrode with special material that would cause the reaction of high pH at cathode.

The water circulation pump would circulate the water from cooling tower sump to the electrolysis chamber or reactor where electrolysis takes place. Because of the DC current passing through reactor, water would be ionized to create OH- ions, which creates high pH at cathode. Because the pH at cathode is high, water would have tendency to precipitate temporary calcium & magnesium hardness on the cathode walls.

At anode, Chlorine gas along with mixed oxidants are generated which will control the microbial and algae growth. The typical reactions that occur in the electrolytic reactor are:

- Primary Anode Reaction (Oxidation of Water)
  $2H_2O - 4e^{-1} = O_2 + 4H^{+1}$
- Primary Cathode Reaction

(Reduction of Water)

$4H_2O + 4e^{-1} = H_{2\,(g)} + 4OH^-$

- Secondary Cathode Reactions

  $Ca^{2+} + HCO^-_3 + OH^- = CaCO_{3\,(Pre)} + H_2O$

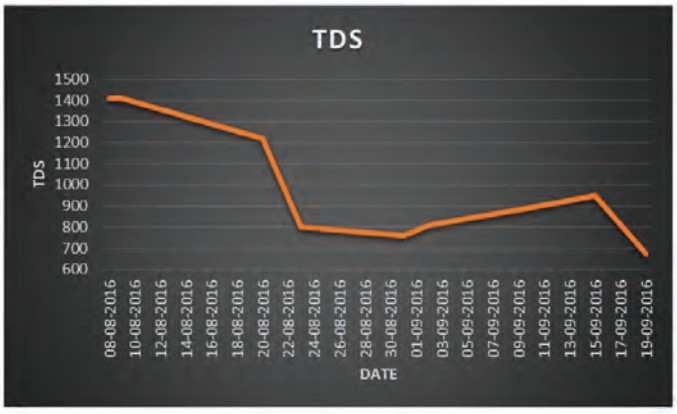
  $Mg^{2+} + 2\,OH^- = Mg(OH)_{2(Pre)}$

- Secondary Anode reactions

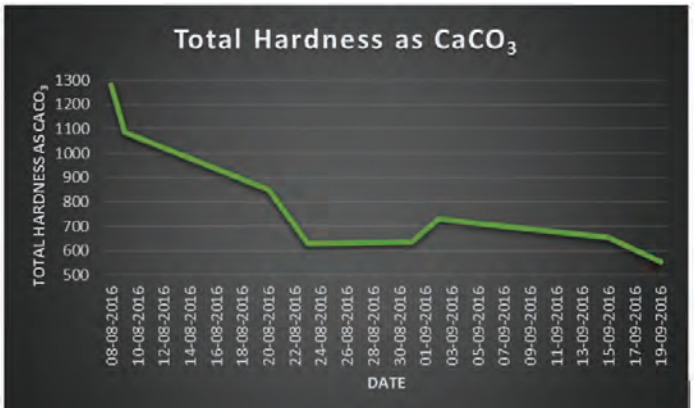
  $2Cl^- = Cl_{2\,(g)} + 2e^-$

As the temporary hardness reduces, scaling in heat exchanger pipes, cooling water pipes and the entire cooling circuit is reduced to a great extent. Corrosion in the cooling water circuit is also reduced because water pH is maintained in circulation water is towards less aggressive. Chemical dosing in the cooling towers is eliminated or reduced drastically. Because the temporary hardness is removed, circulation water can be at a higher TDS. This would result into reduction of up to 60% blowdown water consumption.

The Case Study:



Reduction in TDS



Reduction in Total Hardness

Removed Scale collected in the reactor

Loose scale easily scrapped off from reactor

The Case Study

Benefits:

- Saving in chemical dosing cost in cooling towers
- Up to 60% reduction in blowdown water consumption
- Saving in ETP treatment cost
- Substantial saving in energy cost in case of ZLD plants
- Reduction in cooling tower fills cleaning & replacement frequency

A Case Study of a Pharma Company that Saves Water & Energy with ECOMax-CT®

Pharma companies need Cooling Towers for water cooled chillers for their operations. These Cooling towers must continuously replenish their chemically treated cooling water by frequent blowing. This is expensive, water intensive and environmentally sensitive.

One of India's largest multinational generic pharma company with headquarters in Mumbai, installed a 1500 TR Cooling Tower for cooling needs in their research center in Pune. They faced problems of high-water consumption, chemical usage and high energy consumption in their ZLD plant where blowdown water is sent. The challenge was to reduce blowdown water consumption, eliminate chemical dosing and save energy in ZLD plant.

ECOMax-CT® Electrolytic Cooling Tower Water Treatment System was installed to reduce blow down water consumption.

The ECOMAX impact

- Resulting measured blow down water saving was 80%
- Sump water TDS was maintained below 1500 ppm
- Total hardness in sump was maintained below 100 ppm
- pH was maintained around 8.0
- Resulted in over 4500 kL of water saving per year
- Chemical dosing in cooling tower is totally stopped
- Resulted into substantial steam savings in ZLD plant with lesser cooling tower blowdown
- Pay back on the investment was around 11 months ■

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