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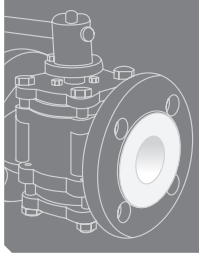

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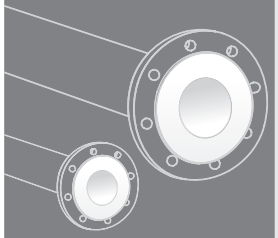

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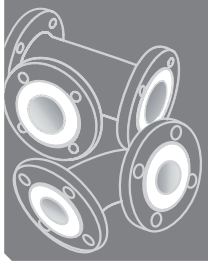

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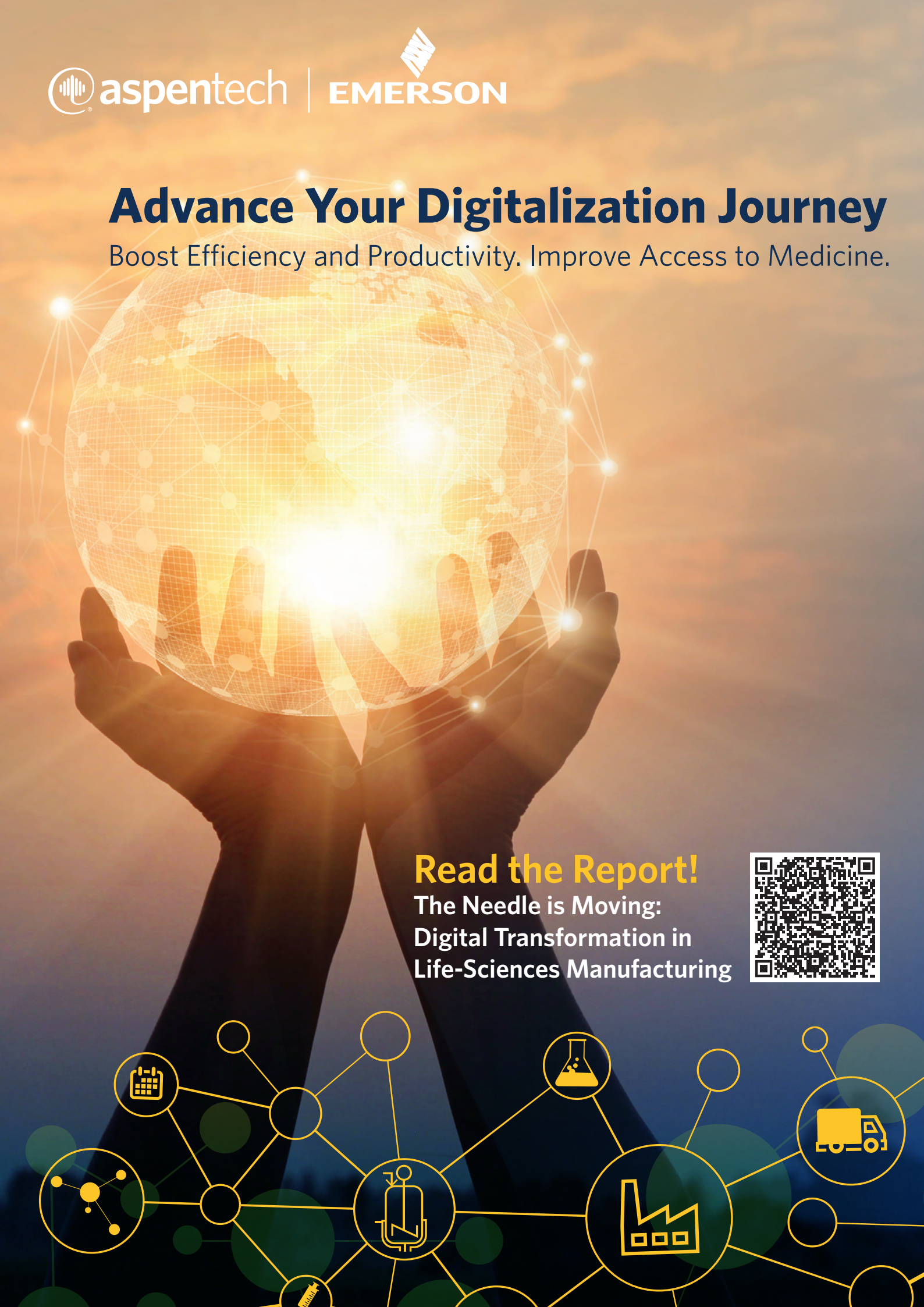

Read the Report!

The Needle is Moving: Digital Transformation in Life-Sciences Manufacturing

Year End Review of Department of Pharmaceuticals-2022

Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

New Delhi, India: In the year 2022, various programs and initiatives were implemented in the Department of Pharmaceuticals. Major achievements of the Department this year include schemes like 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' to provide quality generic medicines at affordable prices to the poor and underprivileged and PLI scheme to strengthen India's manufacturing capacity in the pharmaceutical sector by increasing investment and production. Apart from this, the department also laid special emphasis on promoting domestic manufacturing of medical equipment and strengthening the pharmaceutical industry.

FDI performance in pharmaceutical sector:

FDI inflows in pharmaceutical sector (in both pharmaceuticals and medical devices) was ₹ 12,097 crore in the financial year 2021-22. During current financial year of 2022-23 from April 2022 to September 2022, FDI inflows has been ₹ 8,081 crore. Further, the Department of Pharmaceuticals has approved 21 FDI proposals worth ₹ 4,681 crore for brownfield projects during 1st January 2022 to 30th November 2022.

Pricing of drugs:

Department of Pharmaceuticals (DoP) notified the amended Schedule-I of Drugs Prices Control Order (DPCO) 2013 on 11th November 2022 based on National List of Essential Medicines 2022 Notified by Ministry of Health and Family Welfare on 13th September 2022. Based on the same, National Pharmaceutical Pricing Authority (NPPA), an attached office under DoP is under process of revising the Ceiling Prices of the drugs coming under the Schedule-I as per extant provisions of DPCO, 2013.

Strengthening of Pharmaceutical Industry (SPI):

The Scheme would be operational over a period of five years from FY 21-22 to 25-26 and has an outlay of ₹ 500 crore. The Scheme has 3 components / sub-schemes: Assistance to Pharmaceutical Industry for Common Facilities (APICF), Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

Under sub-scheme Assistance to Pharmaceutical Industry for Common Facilities (APICF), 20 project proposals have been received of which 17 were found eligible under the scheme. Of these 17 project proposals, 7 have been shortlisted and requested to submit the DRP by 15th December 2022 for further examination and finalization for approval of projects. Under Sub-Scheme Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) more than 60 applications have been registered.

PLI for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs):

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The Scheme was approved with the objective of attaining self-reliance and reducing import dependence in critical KSMs/DIs/APIs. The scheme will boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs.

The tenure of the sub-scheme is from financial year 2020-21 to 2029-30, with the total financial outlay of ₹ 6,940 crore. The Financial incentive under the sub-scheme is provided on sales of 41 identified products categorized into four Target Segments. Total 249 applications were received in four Rounds. 51 applicants have been approved with committed investment of ₹ 4,138.41 crore. against which investment of ₹ 1707 crore. has already been incurred. These 51 projects are expected to generate an employment of around 10,598 people. The work on these projects have already generated employment of 1,907 persons up to September 2022. Based on Quarterly Review Report (QRR) of September 2022, 21 project has been commissioned with actual investment of ₹ 890 crore. as against total committed investment of ₹ 843.79 crore.

PLI Scheme for Pharmaceuticals: -

The objective of this scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification towards high value goods in the pharmaceutical sector. The scheme covers pharmaceutical goods under following three categories-

Category 1: Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals; Other drugs as approved.

Category 2: Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates (except for the 41 eligible products already covered under the "PLI Scheme for promotion of domestic manufacturing of critical KSMs / DIs / APIs"

Category 3 (Drugs not covered under Category 1 and Category 2): Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, and anti-retroviral drugs; In vitro diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

The tenure of the Scheme is from Financial Year 2020-21 to Financial Year 2028-29. The scheme provides for incentives on incremental sales to selected participants under these categories at varying rate over the years ranging from 10% to 3%. The scheme is expected to bring in investment of more than 17,000 crore in the pharmaceutical sector, promote the production of high-value products in the country and increase the value addition in exports. The actual investment of ₹ 15,164 crore has already been made by these 55 applicants.

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Transfer of technology 'Inactivated low pathogenic avian influenza (H9N2) vaccine for chickens' developed by ICAR-NIHSAD, Bhopal

Bhopal, India: 'Inactivated low pathogenic avian influenza (H9N2) vaccine for chickens', developed by the scientists of ICAR-NIHSAD, Bhopal was transferred to M/s Globion India Pvt. Ltd., Secunderabad, M/s Venkateshwara Hatcheries Pvt. Ltd., Pune, M/s Indovax Pvt. Ltd., Gurgaon and M/s Hester Biosciences Ltd., Ahmedabad today, facilitated by M/s. Agrinnovate India Ltd. at NASC, New Delhi.

Dr. Himanshu Pathak appreciated the sincere efforts of the ICAR-NIHSAD scientists in development of the first indigenous vaccine for H9N2 virus and commended the Agrinnovate India limited (AgIn) for the efforts in the transfer of the technology to industry. DDG (AS) asserted that the vaccine will meet the standard of the market both in India and abroad. The vaccine will contribute significantly to increasing the income of poultry farmers by reducing the economic loss due to the disease.

Pharmaceutical Technology Upgradation Assistance Scheme for MSMEs

New Delhi, India: MSMEs have availed the benefit under erstwhile PTUAS scheme. However, the PTUAS has been incorporated as a sub-scheme under the Scheme - Strengthening of Pharmaceutical Industry (SPI), which was launched in July 2022.

The Strengthening of Pharmaceutical Industry (SPI), with the financial outlay of Rs. 500 crores and with a tenure from FY 2021-2022 to FY 2025-26, has following three components, to provide infrastructure support for pharma MSMEs in clusters and to address the issues of technology upgradation of individual pharma MSMEs: Assistance to Pharmaceutical Industry for Common Facilities (API-CF); Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS); Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

The sub-scheme PTUAS is aimed to facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards (WHO-GMP or Schedule-M), interest subvention or capital subsidy on their capital loans will be provided, which will further facilitate the growth in volumes as well as in quality and it is envisaged to support about 400 Pharma MSME units under this sub-scheme during the scheme tenure.

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New Delhi, India: 'Make in India' is an initiative which was launched on 25th September 2014 to facilitate investment, foster innovation, build best in class infrastructure, and make India a hub for manufacturing, design, and innovation. It is one of the unique 'Vocal for Local' initiatives that promoted India's manufacturing domain to the world.

'Make in India' initiative has significant achievements and presently focuses on 27 sectors under Make in India 2.0. Department for Promotion of Industry and Internal Trade (DPIIT) coordinates action plans for 15 manufacturing sectors, while Department of Commerce coordinates 12 service sector plans. Investment outreach activities are done through Ministries, State Governments and Indian Missions abroad for enhancing international co-operation and promoting both domestic and foreign investment in the country.

CDSCO and State Drugs Control Administration commence joint inspection of Drug Manufacturing Units

New Delhi, India: Under directions of Union Minister of Health & Family Welfare and Chemicals & Fertilizers, Dr. Mansukh Mandaviya, the Central Drugs Standard Control Organisation (CDSCO) has started conducting joint inspection of identified Drug Manufacturing Units along with State Drugs Control Administration as per risk-based approach.

The Joint Inspections are being conducted all over the country as per the Standard Operating Procedures. A committee of two Joint Drugs Controllers has been constituted at CDSCO (HQ) to monitor the process of inspection, reporting & subsequent action so as to ensure compliance to the Drugs & Cosmetics Act, 1940 and Rules thereunder. This will ensure high standards of quality compliance with respect to drugs manufactured in the country.

An action plan for nationwide inspection of manufacturing units which are identified to be at the risk of manufacturing Not of Standard Quality (NSQ)/adulterated/spurious drugs was made prior to carrying out of inspections.

The objective of drug regulation is to ensure safety, efficacy, and quality of the drugs available in the country. The drug control administration is required to ensure that manufacturing units comply with Drugs & Cosmetics Act, 1940 and Rules thereunder especially to the requirements of Good Manufacturing Practices (GMP).

Union Minister of Health and Family Welfare, Dr. Mansukh Mandaviya virtually inaugurates new building of CDSCO Bhawan, South Zone in Chennai

Chennai, India: Government of India is on a mission to safeguard and enhance public health by ensuring top notch quality of drugs, cosmetics, and medical devices along with maintaining their safety and efficacy in the country. The new building of CDSCO, South Zone will further facilitate Government's vision of providing safety and regulatory best practices, especially for the southern States/UTs including Tamil Nadu, Puducherry, Kerala, and Lakshadweep". This was stated by Union Minister of Health & Family Welfare Dr. Mansukh Mandaviya as he virtually inaugurated the new building of CDSCO Bhawan, South Zone at Chennai. CDSCO is playing a crucial role in manufacturing, importing and distribution of health products along with ensuring their safety efficacy and quality. They have facilitated right medicine at the right time for our citizens, especially during the COVID pandemic.

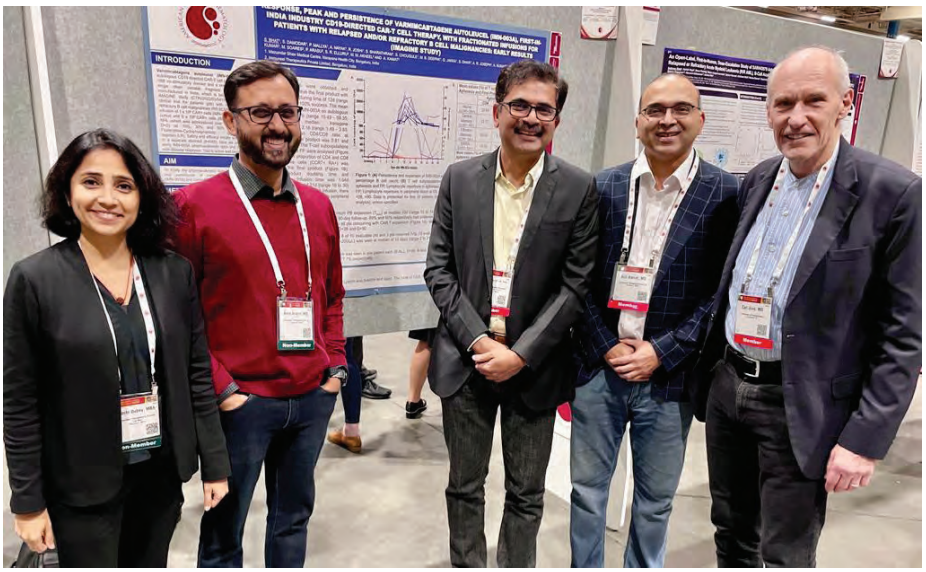
Given the rapid progress in the field of pharmaceuticals, diagnostics and medical devices sector, Dr. Mandaviya reiterated the clarion call made by Hon'ble Prime Minister for "Make in India" and "Aatmanirbhar Bharat" which has provided impetus for manufacturing medical products indigenously and foster public health goals. He said that "Government of India is focusing on the key areas like quality, accessibility, affordability of medicines as well as encouraging the industry players and other stakeholders." He also highlighted Government's willingness towards adapting new technologies and innovations like drug trials through humanoid chips.

VAV's Lipid Solutions for Advanced Vaccines and Formulations

Mumbai, India: VAV's high-quality lipids potential to help pharmaceutical companies to develop multiple projects in drugs and biologics delivery has gained significant attention from the pharma industry. These included applications of lipids in developing thermostable vaccines and formulations, cancer therapy based on liposomes, and treatment of chronic autoimmune and neuromuscular diseases like myasthenia gravis and multiple sclerosis.

There was specific interest in new upcoming technologies based on lipids, especially in the development of antibodies, RNA, oligonucleotides, and several advanced medical products. There was also interest in VAV's lipids for developing animal vaccines and aquaculture. The applications of lipids in reformulating generic drugs to make them more efficient also received significant attention from global generic pharmaceutical companies.

Immuneel Therapeutics Presents Early data from India for Varnimcabtagene autoleucel (IMN-003A: Autologous anti-CD19 CAR-T cell therapy for B cell malignancies)



Bangalore, India: Immuneel Therapeutics has announced early results for Varnimcabtagene autoleucel (IMN-003A) from the IMAGINE study – India's first Phase 2 and industry sponsored trial for a novel autologous CD19 directed CAR-T cell therapy in patients with relapsed / refractory B cell malignancies.

The early results reported results from the first 10 patients of the planned 24 patients to be enrolled. Both adult and children with acute leukaemia as well as lymphoma patients post median 2 lines of treatment, including in post-transplant setting were enrolled. 80% of patients experienced complete clinical response at Day 28. At Day 90, the results from IMAGINE showed an overall response rate of 77%, with 6 out of 9 evaluable patients demonstrating complete responses. Day 28 and Day 90 read-outs in the B Acute Lymphoblastic Leukaemia patients indicate 100% and ~83% MRD-negative complete remissions respectively, indicating rapid, deep, and sustained responses. The median time to manufacture and release Varnimcabtagene was 12 days, with 100% manufacturing success. The peak expansion of Varnimcabtagene was 10 days and the CAR-T cells persisted beyond 28 days in this early data read-out.

The data set for safety in IMAGINE was favourable, without severe neurotoxicity, and comparable to the cumulative safety dataset for Varnimcabtagene, that now includes 125 patients in Spain and India. Only one subject developed ≥ grade 3 cytokine release syndrome. There were no unexpected serious adverse events.

Nanobiotix begins patient dosing in NANORAY-312 Phase III trial evaluating radio-enhancer NBTXR3 in head and neck cancer

Paris, France: Nanobiotix specializes in advancements that can expand treatment possibilities for patients with cancer. They have announced the first patient in the United States has been randomized in NANORAY-312, a global Phase III registrational trial evaluating NBTXR3 for the treatment of elderly patients with locally advanced head and neck squamous cell carcinoma (LA-HNSCC) who are ineligible

for platinum-based chemotherapy. NBTXR3 activated by radiotherapy will be evaluated alone or in combination with cetuximab. NBTXR3 is a potentially first-in-class radio-enhancer with broad application across solid tumours, with prioritized focus in head and neck cancer.

NBTXR3 is a novel, a potential first-in-class oncology product formed of functionalized hafnium oxide nanoparticles that are administered via one-time intratumoral injection and activated by radiotherapy. It's physical mechanism of action (MoA) is designed to induce significant tumour cell death in the injected tumour post activation by radiotherapy, subsequently triggering adaptive immune response and long-term anti-cancer memory. Nanobiotix believes that NBTXR3 could be scalable across any solid tumour that can be treated with radiotherapy and across any therapeutic combination, particularly immune checkpoint inhibitors.

FDA APPROVED

Roche's Lunsumio for follicular lymphoma

Roche announced that the US Food and Drug Administration (FDA) under accelerated approval based on response rate- Lunsumio (mosunetuzumab-axgb) for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy (Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial). Lunsumio is a CD20xCD3 T-cell engaging bispecific antibody, represents a new class of fixed-duration cancer immunotherapy, which is off-the-shelf and readily available, so that patients do not have to wait to start treatment. Lunsumio will be available in the United States in the coming weeks.

Lunsumio is administered as an intravenous infusion for a fixed duration, which allows for time off therapy, and can be infused in an outpatient setting. Hospitalisation may be needed to manage select AEs, should be considered for subsequent infusions following a Grade 2 CRS event, and is recommended for subsequent infusions following a Grade 3 CRS event.

Lunsumio is being further investigated as a subcutaneous formulation (i.e., administered under the skin) and in phase III studies that will expand the understanding of its impact in earlier lines of treatment in people with non-Hodgkin lymphoma.

Immuron to proceed with clinical evaluation of Travelan

Immuron Limited, a globally integrated

biopharmaceutical company based in Australia, will proceed with the clinical evaluation of Travelan. As a result of this approval the company will proceed with the planned clinical trial in the United States.

The Investigational New Drug (IND) application to evaluate the efficacy of a single dose of Travelan to prevent infectious diarrhoea caused by enterotoxigenic Escherichia coli (ETEC) is now active. The safety and protective efficacy of Travelan will be tested utilizing a controlled human infection-model clinical trial design. Immuron is the sponsor of the IND, and the clinical study will be conducted by the Contract Research Organisation Pharmaron CPC, Inc at its FDA inspected clinical research facility located in Baltimore, Maryland, USA.

The phase II clinical trial will evaluate the efficacy of a single dose regimen of Travelan in a controlled human infection model (CHIM) using the ETEC strain H10407. The clinical study aims to enrol up to 60 healthy adult subjects each will be randomly assigned to receive either a once-daily dose of 1200 mg of Travelan (30 subjects) or placebo (30 subjects). Recruitment is planned to be initiated in 1st half of 2023 and by end of 2023, the headline results from the clinical trial expected to be reported.

IASO Bio's clinical trial application for BCMA CAR-T CT103A for relapsed/ refractory multiple myeloma

IASO Biotherapeutics (IASO Bio), a clinical-stage biopharmaceutical company, announced that the Investigational New Drug (IND) application for its in-house developed BCMA CAR-T CT103A (equecabtagene autoleucel) has been approved by the US Food and Drug Administration (FDA) for use in US clinical trials for relapsed/refractory multiple myeloma (R/R MM).

CT103A, a CAR-T cell therapy targeting the B-cell maturation antigen (BCMA), has a chimeric antigen receptor (CAR) structure containing fully human single-chain variable fragments (scFvs), allowing it to bypass potential anti-CAR immunogenicity of the host while retaining anti-tumour activity. Results from a clinical phase I/II (NCT05066646) study in China showed excellent safety and efficacy of CT103A.

Also, data presented showed as of January 21, 2022, 79 subjects have received CT103A infusion at the recommended Phase II dose (RP2D) of 1.0×106 CAR-T cells/kg. The median follow-up time for the 79 subjects was 9 months (1.2, 19.6), and the objective response rate (ORR) was 94.9%. The median time to response (mTTR) was only 16 days. 73 (92.4%) subjects achieved at least once negative minimal residual disease (MRD) status after cell infusion. All subjects who achieved complete response (CR) or better achieved MRD-negative. Subjects who had previously received CAR-T therapy continued to benefit from CT103A infusion.

Alembic Pharmaceuticals' Fulvestrant injection (an equivalent to Faslodex injection)

Alembic Pharmaceuticals has announced the receipt of a final approval from the US FDA for its Abbreviated New Drug Application (ANDA), fulvestrant injection 250 mg/5 ml (50 mg/ml) per single-dose prefilled syringe (PFS). The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Faslodex injection, 250 mg/5 ml (50 mg/m) of AstraZeneca Pharmaceuticals LP. Fulvestrant injection is an estrogen receptor antagonist indicated for the treatment of breast cancer.

Alembic Pharmaceutical added it has received a cumulative total of 179 ANDA approvals which includes 156 final approvals and 23 tentative approvals from US FDA.

Hetero gets WHO prequalification for generic Paxlovid

Mumbai, India: Hetero, India's leading pharmaceutical company with the widest global reach, has received World Health Organization Prequalification of Medicines Programme (WHO PQ) approval for its generic version of Covid-19 oral antiviral treatment candidate nirmatrelvir. This is the first prequalification for a generic version of Pfizer's COVID-19 oral antiviral drug 'Paxlovid.'

The combi pack, launched by Hetero as Nirmacom, will contain nirmatrelvir 150 mg (2 tablets) and ritonavir 100mg (1 tablet). Nirmacom will be manufactured at Hetero's facilities in India. ■

Technology-Based Approaches to Building Resilient Pharma Supply Chains

Gaurav Kaushik
Managing Director & CEO
Meteoric Biopharmaceuticals

The ongoing COVID-19 pandemic has not only led to severe disruptions in public health and everyday living, but has also led to a great deal of uncertainty for businesses. When it comes to businesses, it has impacted operations and exposed the frailties and vulnerabilities of supply chains across sectors. The same is true for the pharmaceuticals sector, which has always thrived on timely production, adequate inventory levels, speed-to-market, seamless distribution networks, cost-efficiencies in terms of raw material and freight costs and coordination between several key stakeholders.

In its wake, the pandemic has undoubtedly brought about several disruptions in pharma sector supply chains on a global scale. Both, demand as well as supply-side aspects of the value chain have been impacted. The key obstacles have been in terms of logistics-related impediments, a depleted workforce, the need to operate with low-contact restrictions in place and issues related to timely procurement of inputs and APIs. The unexpected surge in demand for items such as masks, PPE kits, antivirals, vaccines and others due to the pandemic has led to severe shortages and reiterated the importance of enhancing the resilience of existing supply chains within the pharma sector.

Thankfully, forward-looking businesses have been able to successfully leverage and deploy advanced technologies to enhance their supply chain resilience by several notches and wield a competitive advantage. These technologies are leading to several positive outcomes, which apart from enhancing productivity and efficiencies also include infusing intelligence in processes, enabling real-time visibility across operations, facilitating collaboration and dissemination of valuable insights and information across stakeholders, improving distribution and logistics.

Some of the ways in which technology is being leveraged to transform pharma supply chains include -

Drug Discovery & Development and Innovation in Treatment

According to a survey conducted by GlobalData in 2021, more than 70% of pharma sector respondents anticipated drug development to be the area most benefited by the implementation of smart technologies. Indeed, smart technologies like AI are being leveraged to accelerate drug discovery and to develop new innovative methods of treatment. For instance, NVIDIA launched Cambridge-1, UK's most powerful supercomputer, to help British healthcare researchers accelerate and optimize every stage of drug research. Likewise, a series of similar collaborations have also been announced with several other pharma giants. AI accelerates the drug discovery process by a million times. Multimodal AI can be deployed to process multiple sources of health data, discover patterns in diseases and open up new avenues in the prognosis and treatment of patients. Further, AI can also be harnessed for gene editing as well as gene writing to treat genetic disorders.

Industry 4.0 and Smart Manufacturing

Smart Manufacturing involves the combination of interconnected computing devices and sensors into a cohesive network that makes it possible to collect valuable data on a real-time basis, the collection of such data at a central control centre, the processing of such data with the help of algorithms and AI & ML-powered systems and the generation and dissemination of valuable insights to enable quick and critical decision-making through ERPs and other intelligent systems. Within the realm of pharmaceutical manufacturing, this could cover information such as raw materials variability, visibility of material inventory across facilities, manufacturing floor-related information such as environmental conditions, wear & tear of machinery, performance, quality checks, real-time monitoring of operations and much more.

Real-time connectedness, both within and outside the manufacturing facility, makes this a powerful tool in the hands of pharma manufacturers.

Automation of Document Management and Other Key Processes

The process of introducing new formulations and drugs involves significant volumes of documentation. These need to be recorded, reviewed and managed correctly in order to adhere to regulatory requirements. Such documentation is required at pre-clinical, clinical as well as commercialization & post-marketing stages. Automation of such documentation processes can lead to minimization of errors, expedition of approvals, faster speed-to-market, cost optimization and timely compliance with regulatory norms.

Focus on Reducing Exposure to Shocks

India and China collectively account for nearly one-third of the critical components or raw materials within the pharma sector. Expanding the existing network of suppliers is one way to combat such vulnerabilities. Companies can also seek to strike a better balance between just-in-time and just-in-case inventory levels, focus on hardening physical assets to withstand natural disasters and financially support certain essential suppliers. Besides these approaches, there are technologies available to enable quick changes among suppliers and advanced analytics to predict potential challenges better. The resulting ability to reroute components and flex production can help build robust supply chains

Digital Overhaul of Procurement Process

The procurement process has been long overdue for a major overhaul in the case of most pharmaceutical companies. The pandemic situation has provided an opportunity to enhance the risk management and cost-efficiency aspects of the function. The deployment of advanced digital technologies can help centralize decision making and bring together siloed information to gain better visibility into spends and to facilitate better cost control, spend optimization, better supplier management and even product life-cycle management. At the end of the day, such technologies can help sustain the affordability of end-products.

Transparency and Traceability Along the Supply Chain

Blockchain-powered mechanisms to track, update and authenticate the status of drugs & formulations at every stage of its otherwise unseen journey, right from

procurement of raw material to production and eventual distribution among consumers can prove to be critical in the current landscape. They can help address several objectives, including coordination among several stakeholders, inventory management, manpower requirements, order management, shelf-life of medicines, and much more. They can also enhance the process of optimizing production and storage. This not only facilitates accuracy and compliance in procurement, but also enables better coordination among stakeholders, prevents losses due to stagnation of inventory, and ensures cost-reduction, transparency and visibility.

Cold-Chain Management

Cold chain management and logistics are important aspects of the pharma sector supply chain. These help pharma companies maintain a continual stock of materials and drugs from suppliers and for distributors across locations. The shelf life and efficacy of several life-saving drugs hinge heavily on proper cold chain management, at correct temperatures and storing conditions. It is no surprise then, that the global cold chain logistics market, which was valued at around US$ 160 billion in 2018 is estimated to grow to a whopping US$ 585 billion by 2026.

The key factors for the growth of cold storage supply chain management, especially in India, are addressing regulatory issues, product proliferation and infrastructure gaps, among others. There is a need to create awareness about handling temperature-sensitive goods and bridging gaps in refrigeration equipment, warehouse & infrastructure.

New Solutions for Pharma Logistics

The pharma sector thrives on momentum when it comes to the free and seamless movement of materials and end-products across geographies. Shipping and air-cargo solutions have been the mainstay of such free movement. During the course of the pandemic, while ocean freight shippers remained active, air cargoes and even land-based inland logistics have been severely hampered at various junctures due to restrictions. One of the solutions that have emerged to overcome this problem is the introduction of pharma-centric dedicated logistics services by air cargo companies and airlines (e.g., Etihad's PharmaLife service). Likewise, Health Departments of some economies have created consortiums featuring key freight forwarding agencies to facilitate an effective and sustained distribution network for vaccines and other pharma products (e.g., Abu Dhabi Dept. of Health's HOPE Consortium which features freight forwarding leaders such as Aramex, DB Schenker, DHL, FedEx, UPS and many more).

Deployment of Simulation Systems

Simulators are emerging as powerful supply chain planning tools, which provide comparative analytics for various scenarios. These can lead to better decisions such as selecting right alternative sources to meet demand at minimal cost increase, deciding which plant overloading capacity is optimal, determining freight costs, calculating lead times, and much more.

Contract Manufacturing

The pandemic forced several pharmaceutical companies to lean towards contract manufacturing so as to continue providing quality products to their customers in a cost-effective manner. The rapid growth of contract manufacturing can be gauged from the fact that it grew from US$ 935 billion in 2017 to at least US$ 1.2 trillion by 2021. Even as the world gradually marches towards normalcy, many pharma companies are continuing their reliance on contract manufacturing so they can focus on other key aspects of their business. Such an approach helps them increase their overall productivity and efficiency and enhance their margins. Partnering with local manufacturers can also help address speed-to-market objectives.

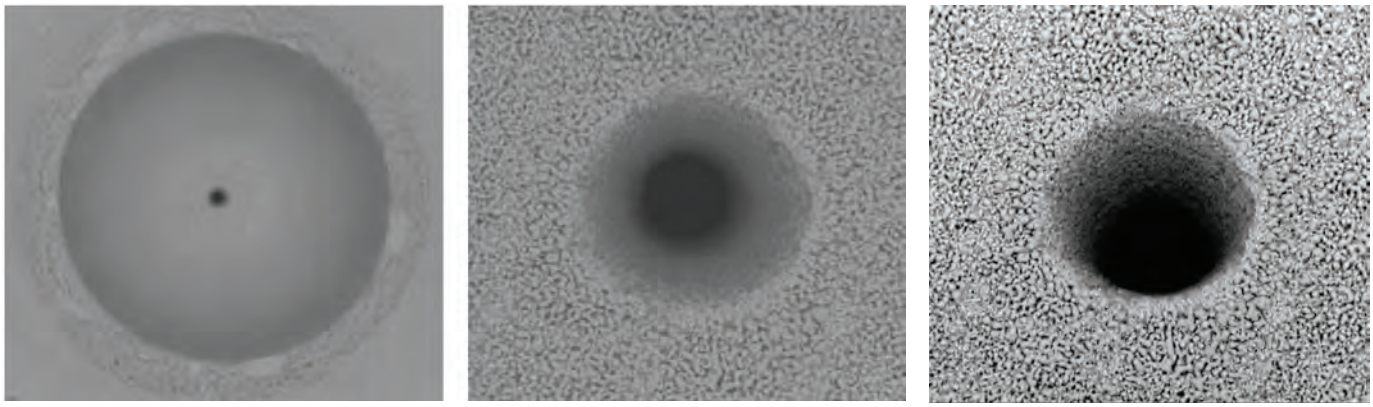
The Way Forward

Although the pandemic has exposed several chinks in the global pharma supply chain, it has also led to a reality check and provided an opportunity for course correction. The pharma sector will do well to invest in and leverage advanced and smart technologies to reinforce their supply chains and deliver superior outcomes, even in the face of headwinds and general uncertainty. The health, not just of the sector, but also of the human race, will rest in safe hands if these priorities are systematically addressed before the next black swan event rears its ugly head. ■

Quality Assurance in Health Technology

Andreas Reitberger
Sales Manager
GFH GmbH

Innovative solutions are needed to quickly and cost-effectively check the required hygiene and quality standards in order to ensure access to high-quality, safe medical and pharmaceutical equipment in the future. Various essential quality and stability tests are already carried out during the manufacturing and processing process of products such as syringe cylinders, vaccine vials or infusion and transfusion bags. Thereby, the control mechanisms used have to reliably detect even the smallest variation and damage in the material, to exclude contamination in the context of the application. Therefore, GFH GmbH offers manufacturers of medical and pharmaceutical products a laser-based solution. A cost- and time-saving opportunity is offered to validate this quality test, which works particularly flexibly and gently on materials by drilling high-precision leak holes of just 5 µm to



Scanning electron microscope images of the leakage hole

Leakage drilling in glas

50 µm diameter into individual specimens of a production line. While the hole sizes can be kept very accurately, no cracks or pressures will arise around the drilling site.

As a result of the ongoing pandemic the demand especially for so-called 'leakage drilling' in Syringe cylinders increases rapidly. During manufacturing, these deliberately selected samples are intended to exclude defects in the material of the vials and cylinders for example to prevent subsequent contamination of the transfusion or leakage during usage. Increasing demand for such control procedures is due not least to global vaccination campaigns and the associated increased demand for flawless medical and pharmaceutical products. Manufacturers therefore need reliable methods that can carry out random quality check with high precision in a time- and cost-saving way. For this purpose, laser technology is a predestined method due to its very precise and non-contact processing beam, which is why some well-known manufacturers have already approached GFH GmbH regarding the generation of leakage drills.

The Bavarian laser experts have developed a process, which allows the drilling of high-precision leak holes validating the control mechanisms used in production without much effort. The resulting (defective) products with micro drill holes are then integrated into the manufacturing process of the medical device manufacturers. These ´prepared´ products then form the control group for the quality- and leak test. "The ultrafast laser serves as an excellent tool to equip the glass vials with leakage holes which are very small and precise, but still do not damage the material around the drill hole", explains Andreas Reitberger, Sales Manager at GFH GmbH. "There are numerous reasons for this: on the one hand, the ultrafast laser pulses that hit the material prevent tensions and cracks in it by means of so-called "cold ablation". On the other hand, there are no limits to the variety of materials used in laser processing. This enables even hard-to-machine materials such as glass or special medical plastics to be processed with high precision." ■

AI Advancements Promising Agility, Accuracy & Efficacy in Drug Discovery

Dr. T.N.G. Sharma
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Technology and automation have affected every aspect of human life in the recent past, from communication, transportation, manufacturing, and industry to medical and pharmaceutical companies.

AI is a trending topic in the biopharma industry and the recent advances in high-performance computing and the availability of large annotated data sets have resulted in an unprecedented acceleration of the field. Implementation of AI promises better results than traditional methods of drug discovery and development.

The data in the publications and the databases are not structured in a way that allows easy analysis; however, data extraction, curation, recognition patterns, and insights can now be optimized by using AI in drug discovery and development.

Major healthcare systems are becoming digitally driven, creating the technical infrastructure to deliver digital health strategies and services. Data is collected by the healthcare system to evaluate outcomes and shape future strategies. AI in the medical field is a good example that depicts the modern era industrial revolution where innovations and development in the medical field are growing rapidly. AI technology will improve efficiency of drug discovery and drug development processes and reduces

reduce cost, time and effort. AI has the potential to reduce timelines for drug discovery and improve the agility of the research process, increase the accuracy of predictions on the efficacy and safety of drugs; and improve the opportunity to diversify drug pipelines.

Technology helps pharmacies improve their efficiency and access to critical medical and patient information in their daily activities. The advantages are the adoption of pharmaceutical technologies like Health information (HI) technology, which consists of various resources for managing and sharing patient data electronically. In innovative ways, HI technology assists pharmacists in providing better care or treatment to patients and in making decisions in real-time. In short, HI technology helps the drug sector reduce healthcare costs and improves patient quality, and has a beneficial impact on the overall healthcare system.

Improving the sophistication of digital customer engagement will be one way in which AI/ML will serve to improve and enhance the current functions of pharmaceutical companies by applying dedicated AI/ML that recommends best actions to the customer-facing team. ML can be useful in handling mailboxes of the safety team, identification of adverse event reports, categorization of adverse event emails into expedited, and non-expedited, and prioritization emails based on the seriousness, initial receipt date, and reporting country. In summary, AI/ML technologies are slowly but steadily transforming the pharma traditional paradigm of drug discovery and development.

Using the strength of supercomputers, taking health care decisions with the aid of AI can rebuild daily medication. These technologies enable a higher degree of automation of processes and equipment, which in pharmaceutical manufacturing enabled concepts such as continuous manufacturing and active control. Human-computer interfaces aided in developing more sophisticated control strategies and higher product and process quality. Remote sensing and monitoring reduced the need for human operators on the manufacturing floor and facilitated better tracking of parameters and metrics associated with production.

As regulatory agencies mandate improved traceability of data, enhanced quality of the complex processes and supplier networks within the industry creates pressures that manufacturers must address, for which they require new or more advanced technologies which can fulfill unmet analytical needs, ranging from new instrumentation, better automation and sophisticated informatics, such as AI

that can be used to displace current data analysis and interpretation approaches. To achieve all benefits, the industry shall incorporate three key elements: digitally-enabled laboratories, automation and distributed quality control.

For better use of data to improve the efficiency and effectiveness of drug development and manufacturing, pharmaceutical companies keep collecting more data. Simplifying the approach to the analysis allows everyday users, data scientists, to make use of the analytical tools. Reaching such levels of improvement in data analysis depend on manufacturers working with biocomputing experts to find the best digital solutions for collecting and managing information. Similar collaborations are required to ensure the successful and optimal integration of digital systems with physical instruments. With that integration, a biotechnology or pharmaceutical company will gain advantages in producing high-quality products thereby with improved reproducibility, increased speed and reduced cost. The future of the pharma industry is digitization and consolidation. It is moving toward consolidation with more manufacturers, and pharmacies merging with one another to achieve control over data. With more data in the hands of fewer players will begin to see more automation and digitization of supply chains.

The best example in this context, in terms of "What India gains from trade deals with Australia and the UAE?" was the Stakeholders' Outreach Programme, is the India-UAE Comprehensive Economic Partnership Agreement (CEPA), and India-Australia Economic Cooperation and Trade Agreement (ECTA) that was held recently. Landmark developments in India's trade policy took place recently as India signed two trade agreements in a gap of fewer than 50 days. This happened for the first time in India's history of trade engagement. On February 18, 2022, India and the United Arab Emirates (UAE) signed the Comprehensive Economic Partnership Agreement. On April 2, 2022, India and Australia entered into an interim trade agreement and to the discussion on finalising a comprehensive deal continues. Both agreements will have significant implications for India's trade as they are expected to unleash avenues for the business and its professionals. ■

De-bottlenecking Scale-up Challenges for Large Scale Viral Vector Manufacturing

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The rush to develop an affordable and accessible COVID-19 vaccine not only accelerated research and development of therapeutic modalities like viral vector, mRNA and pDNA based vaccines but also challenged the bioprocess community to solve for unique scale-up related challenges to manufacture these important life-saving medicines. This article illustrates our current thinking and experiences on debottlenecking potential challenges to scale adenoviral vector technology at 2000 L and beyond.

Adenoviral vectors are attractive vectors for delivering genes into specific human cells, either for covid19 vaccine or other gene therapy applications1,2. These vectors can accommodate large transgenes, transduce quiescent and dividing cells, and do not integrate into the host's genome. Adenoviral vector technology using HEK293 host cells has been around for a long time and the manufacturing process (as illustrated in Figure 1) include combination of HEK293 growth and infection phases during upstream processing, followed

by series of filtration, concentration and chromatography steps during downstream processing to produce drug substance with high purity. Although, the process unit operations seem uncomplicated, manufacturing at large scale has remained a major challenge due to poor and inconsistent cell growth, low viral titers, product aggregation, inefficient separation of empty and filled viral capsids, as well as operational complexities related to handling large volume viral infection. The expected challenges during process scale-up and possible mitigation strategies have been detailed in Table 1.

Upstream Challenges & Mitigation Strategies

The entire gambit of HEK293 based viral vector serotype production in large scale bioreactors revolves around three factors: optimal HEK293 cell growth during scale-up stages, high-quality viral seed to achieve optimal Multiplicity of Infection (MOI) and optimal process parameters to maximize viral titer output during production.

Although HEK293 cells have been significantly utilized for biopharmaceutical applications, it is critical that optimal media, supplements and process parameters are selected to avoid cell clumping, lag in cell growth and drop in viability. The typical cell culture parameters like pH, temperature and dissolved oxygen levels are usually well controlled in bioreactors, however growth of HEK293 cells demonstrate higher sensitivity to dissolved CO2 levels, osmolality, media feed strategy, and metabolite levels relative to other commonly used mammalian cell types. Hence, developing control strategies to control these important parameters is highly critical to achieve consistent cell growth and product titers.

The quality of viral seed used to infect the HEK293 cells at various scale up stages during manufacturing is another important parameter, since it defines the number of viruses available to infect a single HEK293 cell during production and hence, impacts the batch output in terms of viral titer. One of the most important factors to avoid is cell clumping, which can lead to sub optimal growth and loss of infection efficiency leading to lower productivity at the end of harvest. While in some cases, addition of anticlumping agents may help in solving the clumping issues, in most cases suboptimal agitation is the root cause. Hence, agitation rates need to be optimized with well-designed strategies (P/V, KLa, Shear stress, Tip speed etc.) to avoid any mass transfer limitation and mixing limitation but at the same time maintain low shear stress. Additionally, viral titer quantitation analysis (with significantly shorter TAT) needs to be developed to reliably estimate MOI, which

is consequently used to calculate viral seed volume for infection.

Finally, the viral titer productivity at the end of harvest can be significantly impacted by parameters during the infection phase, including temperature, optimal cell cycle phase, cell density at the time of infection, infection duration as well as culture pH. These parameters need to be carefully optimized using a multivariate design of experiment approach to achieve maximum viral titer output.

Downstream Challenges & Mitigation Strategies

The major challenge in large scale downstream manufacturing is inconsistency in recovery product quality and stability at the end of purification process. Viral particles are prone to aggregation, which could be induced by pH, thermal or mechanical stress during various unit operations3. These aggregated particles bind non-specifically and strongly to the resin leading to major product loss. To minimize loss due to aggregation, the entire midstream and downstream needs to be carefully designed. Unit operations like cell lysis, endonuclease treatment and TFF need to be optimized to avoid shear stress which may also contribute to lower aggregation of viral particles. While some of the stabilizers in the buffers like Magnesium Chloride, Polysorbate 80 and Sodium Chloride can help in stabilizing the virus particles, other strategies are related to minimizing process hold times and holding process intermediates at lower temperature.

Another concern which may get exacerbated with larger scale is robust separation of unwanted empty capsids from the filled capsids (desired product) at the end of the purification process to

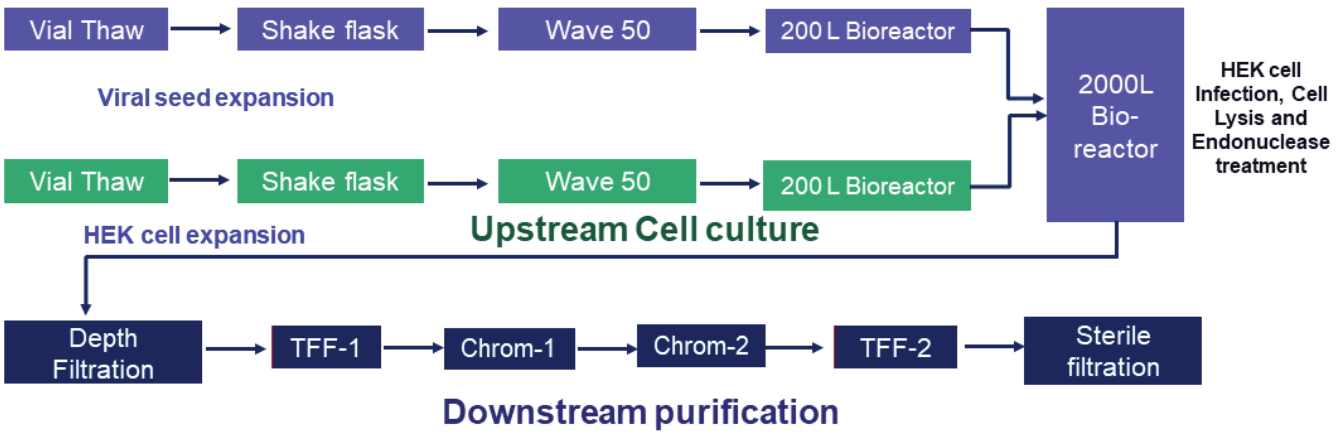

Figure 1: Manufacturing Process flow for production of Adenoviral Vector at 2000L scale

Table 1: Expected challenges during scale up of viral vector manufacturing and possible mitigation strategies

Area	Challenges	Possible Mitigation strategy
Upstream Challenges	Growth of HEK cells	Check for Premature cell infection and Optimization of cell culture parameters
	Clump Formations	Use of anticlumping agents and optimization of agitator seed
	Productivity of virus particles	Maintaining virus to cell ratio, Viral seed quality check by infectivity assays and optimization of post infection conditions
Downstream challenges	Inconsistent recoveries and quality	Check for variable input quality to downstream, Empty vs Filled particle separation optimization
	Aggregates	Minimize shear stress in TFF and other unit operation, Use of stabilizers in buffers and process intermediates
	Lower recovery	Minimize process induced aggregation, minimize process hold and define hold temperature
Facility related challenges	Premature Infection	Complete segregation of clean cell growth area, Effective cleaning procedures, Restricted man and material movement

achieve the desired ratio of empty and filled viral capsids. This inconsistency is primarily driven due to poor separation of empty and filled capsids in downstream chromatography unit operations. A thorough optimization of the anion-exchange unit operation step can help in enrichment of the filled capsid for getting better consistent ratio of these two at the final product level. specific analytical methods also need to be developed at different process intermediate stages to monitor this important product quality attribute,

Facility Design & Adequate Cleaning Controls

Careful design of facility for a viral vector product is key to achieving predictable and robust operational outcomes, because of nature of the product. One of the major challenges in adenoviral vector production is the risk of pre-mature infection of HEK293 cells, which can result in poor cell growth and early batch termination, yielding suboptimal product output. Hence, by design, different cleanrooms in the facility need to have appropriate controls in terms of

man-material movement, segregation of air handling units and other procedural controls between viral and non-viral areas. Additionally, an effective and robust cleaning, sanitization and environmental monitoring program, aided with product specific analytical assays need to be established to control and circumvent any residual risk of viral contamination.

Summary

Large-scale processes for manufacturing of important medicines like viral vector vaccine for covid-19 is essential to drive accessibility and affordability across the globe. However, specific technical and operational challenges need to be mitigated through well designed experimental approaches and empirical knowledge to ensure successful process scale-up. Stelis Biopharma was able to setup a state-of-the-art large-scale viral vector facility (with operational capacity of 10 X 2000L) to manufacture a covid19 vaccine. In a short amount of time, Stelis was also able to successfully scale-up the process at 2000L scale, through focused design of experiments and structured scale-up approaches, and consistently achieve high viral titers with uncompromising product quality, delivering close to ~5 million doses of covid-19 vaccine per 2000L batch. ■

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The Cold Chain of the Future

Nick Gilmore
Global Head of Sales and Marketing
Tower Cold Chain

In today's continuously volatile market, with customers demanding greater efficiencies at increasingly lower costs, logistics providers are constantly searching for new technologies and processes that will not only improve operations but help give their business a competitive edge. With the cold chain logistics market for the pharmaceutical industry set to grow by USD 9.37 billion from 2020 to 2025, according to Technavio, specialist freight providers must be forward thinking to stay ahead and make its processes as efficient as possible.

Product images

Adapting to meet new demands through product innovation

Putting the triumph of the COVID-19 vaccine rollout to one side, the demand for

effective temperature sensitive solutions in the pharmaceutical supply chain has increased hugely in recent years. With a growing prominence for personalised medicines, we are now beginning to see the advancements of precision therapies in the pharmaceutical cold chain industry. There is no longer a "one-size-fits-all" approach to medical practice. Instead, we're seeing a shift towards bio-specific treatments, tailored to a particular

individual's needs based on their genetic material. And, with manufacturing adjusting to smaller batch, precision medicines, the vendors and outsourcing partners must adapt too as the need for transparent, closely controlled global chains demands rise.

Thus, it is vital for pharmaceutical manufacturers to have a cold chain partner that is committed to continually expanding and evolving to keep pace with the complexities of transporting pharmaceuticals. Cold chain shipping providers should have the technology, resources, and network in place for handling lower volumes of products with tight manufacturing-to-patient timeframes. Delivering a consistent customer outcome, is a need not a want. Put simply, manufacturers will choose partners who can assure products will arrive on time, undamaged, and with no temperature excursions.

Tower's critical and mission-defining objective is to improve the quality and consistency of pharmaceutical deliveries across a global market. An example of how this has been achieved is the recent development of the KTEvolution – a robust, lightweight, handleable solution that provides the same reliable thermal protection and reusable durability as Tower's existing range. With the growing trend in smaller shipments such as direct-to-patient, sample shipment, clinical trials and last-mile deliveries, combined with customer feedback, it became clear that there was a gap in the cold chain shipping market for a passive solution, ideal for manual handling.

Hence, the KTEvolution was born, striking the optimum balance between high performance, durability and optimised weight. And, like all our range of passive containers, any pharmaceutical products stored in a Tower solution, require zero in-transit manual intervention, or electricity. Passive solutions have contingency built in, providing 120+ hours of product protection, whether the requirement is for frozen, chilled, or ambient temperatures. Our robust containers are intended to perform in all supply chains regardless of transport type or environment, delivered to patients reliably when, and where they need them.

The network approach to planning and beyond

With the amount of sensitive biopharmaceutical and biologic products expanding, coupled with the demand for advanced pharmaceuticals in middle to low-income countries, cold chains will continue to be pushed to globalise in the coming years. Pharmaceutical organisations are increasingly relying on their external suppliers to operate lean supply chains, with extended distances to ship products quickly and efficiently. Logistic providers must ensure these needs are met, offering a global network for localised deliveries – all whilst complying with each country's regulations and maintaining the strictest requirements.

For Tower, our international hub network is expanding month on month and is set to double in 2022 alone. With new hubs and service centres opening in Europe, throughout the APAC and Americas regions, this is set to further improve the proximity and availability of Tower containers, whilst being the securest way to reduce the risk of disruption. An optimised global network for localised shipments, enables Tower to react even more quickly to customer requests, and provide assurance of supply, anywhere in the world.

Knowledge is power

The unpredictability of the market, combined with today's increasingly connected, world, means pharmaceutical businesses are depending on their third-party cold storage partners to deploy end-to-end tracking processes and capabilities to ensure product integrity and maintain profits. Data is no longer a bonus feature, but a vital part of cold chain operations and smart packaging which delivers traceability is becoming a cornerstone of supply chain fulfilment.

A key aspect provided by Tower are dataloggers, designed to monitor external and internal temperatures throughout each individual container's journey. These advanced features, integrated into the external body of the container, inform customers of the solutions' pre-conditioned temperature, prior to the loading process, thus guaranteeing product integrity from the very beginning of the cold chain. Using Bluetooth Low Energy Technology, each logger communicates wirelessly, sending accurate data to the cloud. Users can get a text or email notifications of temperature excursions, as well as automatic data downloads throughout the transit when it's in range of an InTemp Gateway device. This data communication allows for accurate compliance checks and on-delivery sign-off, providing complete visibility and transparency to customers.

And yet, as with everything we do at Tower, we are constantly innovating and improving our offering to ensure all cold chain pharmaceutical products make it to their destination safely and securely, ensuring critical medicines are delivered intact and always within the manufacturer's temperature stability requirements. To stay ahead of the curve, we're actively looking into the sphere of cellular GPS tracking geared specifically towards pharmaceutical shipments and compatible with airline regulations. Ultimately, strength is already there but technology is helping us to take that process to the next level to maintain a robust, reliable, reusable supply chain.

The example of the last few years underlines how turbulent and fast changing the pharmaceutical supply chain can be. With demand set to increase further, this complexity isn't going to go away and that's why it's vital to anchor cold chain decisions in the essential elements that won't change. For Tower, our customers continue to require robust, reliable, reusable cold storage solutions, to provide effective temperature sensitive control to protect the integrity of pharmaceutical products – and, at our core, is what we will continue to do, whilst providing peace of mind that, whatever happens in the world, your pharmaceuticals products will arrive safely and on time. ■

Digitalisation: The key to smarter facilities monitoring

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By consequence, the economic surge of pharmaceuticals sector in India has accelerated pharmaceutical pollution across the country. Varieties of pharmaceuticals have been detected in the surface, ground, and even in drinking water, with sources of pollutants traced back to pharmaceutical manufacturing plants, hospitals, and wastewater treatment plants. Furthermore, to ensure the high standards, safety, and efficacy of pharmaceutical products, stringent regulations must be observed.

In the global pharmaceuticals sector, India has grown from a rising player to a significant contributor. Low cost of production and R&D places India competitively as the world's largest provider of generic medicines, with 20% share of total pharmaceutical exports, and the largest vaccine supplier in the world.

About 3,000 drug companies and 10,500 manufacturing units are advancing the country's reputation for producing high-quality, low-cost generic drugs.

As a solutions provider observing this shift across numerous industries, we have found that digitalisation offers tremendous opportunities to comply to environmental

regulations while improving efficiency. Artificial intelligence (AI) and Machine Learning (ML) make it far easier for reliability engineers and technicians to evaluate water and air filtration systems across sensitive environments like biotech labs and hospitals, maintaining quality control with fewer errors. From processing facilities like cleanrooms to air quality at the manufacturing unit, air purity levels need to be kept pristine to avoid the threat of airborne contamination.

To help customers optimise their filtration systems and the assets they protect, MANN+HUMMEL ventured into providing new digital solutions platforms, STREAMETRIC and qlair, to complement our products. As a company that has been in business for 80 years, constant innovation and support is something our customers can rely on us to provide.

Predictive monitoring for water systems

The effects of the **accumulation of pharmaceutical residues** in the environment are many folds, affecting species living in the water to the spread of **antimicrobial resistance.** However, facilities can improve the reliability of their filtration systems, reduce engineering hours, and even enjoy enhanced reporting if they implement digital water quality monitoring through a platform like STREAMETRIC.

Features of AI enabled water monitoring system (Streametric)

- Wide range compatibility in regards to Membrane types.
- Compatible with majorly used PLCs and Protocols.
- High scalability- from pilot plants to full-scale manufacturing facilities.
- Centralized data storage over Cloud with high ease of access.
- Accelerated reporting & digital logging of anomalies.
- Forecasting Membrane permeability and trans-membrane pressure.

Through a streamlined framework, engineers can build cleaning schedules and prediction parameters, use AI-based predictive technology to set limits and detect anomalies, including forecasting membrane permeability

and transmembrane pressure. More importantly, STREAMETRIC is compatible with all membrane types and most major PLCs and protocols, and can be installed on systems ranging from small pilot plants to full-scale manufacturing facilities.

To facilitate reporting for engineers and technicians, managers can also design personalised dashboards for team members, operators, and service providers. All data is gathered and stored in the secure and scalable STREAMETRIC cloud, while a digital logbook allows teams to capture and store all historical data without the need for manual referencing or data entry. When it comes to sustainability and environmental reporting, data and insights can be readily obtained to ensure a facility remains in compliance with company or government regulations.

Setting the standard for clean air management

Air purification is vital to pharmaceutical companies and it's easy to understand why. Unclean air can contaminate drugs which leads to devastating health impacts, for both workers at the lab as well as those who consume these products. Improved ventilation and filtration in pharma environments can be achieved with intelligent air quality monitoring. Which is why we developed qlair: a platform that leverages machine learning for proactive clean air management in commercial buildings.

qlair's Indoor Air Quality (IAQ) Monitoring platform uses highly accurate sensors that can help pharmaceutical facilities meet air filtration guidelines set forth by ASHRAE, the CDC, and WHO. In addition to getting real-time IAQ data across multiple spaces, technicians can integrate qlair analytics into existing systems for more effective air quality recommendations — all on-the-go through web and mobile applications.

Enabling user success

With these data-driven insights, companies can generate up to 20% savings in heating, ventilation, and other energy costs. In the case of Atrium Health, a North Carolina-based healthcare group with 40 hospitals and more than 1,400 care locations, the facilities management team was changing out their Air Handling Unit (AHU) filters every 3 months on a time-based schedule. However, by installing AI enabled Filter Life Cycle Monitoring systems, they found that their air handling unit (AHU) filters only need changing every 10-12 months. This led to a cost

savings of 345 USD per AHU, and the ROI from implementing qlair was reached within 9 months.

Translating Data for accurate interpretation

Besides manufacturing conditions, businesses also need to consider the impact of indoor air quality on occupant health, and the COVID pandemic has made this patently important. Yet, how can facility managers without HVAC expertise be able to maintain optimal IAQ at all times? To solve this, qlair patented the COVID Airborne Infection Risk Score (CAIRS). CAIRs automatically analyses all relevant IAQ factors that have a scientifically proven impact on indoor virus transmission, producing an easy-to-understand score so facility managers can promptly work on factors needing improvement, and occupants enjoy greater health and well-being.

Conclusion

In a climate of uncertainty and fluctuating costs, having reliable real-time data to manage your research or manufacturing facility's air and water quality can provide a much-needed dose of confidence in remaining productive and profitable. Digitalisation is the way forward, and as a global leader in filtration, we will continue to innovate and provide key technologies alongside the pharmaceutical industry to ensure a healthier planet. ■

New Frontiers of Growth in the Life Sciences Industry

The life sciences industry is on the cusp of change. While this change does give rise to some challenges, it throws open doors for new opportunities and possibilities. In order to capitalize on these opportunities, an organization must be on a dual mission of 'renew - new' – one that simultaneously focuses on renewing existing systems and processes for greater efficiency and adopting new advancements in technologies to gain value. In this paper, we discuss these opportunities and the way forward for the life sciences industry.

Subhro Mallik
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Recent scientific and technological advances coupled with an aging population, expansion in the emerging markets, and an exponential increase in mainstream adoption of digital technologies have set the ball rolling for the life sciences industry, providing it with a renewed platform to revive its fortunes.

With an explosion of digital data availability – electronic health records, social, genomics, clinical, insurance, and more digitally engaged consumers, the stage is set to derive benefits from an integrated drug development and manufacturing environment. Such an environment not only provides the best care for patients but also generates

significant revenue growth. Furthermore, there is significant focus on personalized healthcare from both the Life Sciences industry and policy maker perspective. A case in point is President Barack Obama's precision medicine initiative. Personalized healthcare, however, would require a complete shift in how the industry evaluates the market (focus on an individual instead of a population), analyzes higher volumes of data, and puts in place newer processes and methods to complete their studies. The spate of recent investments in the immuno-oncology therapies is pointing towards a significant growth in the coming decade.

Technology is playing a massive role in enabling the industry to achieve these objectives, be it analytics in personalized medicine, cloud computing in collaboration, or wearable devices in remote and self-health monitoring. As the world becomes increasingly connected, information and communication technologies will fundamentally reshape both the consumption and delivery of services in life sciences. The industry must prepare for the future by embracing next-generation technologies and systems throughout the life sciences value chain.

We believe life sciences companies must adopt a more proactive strategy, one that allows them to maximize value from prior investments by renewing existing solutions and processes and generate new value by embracing new technologies, systems, and best practices.

Opportunities for 'renew' in Life Sciences

The Life Sciences industry is undergoing a major transformation. A large part of this is fueled by the integration of digital that has driven a powerful re-imagination of the Life Sciences industry landscape.

This transition has opened up new opportunities for development, but also comes with its own challenges.

- **Innovate through cloud:** Cloud's greatest impact is in facilitating innovation through increasing accessibility of both internal and external data. While initially the reasons for cloud adoption were

centered on reducing the cost and the time for infrastructure provisioning, it is now providing many more strategic benefits such as enhancing collaboration and providing much greater computing power across the entire value chain from R&D, sales & marketing to enabling functions such as HR and finance.

In pharmaceutical research where large volumes of data (notably next-generation DNA sequencing systems and genomic tools) needs to be mined and the cost of obtaining this sequence is rapidly decreasing, data has further increased the number of both, instruments being used and labs using them. Through cloud's agility of provisioning and pricing (pay-per-use), setting up massive infrastructure resources for data crunching, analysis, or simulation is no longer an impediment.

Similar cases are happening in clinical research. A large pharma company is setting up a cloud-based solution to integrate clinical data across all its global trials and provide it to its global operations team for analysis. These big data solutions that receive clinical data instantly from all the current trails will reduce the time taken to

analyze and predict the path of the trials, while decreasing the operating expenses substantially. On a broader application, the scope of collaboration is expanding to include R&D processes outsourcing, exemplified in virtual laboratories where thousands of researchers from contract research organizations can seek and provide help. Overall, by opening the doors of collaboration, exploding analytical power, and making information more accessible and manageable, the cloud is encouraging new practices such as open innovation in life sciences.

The industry must leverage these to the fullest.

- **Smarter and transparent supply chains:** Due to globalization and the ever increasing size of organizations, the need to integrate supply chains and gain visibility into them has become critical. Wide diversity of the product mix (biologics versus small molecule) will further compound the need for supply chains that can handle this mix. Furthermore, regulatory policies on transparency are evolving and several states in the U.S. have passed product pedigree laws, and many others are contemplating such legislations. In summary, supply chains will need to transport an increasingly diverse range of products in a challenging environment with resources that are much more geographically scattered while simultaneously optimizing costs.

As technology erases the distinctions between the virtual and the physical, it sets up the opportunity to create intelligent, analytics-driven, next-generation supply chains that provide real-time, end-to-end visibility and control. A smart supply chain, integrated across all business processes and systems, can also leverage real-time data and analytics to enable more accurate forecasting, shorter response times, optimized supply chain processes, and faster decisions.

To enable transparency, pharma organizations are not only implementing global track and trace solutions but are also experimenting with cloud-based, leaner supply chain management solutions. While more prevalent in the CPG Industry, discussions in the pharma community on these lean solutions that can provide visibility on their products after they leave their warehouses have taken place. These solutions are being used in the developing nations that have a more complex network of distributors and wholesalers. Such solutions will promote growth by preventing stock-outs and allowing further optimization of inventory and support recalls.

- **Renew through automation and modernization:** Most large pharmaceutical organizations are born out of numerous mergers and acquisitions and have inherited portfolios of IT applications in various stages of modernization. In our experience, a substantial part of the legacy portfolio is either outdated or manual, creating high cost burden of managing them while ensuring they meet the complex and evolving regulatory compliance standards. While legacy systems are integral to the continued operational maintenance, they hinder the adoption of newer digital solutions.

  Best-in-class companies are standardizing business processes, measuring manufacturing, focusing on visibility, and using the right tools. They are using automation to manage the processes and drive increased business value. Automation is being welcomed in the industry as an alternative to manual steps, especially across processes that have repetitive steps. Automation not only reduces the time taken to execute a task but also frees up time for valuable resources to focus on productive tasks. In manufacturing, Process Analytical Technologies (PAT) are being integrated across the assembly line to automatically capture unit operations data and integrate it with the plant quality equipment. This automation allows instant feedback on the batch quality based on the analysis of data while preventing waste and reducing costs. In R&D, numerous research labs are going paperless by integrating their critical solutions such as ELNs and LIMS with their high throughput chromatographs.

  This has not only reduced the time taken, but also minimized errors and allowed scientists to collaborate more effectively leveraging digital data. Additionally, in core IT services, a novel use of automation is in enabling testing of large and complex enterprise solutions. Panaya, which was recently acquired by Infosys, uses artificial intelligence to provide impact assessment and execute automated testing of their enterprise solutions. As a result, it can achieve 75-80% reduction in time and resource consumption. This is now being utilized across a number of large organizations with substantial time and resource savings. Automation is also being effectively utilized in executing the many repetitive tasks in application support services resulting in greater than 35% efficiency savings for organizations.

  We envision that the automation of IT processes will soon become a key component of the life sciences operations and new-generation

leaders will mandate these efficiency savings within their lean organizations.

New opportunities for life sciences

Populations are aging. Chronic illnesses are increasing. New disease strains are emerging at an alarming rate. Add to this mix, the soaring number of patients in a greater spread of geographies. Top it with global regulatory mandates. Then, factor in the variable dosage needs. Think about the shelf life of pharmaceutical drugs and medications. And, we are looking at skyrocketing global healthcare costs. At the same time, there is pressure to develop innovative drugs to save more lives.

Here are the opportunities that await the life sciences industry:

- **Connected patients and partners:** In today's socially connected world, pharmaceutical companies have a clear opportunity to play a greater role in delivering a better experience for patients and their providers. Patients are becoming demanding about how they want their care. This has precipitated a major transformation in business and technology and has led organizations to adopt a patient-centric model. Earlier attempts at creating these solutions were exclusively focused on adherence to

the medication. However, an emphasis on continuity of care provides an opportunity for pharma companies to play a bigger role. Digital solutions are facilitating patient education, behavioral change, and better communication with clinicians. There is also a wide variety of solutions that facilitate this connect including web portals, body sensors, and apps. These help the patient self-monitor and get needed support, between visits to the physician.

These solutions now provide health advice anytime, anywhere, by developing patient-centric smart tools and devices. These devices also detect and track data regularly and accurately and relay the same to physicians.

Mobility is another key feature of these solutions, making it easier for the patient to communicate. A hospital network in Boston empowers patients to use their home devices to track and report data to their doctors.

Patient and physician- centric portals, where comprehensive information about treatments and drugs is actively shared, are also on the rise.

In the future, pharma companies will design holistic Medical-health (M-health), platforms that connect the patients and physicians across the globe, drive patient and physician engagement, and activation – all with the objective of improved care experience for patients, better clinical outcomes, and lower total cost of care. In the new collaborative, omni-access data world, this will be a key factor in attracting and retaining patients, partners and clients. To keep pace with a rapidly changing technology landscape, organization, would need to develop a deeper integration, collaboration, and synchronization of activities across all channels.

- **Adoption of IoT and wearables across the value chain:** Ubiquitous presence of smartphones and substantial investments in Internet-of-things (IoT) are providing an exciting opportunity to reduce the gap between the patients and the pharmaceutical industry. While still in its nascent stage, higher adoption of IoT has already started to facilitate at-home diagnostic testing, self-management of chronic diseases, and remote patient-health care provider interaction in the healthcare industry.

For life sciences companies, the adoption of IoT can improve medication adherence and reduce time by capturing critical clinical indicators directly and sending them to the EDC system, produce better outcomes based on analytic insights such as in clinical trials where patient data through wearables has been found to be useful for tracking recovery from cardiac surgery, judiciously replace physical interaction with digital intervention, and lower the cost of treatment. Doctors are turning to wireless devices such as Fitbits to understand the factors that help the recovery of patients. A report published in the Annals of Thoracic Surgery says, "Wireless monitoring of mobility after major surgery was easy and practical. This opens the door for changing recovery models and improving outcomes in surgical practice."

Early market movers already see the use of pill-shaped micro-cameras that traverse the human digestive tract, sensors in pills that track concordance, hip replacements that detect falls and send messages to care providers, and thousands of health-monitoring applications that send messages and data from the home to the hospital or patient to the HCP to improve early diagnosis and treatment solution.

One critical innovation in this area is the advancement by Proteus Digital Health. It has created an FDA-approved small pill that consists of a pinhead- sized sensor embedded in the pill and a battery-powered patch that monitors various health indicators such as sleep, activity, respiration, and heart rate. The recent announcement by Novartis of partnering with Google on developing contact lenses that will monitor blood sugar levels and even correct impaired vision will further transform eye care and exemplify another frontier in adoption of IoT.

The adoption of IoT is yet to pan out in the life sciences industry. The industry must work cohesively to overcome the barriers to wearable technology adoption – concerns of security and privacy, data sharing and protection, regulatory compliance, among others – to take life sciences to the next level. In our view, companies that are proactive in using IoT will be the leaders of the future.

- **Effective big data utilization to generate insights:** From next-generation sequencing data and patient information to supply chain monitoring, pharmaceutical firms have been managing massive amounts of data for years. In recent years, rapid digitization has made access to larger volumes of data (EMR, clinical, genomics, wearables), an everyday

reality. The need to design solutions that will systematically analyze and generate real-time insights from these mountains of data more effectively is critical for success. To develop and deliver the next generation of successful therapies, the industry must simultaneously minimize the cost of processing / managing data while maximizing its value. This is complicated by the need to continue integrating new data types and sources from around the globe and to glean insights from unstructured data, while complying with multiple complex regulations governing drug safety, supply chain security, patient privacy, and other sensitive information.

Since early 2000, research units within biopharmaceutical organizations have been actively harnessing the powers of big data by leveraging the advancements in next-generation sequencing. This includes a variety of studies including whole-genome sequencing, targeted re-sequencing, discovery of transcription factor binding sites, and noncoding RNA expression profiling, among others. Organizations are now able to leverage the vast library of available molecular and clinical data, utilize predictive modeling techniques, and identify new potential candidate molecules with a high probability of being successfully developed into drugs while ensuring efficacy and safety.

Clinical development now is also benefiting from big data solutions. We have already mentioned earlier how a large pharmaceutical company is creating a cloud-based aggregated clinical data solution that will house results from all of its global trials.

Faster access to and analysis of this data will reduce the time-to-market and enable rapid decision-making capability. We envision that a further integration of clinical operations data with safety data will allow near real-time monitoring of trials and provide the ability to rapidly identify safety or operational signals demanding action to avert adverse events and unnecessary delays.

We believe that the need to uncover valuable relationships within the existing data is the key to boosting innovation and driving new value. With computing power and storage becoming cheaper, as well as increase in cloud adoption, the life sciences industry stands to benefit tremendously from big data solutions.

Conclusion

There are several reasons for the conservatism of the life sciences industry. But given the current dynamism in the sector, occasioned by regulatory, market, and technological forces, life sciences companies can no longer hold back. We believe this is a time of great opportunity, albeit with some challenges, for this industry. As the industry looks to grow while managing existing investments, it must adopt a dual strategic approach towards technology- renew existing systems and processes for greater efficiency while adopting completely new technologies and practices for value creation. ■

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Open Innovation Strategy: Industry Academia Collaboration

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With ever increasing costs of research activities, failure to commercialize an innovation becomes a major setback for the company. Many companies are opting for 'open innovation' strategy using externally generated innovations along with the internal research. The author discusses how pharma companies in US and Europe have been working closely with academic institutions for a long time that has resulted in commercialization of many active ingredients, complex formulations as well as excipients.

Pharmaceutical companies have a conservative approach in terms of their research activities and innovations. Thorough research is carried out within the company for which they engage state of the art research facilities and manpower. There is a great deal of secrecy involved in the research, data generated and the product innovations. Secrecy guarantees data confidentiality and avoids unnecessary competition.

However, not all innovations can be commercialized, which means that solitary research can become quite a costly affair. Similar research activities ongoing in different companies increase competition and decrease the chances of product commercialization. With ever increasing costs of research activities, failure to commercialize an innovation becomes a major setback for the company. This has led to a paradigm shift in the conservative approach of companies and many are opting for 'open innovation' strategy.

Open innovation refers to using externally generated innovations along with the internal research. The open model of research has been adopted by many industries such as IT, computers as well as healthcare. This is evident from the fact that there is a steep increase in joint literature published in the form of journal articles and patents in recent years. A survey has found that open innovations in medical and pharmaceutical research began to appear in the literature in mid-2000s and most of the research was done in North America and Europe, with Asia lagging behind [1]. One of the important sources of external innovations are academic institutions.

Need for Academic Partner

Academic institutions impart knowledge and thinking abilities in students. Academia majorly deals with basic research that is more exploratory in nature. It may be difficult to generalize this statement as this would totally be subjective. However, more emphasis is given to the proof of concept and prototype development. This helps industries to focus more promising research strategies as well as generate data for diversification in future. Academia, with its basic research and industry undertaking development activities, work in a complementary manner to provide good scope for innovations.

Few Global Top Industry Academia Collaborations

- University of Basel (Switzerland) & Novartis
- University of Oxford, University of Manchester, (UK) & Astrazeneca Plc.
- University of Copenhagen (Denmark) & Novo Nordisk
- Harvard University (US) & Pfizer Inc.
- University of Cambridge (UK) & Glaxo Smithkline Plc.

Industry Academia Collaboration (IAC): Global scenario

The pharmaceutical companies in US and Europe have been working closely with academic institutions for a long time. These collaborations have resulted in commercialization of many active ingredients, complex formulations as well as excipients. A recent survey suggests that academic inventors or founders have contributed to more than a quarter of all medicines approved from 2001 through 2019[2]. Few top collaborations in recent years include universities such as University of Basel, Switzerland, (Collaborator: Novartis) University of Oxford, University of Manchester, UK, (Collaborator: Astrazeneca plc) University of Copenhagen, Denmark, (Collaborator: Novo Nordisk) Harvard University, US, (Collaborator: Pfizer Inc.) University of Cambridge, UK, (Collaborator: Glaxo Smithkline plc).

IAC: Indian Scenario

India has seen a tremendous increase in academic research in the past decade. In fact, India has ranked 3rd in the world in terms of number of publications, as per the NSF database, US[3]. Additionally, our country has also recorded the highest number of PhDs. This data is encouraging as it would mean that India has highly qualified researchers involved in research activities. Despite these facts, the industry academia collaboration in India has not enjoyed the success that has been observed in the western countries. There are two major reasons for this observation,

- Industry focus: Indian pharmaceutical industry has focused predominantly on development of generic products. Very few companies are actually involved in drug discovery process that may need basic research inputs from academia. This is primarily due to the high cost and low success rates involved in introducing new molecule in clinic. Majority of the research work in such companies is confined to developmental activities only. This may limit the involvement of academic institutions as product development is relatively easy and does not require innovative inputs from academia. Development of complex generic products on the other hand is a challenging job that requires expertise as well as elaborate research. Most IACs in India are involved in development of such products. In the recent years, the number of companies engaged in developing complex and biopharmaceutical products is also increasing and so is the scope of IACs.
- State of academic institutions: The academic institutions have severe resource crunch. Except for government funded institutions such as NIPERs (National Institute for Pharmaceutical Education & Research) and few other top ranking institutions, most of private institutions lack the infrastructure necessary for undertaking industrial research. Additionally, the students as well as faculties of many institutions fall short in meeting expectations of industrial collaborators in terms of keeping themselves updated with technological advances. One of the major reason for this observation is the lack of industry academia interaction. It has also been noticed that although India has a high publication rate, the ratio of research to commercial products is very poor. Similar is the situation with the Intellectual Property (IP) coming out of this research, indicating lack of resources and/ or narrow focus of research. There is a need to have a radical change in conventional teaching learning process in order to cultivate research attitude and out of the box thinking abilities in students that is required for innovation.

To improve this situation, the Pharmacy Council of India (PCI) has taken efforts in framing a uniform syllabus for bachelors as well as master's programs which includes research projects at the bachelor's level. The National Education Policy (NEP)-2020 has placed priority on research in higher educational institutions. To boost research environment in higher education, the NEP has devised the following roadmaps to

a. Develop research capabilities among the faculty members and to facilitate the development of research culture in the state universities and other public institutions

b. Seed, grow and fund research at academic institutions with the establishment of National Research Foundation (NRF).

Government initiatives

Considering the global rate of success in IACs the Indian government has taken valuable measures which can help in building a strong partnership between industries and academia. It has implemented various industry academia support programs that have been instrumental in bringing industry and academia together. Some of the key government departments that fund such programs are mentioned in Table 1.

The Government of India has also incentivized the industry for undertaking collaborative research with academia. These incentives include financial assistance under Industry academia joint projects, and tax benefits.

Benefits of IAC

With IAC, companies gain skilled workforce with expertise which can be utilized for accelerating innovations. Additionally, the efforts and finances can

Sr. No.	Funding Agency/Ministry Department	Programs & Schemes
1	Department of Science & Technology (DST)	Indian Innovation Growth Program (IIGP)
2	Department of Scientific & Industrial Research (DSIR)	Patent Acquisition and Collaborative Research & Technology Development (PACE)
3	Science & Engineering Research Board (SERB)	Prime Minister's Fellowship Scheme for Doctoral Research
4	Department of Biotechnology (DBT)	Contract Research Scheme
5	University Grants Commission (UGC)	University-Industry Inter Linkage (UIL)

Table 1: Government agencies and schemes for funding IAC

be minimized by outsourcing the basic research activities which have narrow scope of actual commercial success. On the other hand, such partnering can definitely provide source of funding for academic institutions which can be helpful in building the infrastructure.

Conclusion

Collaboration is the key to have a win-win situation for industry as well as academia. The direct involvement of academia in research and innovation is a highly potent collaborative approach for gaining new ideas, enriching knowledge and broadening the ongoing activities in industry. Consequently, the academia is also benefited in terms of funding that help them to develop their infrastructure. The open innovation model has worked out beautifully in the western countries. We hope that the same may prove useful in India and help the Indian Pharmaceutical Industry in scaling greater heights.

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Simpler Quality Control Processes with Enhanced Oversight

Effective quality control in the chemicals industry must take into account not only the range of substances to be tested, and their properties, but data management as well. METTLER TOLEDO's LabX® laboratory software orchestrates the quality control process—from SOP creation to automatic, complete data capture and storage.

Timely release of product batches is necessary for smooth operations in every industry, yet quality control processes are widely divergent — particularly in chemicals production, where quality control encompasses a broad range of instruments and procedures.

When throughput is high, or materials with challenging properties, that are hazardous, and that are in limiting quantity must be assessed, automation systems are often employed. METTLER TOLEDO's Excellence instrument portfolio and LabX laboratory software support such analyses effortlessly, enhancing productivity and safety while simplifying lab operations.

Efficient and secure workflows

The LabX software permits the creation, and scheduling on all connected devices, of standard operating procedures (SOPs) for balances and analytical instruments. It guides the user through every step of a workflow, with prompts displayed directly on-screen. As the workflow proceeds, LabX records, analyzes, and securely stores all results, standardizing data-archiving and eliminating the risk of mistakes from manual data-transfer or analysis. LabX-defined SOPs can include one or more instruments.

In higher-throughput environments, LabX helps to coordinate automation systems for gravimetric or analytical instruments, increasing efficiency and protecting operators from toxins. And to expedite analyses and minimize data-transcription errors, the barcode–based SmartCode™ tracking system assists in managing a sample's journey from instrument to instrument. Operators can thereby react quickly to changing needs without making otherwise costly or disruptive mistakes.

Operator, sample, and data traceability

With features such as user management and access rights, LabX ensures that resources are utilized appropriately, and users' actions and data are permanently

visible to responsible personnel. For example, only designated users may create SOPs, and each additional user may view only the SOPs relevant to their own workflows.

At the same time, all user activities are logged for full transparency over assays performed and data collected using LabX-connected instruments, supporting compliance with applicable regulations.

Summary

LabX enables the launch of SOPs from an instrument or remotely, from a computer, reducing confusion and the risk of errors, as well as preparation time for individual assays. And by coordinating data collection and storage, LabX supports efficient, compliant data management.

Both raw data and calculations are maintained in a secure archive along with metadata, ensuring full, audit-ready documentation of chemical quality analyses. The single LabX interface also enables easy data integration with an existing LIMS, for more efficient oversight and better process control.

LabX Safeguards Complete Workflows

The LabX laboratory software interfaces with METTLER TOLEDO Excellence series instruments to accelerate and standardize data-capture. LabX workflows integrate data-analysis; the software's secure database enables compliant storage of

complete data (with metadata).

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About METTLER TOLEDO

METTLER TOLEDO is a leading global manufacturer of precision instruments. The Company is the world's largest manufacturer and marketer of weighing instruments for use in laboratory, industrial and food retail applications. The Company also holds the top-three market positions for several related analytical instruments and is a leading provider of automated chemistry systems used in drug and chemical compound discovery and development. In addition, the Company is the world's largest manufacturer and marketer of metal detection systems used in production and packaging. Additional information about METTLER TOLEDO is available at www.mt.com. ■

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