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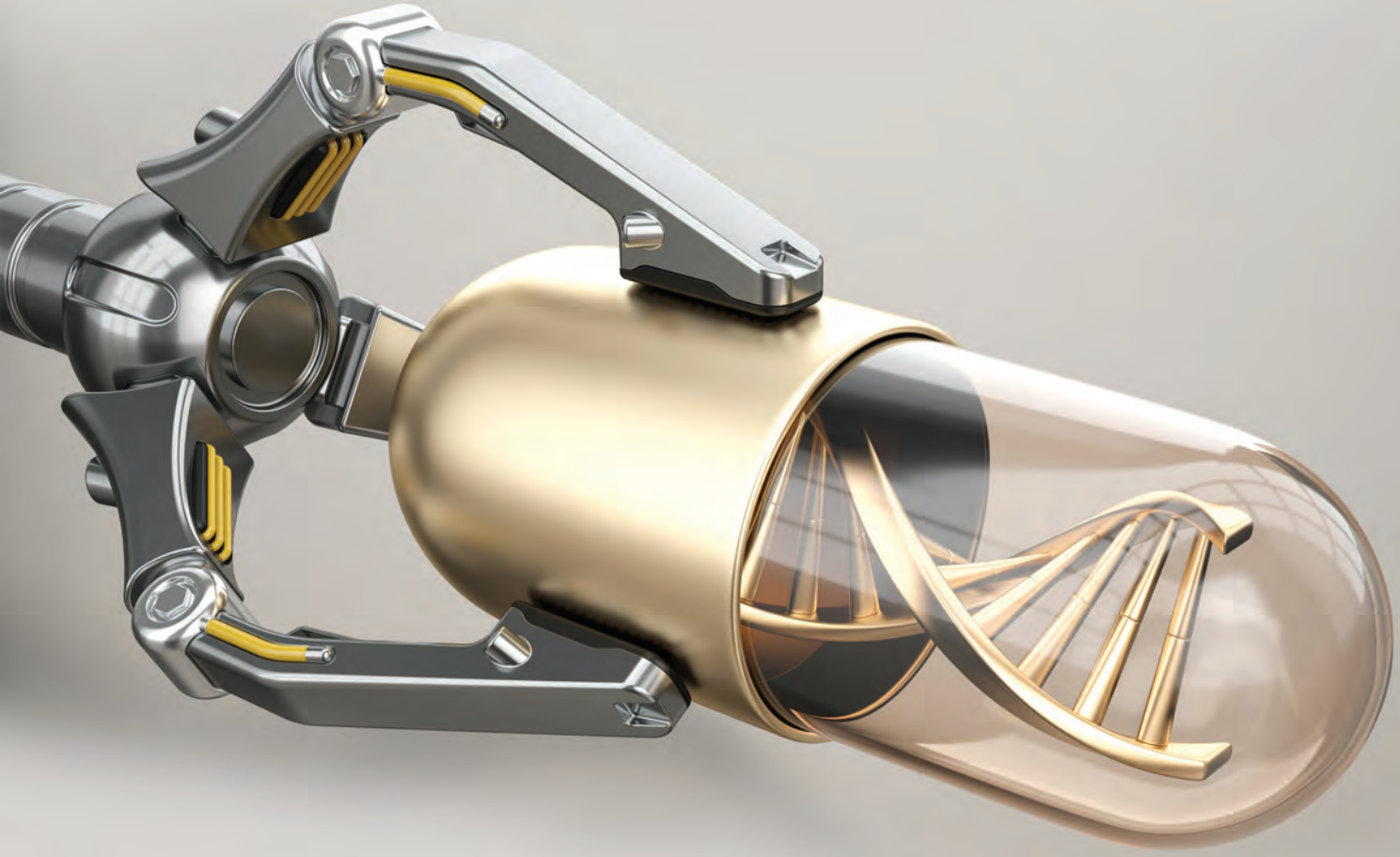
PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES



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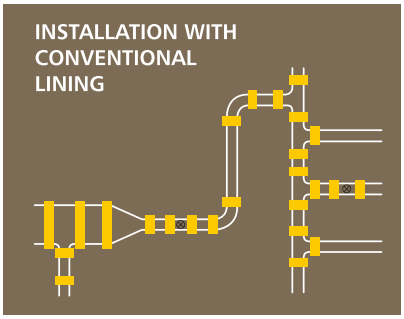

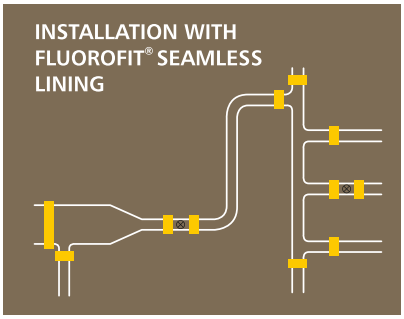

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ENPICOM enters into service agreement with Neogene

ENPICOM B.V., an innovative bioinformatics software engineering company delivering ground-breaking products and customized solutions to decode the immune system and improve human health, today announced the company has entered into a service agreement with Neogene Therapeutics to grant the company access to ENPICOM's cloud-based IGX Platform to manage, organize, and analyze T cell sequencing data. ENPICOM has additionally developed a number of customizations making sure that the platform's functionality fits Neogene's specific data handling workflow to help Neogene's research team leverage the full potential of their immune repertoire data.

"We are extremely proud to add Neogene Therapeutics to our IGX Platform customer base. Their recent $110 million Series A shows how important this new type of immunotherapy has become in the last few years," stated Jos Lunenberg, CEO of ENPICOM. Dedicated to developing personalized neoantigen T cell receptor (TCR) therapies for cancer, Neogene Therapeutics extensively studies immune repertoires of cancer patients by high-throughput T cell sequencing in order to identify T cell receptor genes with therapeutic value. Personalized neo-antigen TCR therapy is a novel approach to cancer treatment, where a patient's T cells are genetically engineered with neoantigen specific TCR genes to enable them to identify and destroy tumor cells.

Since immune repertoire sequencing implies the generation of large amounts of data, there is a need for specific expertise to efficiently manage and fully exploit the potential of the data collected. ENPICOM's IGX Platform provides Neogene with an efficient solution to manage and annotate T cell sequencing data. Dr. Carsten Linnemann, CEO of Neogene Therapeutics, added: "ENPICOM and the Neogene team have been collaborating for several years on various projects. ENPICOM has always been a thoughtful and highly reliable partner. It is a pleasure to utilize their innovative and unique IGX Platform."

The IGX Platform comes with powerful data management features and an intuitive user interface out of the box. Its modular, flexible structure allows for further enhancements and customizations. The custom robust workflow of the IGX Platform uniquely positions it to support high-throughput studies required to power Neogene's research in personalized T cell therapies.

Thermo Fisher Scientific Extends Collaboration to Advance Biopharmaceutical Discovery and Development

Thermo Fisher Scientific and Symphogen, an affiliate of and the antibody center of excellence within the international pharmaceutical company, Servier, announced the extension of a strategic collaboration to deliver industry-proven, innovative characterization and quality control workflows for the simplified analysis of complex therapeutic proteins to

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advance biopharmaceutical discovery and development.

Since the collaboration was established in 2018, Symphogen has been utilizing the analytical capabilities of the Thermo Scientific Q Exactive Plus Orbitrap liquid chromatography-tandem mass spectrometry (LC-MS/MS) system with BioPharma Option, and most recently the Thermo Scientific Orbitrap Exploris 480 mass spectrometer, to develop, test and routinely implement platform workflows for intact and native mass analysis of therapeutic monoclonal antibody (mAb) mixtures. The high-performance, easy-to-use, analytical workflows were developed to enable dynamic biopharmaceutical companies like Symphogen to deliver novel treatment options for patients.

In addition to the Q Exactive Plus Orbitrap and Exploris 480 LC-MS/MS systems, Symphogen also uses the Thermo Scientific Orbitrap Fusion Tribrid mass spectrometer. The company's network of Thermo Fisher mass spectrometry analyzers is completed with Thermo Scientific Vanquish ultra high-performance liquid chromatography (UHPLC) systems and Thermo Scientific Chromeleon Chromatography Data System (CDS) software, which Symphogen has been using for more than a decade.

Medanta launches eClinic and Nursing Station

In continuation of delivering world-class healthcare while ensuring patient safety, Medanta *(https://www.medanta.org/)*

launched flagship eClinic and Nursing Unit at Park View City-1, Gurugram. This facility will cater to the medical needs of residents by connecting them with Medanta's super specialist doctors through remote consultation.

The eClinic was launched by Shri Dheeraj Setia (IPS), DCP, South and East, Traffic, Gurugram along with Dr. Naresh Trehan, Chairman and Managing Director, Medanta – The Medicity, Dr. Shyam Bihari Bansal, Director Nephrology, Kidney and Urology Institute, Medanta – The Medicity along with Capt. Ashutosh Shekhar, General Secretary, Park View City 1 and other the RWA members.

Launching the eClinic, Dr. Naresh Trehan said, "Medanta is strongly committed to providing world-class healthcare to patients. Our flagship eClinic and Nursing Unit initiative is a step towards strengthening this commitment. The Medanta eClinic at Park View City-1 will enable us to cater to the specialised medical needs of the residents in a safe and protected environment."

Cadila Pharma strengthens its HR team by adding Dr Sanjeev Dixit

Cadila Pharmaceuticals have strengthened its Human Resources function with the addition of Dr. Sanjeev Dixit as the Global President – Human Capital Management.

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This is a second strategic hire in the HR function in the last two months. Mr. A. Thiru, a seasoned industry HR professional joined Cadila Pharma as Global President, Human Resources, in September. With addition of Dr Dixit, Cadila aims to strengthen its people processes and practices by keeping employees at the core of its decision-making.

INTAS launches THYMOTAS

Intas announces the launch of Thymotas – a novel, patented research formulation of Thymoquinone that fortifies immunity and ensures higher success in fighting infection. Thymotas has been tested clinically as a significant add-on to the standard COVID-19 treatment.

Thymoquinone (Thymotas) is the active biological component of Nigella sativa. There are various scientific publications available that prove Thymoquinone's multiple pharmacologically beneficial properties. Thymoquinone has been developed as a stable, standardized and ready-to-use tablet by Intas for the first time in the world.

Thymotas fortifies immunity and fights infections through multimodal actions such as Anti-viral, Anti-bacterial, Anti-inflammatory,

Immuno-modulatory and Antioxidant. Thymotas' anti-viral effects have been demonstrated via an in-vitro test against SARS-CoV2 and has tremendous potential as a potent add-on to the standard treatment in COVID-19.

Dr Alok Chaturvedi, Senior Vice-President & Head-Medical Affairs said: "In the current pandemic, Thymotas 12.5 mg is very successful in building immunity and combating infections effectively." Manufactured in a WHO-GMP certified plant, Thymotas as an immunity booster & prophylaxis is recommended one tablet of 12.5 mg daily after meals or as directed by the physician. As an adjunct to infection treatment, Thymotas is recommended up to 50 mg per day after meals based on the severity of infection or as directed by the physician. Thymotas is to be swallowed as a whole and not to be crushed or chewed.

Repositive expands global cancer model network with CRO from Finland

Repositive, the world's largest directory of preclinical cancer models, has expanded its global network of contract research organisation (CRO) partners with the addition

of Pharmatest, a CRO providing clinically predictive preclinical efficacy services for oncology and skeletal diseases. Pharmatest brings to the partnership more than 20 years of experience in disease modelling, enabling Repositive to further grow its global reach to serve more biopharmaceutical companies in their quest for the right preclinical cancer models to accelerate oncology drug development programmes.

"At Repositive, we are committed to establishing new partnerships with specialist CROs to further enhance and strengthen our world-class offering of preclinical cancer models to biopharmaceutical researchers worldwide," said Fiona Nielsen, CEO of Repositive.

At present, the Repositive Cancer Models Platform displays curated and standardised metadata from over 8,000 preclinical cancer models. Biopharmaceutical researchers can browse the available models with the option of filtering content by primary site, model type and subtype, gene mutation, variant, treatment, and treatment response. In vivo oncology researchers and in-house bioinformatics teams can rely on the platform for automated processing, organisation and streamlining of cancer model inventories, while the system's easy-to-access interface allows complex modelling queries to be effortlessly performed.

Lonza Announces Broad Selection of High-Resolution HLA-typed Primary Cell Lots to Support Biologic Drug Research

Lonza has announced that it now provides an expansive selection of high-resolution Human Leukocyte Antigen (HLA)-typed primary cells spanning all major cell and tissue types. The ready-typed lots will eliminate the need for burdensome in-house sequencing processes and provide drug developers with a critical tool for the more effective development of personalized therapies. Nearly 50 different cell types are available from Lonza's broad donor inventory, with detailed HLA data derived from gold-standard next-generation sequencing techniques. The new offering builds on Lonza's renowned human primary cell capabilities to meet rapidly growing market demand for deeper and more comprehensive cell characterization.

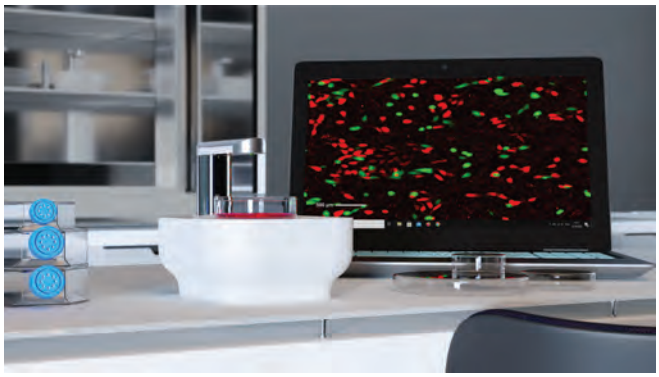
A person's HLA type is a key determinant of the immune system's response to foreign substances. HLA data is critical for preclinical exploration of cross-reactivities and off-target drug effects. HLA information is also needed for the development of engineered biotherapeutic T cell receptors and antibodies, better patient stratification to optimize the clinical effectiveness of cancer therapies, and is fundamental for the development of new cancer vaccines. As such, there is a rapidly growing market need for high-quality HLA-typed primary cells.

However, screening cell lots for HLA type can be lengthy and cumbersome to conduct in-house, and there is no guarantee that unscreened purchased lots will be the desired HLA type. Further, many vendors are only able to offer lots with lower-resolution HLA information obtained from serological typing methods, which can lead to incomplete HLA matching and poorer predictivity of in vitro models as a result. Being able to select lots with the desired high-resolution HLA data thus confidently enables a time- and cost-efficient preclinical development and boosts

chances of drug development success.

Having previously offered HLA-typing services to its customers on a custom basis, Lonza is now providing high-resolution HLA information at no additional cost for a wide selection of its cell lots. With a diverse donor inventory that includes different age groups, genders, and ethnicities, a broad range of donor cell lots with various HLA types are currently available, including HLA-A2*01.

CytoSMART Technologies launches its first fluorescence live-cell imager Lux3 FL



CytoSMART Technologies announced its first fluorescence live-cell imager. The CytoSMART Lux3 FL is a small live-cell imaging microscope equipped with one brightfield and two fluorescent channels (green and red). The device enables researchers to unravel cellular processes in real-time, while the cells are kept in a controlled environment inside a standard cell culture incubator. CytoSMART's first fluorescence live-cell imager allows users to track dynamic cellular processes with high specificity by taking high-quality images to create real-time time-lapse movies.

Said Jan-Willem van Bree, CTO at CytoSMART Technologies, "Currently, fluorescent labelling is mostly used as an end-point measurement. However, time-lapse imaging of live cells can give much more information about biological processes. By using automated imaging at regular time intervals, the temporal resolution of the fluorescent data is increased, leading to even more relevant data about the cellular processes. In this way, researchers can not only determine if a certain process has occurred, but also when it occurred and at what speed. Our customers have been asking us to develop a small and easy-to-use microscope with integrated image analysis of bright-field and fluorescence data. We have listened and made it happen."

The main features and benefits of the CytoSMART Lux3 FL include:

- Integrated image analysis of bright-field and fluorescence area or fluorescence object count.
- Time lapse movies to investigate the development of cellular processes.
- Expanded number of variables researchers can analyze in their cell culture using green and red fluorescence.
- Remote data accessibility via the CytoSMART Cloud with a smartphone, tablet, or laptop outside the lab.

Portable, easy-to-use and incubator friendly live-cell imager

Applied Materials Acquires Perceptive Engineering

Applied Materials has acquired Perceptive Engineering Ltd., headquartered in Manchester, UK, a leader in advanced process control and model predictive control in the pharmaceutical industry. Perceptive' s PharmaMV® advanced process control (APC) platform complements Applied Materials' SmartFactory Rx® portfolio by bringing the

value of multi-variate data analysis, model predictive control, and machine learning algorithms to the pharmaceutical industry.

Amos Dor, Managing Director of Applied Materials Pharma noted, "Adding the domain expertise and power of PharmaMV to the SmartFactory Rx Industry 4.0 platform and team, enables the customers we serve to bring powerful new therapies to market with assured quality, higher yields, reduced costs and all with optimized productivity."

SCHOTT Glass India inaugurates new glass melting tank

SCHOTT AG has been a frontrunner in the global fight against Coronavirus, with commitment to provide its specialised pharma glass used for storing billions of COVID-19 vaccines. The melting furnace has been constructed within a span of one year, to enable a 25% increase in the facility's overall production capacity, to support the pharma industry that is facing a huge demand surge for pharma packaging products.

SCHOTT Glass India's MD, Pawan Shukla shared, "India has stepped up as a responsible leader in the global fight against Coronavirus. SCHOTT remains committed to ensure that there is adequate supply of its high-quality pharma glass for the Indian pharma industry. Moreover, as SCHOTT's manufacturing hub

in Asia, we have taken up the responsibility to cater to our clients in India as well as in neighbouring countries."

The melting tank is a part of the company's commitment to invest over EUR 47 million in its Indian facility, and to double its capacity of producing the highly specialised FIOLAX® tubing material for both domestic and export demands. Despite the pandemic induced lockdown, SCHOTT employees and engineers continued working at the Jambusar facility to enable the construction of the new tank in the defined timeframe.

The expansion has resulted in additional employment of over 120 skilled workforce, taking the overall count to 420 employees. SCHOTT's specialised glass tubing, Fiolax® is the gold standard for pharmaceutical packaging for over a century. The material is best suited for potential COVID-19 vaccines and existing medications, as it avoids the interactions between containers and the drug formulation that can limit its effectiveness.

A-LabInsider launched an app to boost biotech businesses

A-LabInsider has created an application that lists all academic life science labs in Europe with an intelligence to filter through them to make it easier for small and medium biotech companies to discover labs and do business

with them. The concept was to create a central place for biotech SMEs to find academic labs through the content of available websites and scientific literature the labs have produced, as well as to keep an eye on the new labs, gain lead generation and market intelligence to get an overview and benchmark performance of each lab to figure out which lab is the best fit.

A-LabInsider equips companies with the latest data, guides what to do with it, and how to apply it to achieve best possible results. By doing those things, the app is the "market watch" on academic life science labs and will always be updated with a new information arising daily.

With the abundance of academic labs being twice as much as biotech SMEs, it has been very time-consuming and tedious to search manually for the information on the websites and in scientific literature. Through the app, SMEs can make their decision about the right labs through the literature the labs have produced, and gain an overview and benchmarking of their performance in any topic. With the ever-growing need for convenient and easily accessible information, A-LabInsider takes away the discovery problem from biotech SMEs and even more makes it easier to follow up with those that are relevant.

The app will positively affect how both sides connect and boost businesses of each other. It also provides SMEs with the low-cost functions that are normally provided to enterprises, but at a more reasonable and affordable price.

The situation with academic life science labs is paradoxical, by number they are twice as many as biotech companies, while by revenue generated from them to biotech companies represent only a quarter. Their budget is often similar to small biotech companies, however difficulty to be discovered represent the main reason for this phenomena. A-LabInsider solves this problem by pouring more innovation developed in biotech companies to academic labs, thus making good for small businesses and publicly funded research groups so they can benefit from latest innovations. It affects the quality of life inside the labs, and happiness of those people who work there, because now they can try latest know-hows developed by someone else to solve their scientific question. For companies, this proves to be an efficient approach for market development, where they can get more results and allocate the rest of resources to some other business parts.

HealthCare Global Enterprises Ltd. reports Q2 FY21 results

HealthCare Global Enterprises Limited ("HCG"), the leader in India in specialty healthcare services focused on oncology, fertility and precision diagnostics announced its financial results for the quarter ("Q2") and six months ("H1") ended September 30 for fiscal year ("FY21").

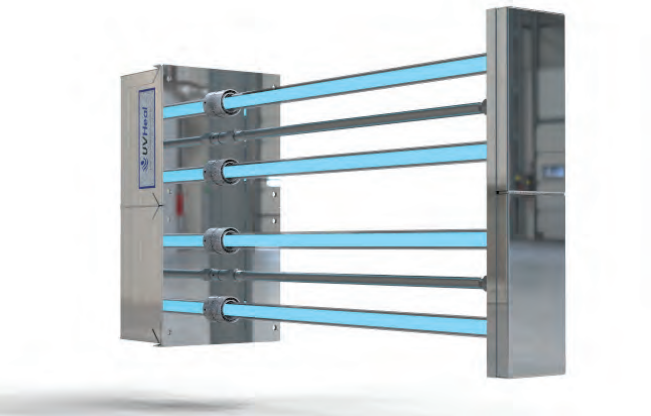
Effective 1 April 2019, the Company has adopted IND AS 116 'Leases' standards, applied to lease contracts existing on 1 April 2019 and all financials are as per IND AS 116.

Highlights for quarter ended September 30th, 2020

- Consolidated Income from Operations ("Revenue") was INR 2,479 mn as compared to INR 2,785 mn in the corresponding quarter of the previous year, reflecting a year-on-year decline of 11% and a quarter-on-quarter growth of 28%
- Consolidated Profit Before Depreciation and Amortization, Finance Costs, Exceptional Items and Taxes ("EBITDA") was INR 340 mn, as compared to INR 471 mn in the corresponding quarter of the previous year, a decline of 28% year-on-year and a growth of 54% quarter-on-quarter
- Consolidated Profit Before Other Income, Depreciation and Amortization, Finance Costs, Exceptional Items and Taxes ("Operating EBITDA"), was INR 300 mn, as compared to INR 456 mn in the corresponding quarter of the previous year, a decline of 34% year-on-year and a growth of 55% quarter-on-quarter
- Operating EBITDA for existing centers was INR 329 mn, a growth of 29% quarter-on-quarter, reflecting an Operating EBITDA margin of 17%
- Loss from new centers was INR 29 mn, as compared to loss of INR 48 mn in the corresponding quarter of the previous year, a reduction of 40% year-on-year and 52% quarter-on-quarter
- Consolidated Profit after Taxes and Minority Interest ("PAT")(4) was a loss of INR 223 mn, as compared to loss of INR 223 mn in the corresponding quarter of the previous year

Commenting on the results, Dr. B.S. Ajaikumar, Chairman and CEO, HealthCare Global Enterprises Ltd. said, "We report Q2 FY21 results with continued resilience amidst an environment struck with economic and social uncertainty brought about by the COVID pandemic. The depth of our operating systems and internal efficiencies have allowed us to uphold our mission of maintaining continuity and quality of care for oncology patients across the country, while minimising revenue and cost disruptions to the extent possible. This is a testament of sustainability of our business model fundamentals, which includes focused delivery of comprehensive cancer care, creating last-mile access on a pan-India basis, while being at the forefront of clinical, technological and digital innovations in the industry. With substantial deleveraging of our balance sheet, reduction in losses across new centers, on y-o-y & q-o-q basis, and focus on free cash flow generation, we are excited to move closer to our inflexion point that augurs profitability and return accretive phase for the company."

Tech start-up Airific Systems introduces UV Heal SafeAir



As the world is going through the worst ever public health crisis, multiple challenges are cropping up with infections taking place from

viruses. Many of these viral infections are proven to be airborne. Experts, scientists and ASHRAE claim that viruses like COVID-19 can easily spread through indoor air circulation systems, which means that a single infected person can trigger the infection to countless others. To overcome this biggest challenge of the pandemic, Airific Systems Pvt. Ltd., a Delhi-based tech start-up, has introduced 'UVHeal SafeAir' – an ultra-modern 'UV-Based HVAC Air Disinfectant' for central air conditioning systems to break the spread of airborne diseases.

UVHeal SafeAir uses the proven UVGI (ultraviolet germicidal irradiation) technology to disinfect the circulated air by destroying the DNA or RNA of the dangerous viruses & bacteria present and hence stopping these airborne pathogens from replicating– right at the point from where the air is supplied to any premises. The product is suitable to be used in all the public places equipped with central air conditioning systems like airports, hospitals, theatres, hotels, offices, schools & colleges, restaurants, and even industrial areas.

The International Ultraviolet Association (IUVA) & ASHRAE has also suggested that UVC disinfection technology can efficiently combat the viruses responsible for causing epidemics like COVID-19, SARS COV-1, SARS COV-2, MERS-COV, etc.

Pioneering research detects Hormone-Upregulated lncRNA

Pioneering research conducted by University of Virginia in collaboration with Manchester UK-based APIS Assay Technologies Ltd has discovered Hormone-Upregulated lncRNA within the lymphocyte-specific protein tyrosine kinase (HULLK) is detectable in non-invasive prostate cancer patient samples.

The breakthrough data provides a potential new approach to address the unmet medical need of early diagnostics for prostate cancer, in combination with avoiding the invasive cancer tissue sample collection from biopsy.

Dr. Daniel Gioeli, Associate Professor, Microbiology, Immunology, and Cancer Biology at the University of Virginia, has shown that HULLK could be isolated from urine of prostate cancer patients and therefore provides a major advantage compared to current invasive sample collection. APIS Assay Technologies and the University of Virginia entered into a Research Agreement in December 2019, after optioning the HULLK technology, which is described in a previous publication from Dr. Gioeli´s Group (Ta et al, Molecular Cancer, 18:113, 2019) demonstrating the potential role of this biomarker in FFPE samples from PCa patients.

HULLK an unannotated lncRNA is within exon six and the 3'UTR of the LCK gene, is dramatically upregulated by androgen in a dose-dependent manner, and this hormone-induced increase is completely blocked by the anti-androgen enzalutamide. Remarkably, there was a significant positive correlation between HULLK expression and high-grade PCa in three independent cohorts: the University of Virginia, the University of Texas Southwestern, and The Cancer Genome Atlas.

The overall goal of the collaboration between UVA and APIS is to address the unmet medical need associated with PCa and evaluate the level of HULLK in PCa patients in order to establish the parameters necessary for a clinical trial demonstrating the effectiveness of HULLK as a relevant Biomarker.

Isohelix and Precision Genetics Partner to Expand COVID-19 Testing

Isohelix, a specialist provider of DNA and RNA sampling and purification products, announced that its state-of-the-art GeneFiX™ Saliva RNA Collection Device is the technology of choice for COVID-19 testing by Precision Genetics, a leading healthcare technology company and high capacity molecular testing laboratory. The high-performance, easy-to-use device marks the latest addition to Precision Genetics' extensive portfolio of validated COVID-19 testing options submitted under the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

"We are proud that our GeneFix Saliva RNA Collection Device is being used as a valuable, dependable method at the Precision Genetics testing laboratory, where a wide variety of SARS-CoV-2 assays are being implemented to contribute to the global fight against COVID-19," said Tom Hole, CEO of Isohelix. "Precision Genetics reviewed various saliva collection kits and chose the GeneFix Saliva RNA Collection Device for its superior simplicity and reliable performance."

The addition of saliva collection to Precision Genetics' testing capabilities comes at a time when alternative collection methods for COVID-19 testing are increasingly important. Saliva collection allows a person to expel their saliva into a tube, making it far less invasive than the nasopharyngeal (NP) collection method. In addition, saliva collection offers ease and convenience for more populations and demographics.

Syntegon opens new OSD Customer Center

After a one-year construction phase, Syntegon Technology inaugurated its new OSD Customer Center in Waiblingen, Germany, on November 16, 2020. The 600 square meter building includes everything customers from Syntegon need for the formulation,

development and production of their oral solid dosage (OSD) forms – from cleanrooms and assembly areas to offices, meeting and

training rooms. "With this infrastructure and our team of experts, we offer our customers exactly the innovative power they expect from a reliable and future-oriented partner," says Dr. Thomas Brinz, head of the new OSD Customer Center.

In the new OSD Customer Center, Syntegon's clients will meet with experts who take care of problem solving, as well as optimizing and developing their processes and providing seminars and training. Syntegon has increased the cleanroom capacity at its site in Waiblingen sixfold. From laboratory equipment to production scale machines, TPR tablet presses for mono and bilayer tablets as well as GKF capsule filling machines are available for all formats and products in different cleanroom classes – up to the highest containment level OEB5.

The 600 square meter building includes everything customers from Syntegon need for the formulation, development and production of their oral solid dosage forms – from cleanrooms and assembly areas to offices, meeting and training rooms.

Apart from the GKF 720 HiProTect, the OSD Customer Center in Waiblingen offers many further machines to customers for all formats and products in different cleanroom classes – up to OEB5.

US-FDA Approved Foundation Medicine's FoundationOne®Liquid CDx now Available in India

Roche Products (India) Pvt. Ltd. (Roche Pharma India) announces the launch of FoundationOne®Liquid CDx, Foundation Medicine's comprehensive pan-tumor liquid biopsy test for patients with solid tumors in India. US FDA approved the FoundationOne®Liquid CDx, a comprehensive genomic profiling (CGP) test on August 26. This is the first test that can analyze more than 300 genes and multiple genomic signatures to optimize patient care.

"Roche has always been committed to provide best-in-class solutions to serve the needs of cancer patients globally as well as in India. We believe that cancer patients in our country and their physicians deserve the highest quality genomic testing to guide personalized treatment decisions. We are delighted to make this test now available for Indian patients, post US-FDA approval." said Mr. V. Simpson Emmanuel, Managing Director, Roche Pharma India.

Cancer is a disease of the genome. Most tumors harbor a constellation of genomic alterations that may dictate their clinical behavior and treatment response. Blood-based biomarker testing options like FoundationOne®Liquid CDx can help expand access to genomic insights in patients with advanced cancer as compared to a tissue biopsy, which may not be an option for many patients due to reasons such as tumor location and patient's health status. FoundationOne®Liquid CDx is a single non-invasive test based on Next Generation Sequencing technology that gives access to genomic information of over 300 genes. Additionally, the report also provides information about the biomarker signatures microsatellite instability (MSI), and blood tumor mutational burden (bTMB) to support informed decision making for targeted and immunotherapies. ■

Artificial Intelligence & Pharma: What's Next?

Codrin Arsene
CEO, Digital Authority Partners

Artificial intelligence in Pharma refers to the use of automated algorithms to perform tasks which traditionally rely on human intelligence. Over the last five years, the use of artificial intelligence in the pharma and biotech industry has redefined how scientists develop new drugs, tackle disease, and more.

Given the growing importance of Artificial Intelligence for the pharma industry, we wanted to create a comprehensive report which helps every business leader understand the biggest breakthroughs in the biotech space which are assisted by the deployment of artificial intelligence technologies.

Last year, Verdict AI asked businesses how vital artificial intelligence will be in their respective industries and over 70% of them thought it would be very important. From the same group, only 11% of businesses have not considered investing in AI technology.

Furthermore, according to Narrative Science, 61% of companies investing in innovative strategies are using AI to identify opportunities that they would have otherwise missed. For pharmaceutical businesses that thrive on innovation, this is an important statistic to understand.

This article aims to help business executives learn what to expect from artificial intelligence in pharma. It will cover:

- The role of AI in developing new drugs
- How AI can tackle diseases previously deemed too difficult to take on
- AI and drug adherence
- The use of AI to make sense of clinical data
- How AI can help find the correct patients for clinical trials

Artificial intelligence and pharma can help save more lives than ever before.

Developing new drugs

A study published by the Massachusetts Institute of Technology (MIT) has found that only 13.8% of drugs successfully pass clinical trials. Furthermore, a company can expect to pay between $161 million to $2 billion for any drug to complete the entire clinical trials process and get FDA approval. With this in mind, pharma businesses are using AI to increase the success rates of new drugs while decreasing operational costs at the same time.

Novartis uses AI to predict untested components researchers should explore to

Novartis is embracing advancements in AI technology to create new and improved treatments and find ways to get people access to treatment quickly. Novartis is currently using machine learning to classify digital images of cells, each treated with different experimental compounds. The machine learning algorithms collect and group compounds that have similar effects together, before passing on the clean data to researchers who can decide how to leverage these insights in their work. Drug discovery often takes a long time to test compounds against samples of diseased cells. Finding compounds that are biologically active and are worth investigating further requires even more analysis.

To speed up this screening process, Novartis research teams use images from machine learning algorithms to predict which untested compounds might be worth exploring in more details.

As computers are far quicker compared to traditional human analysis and laboratory experiments in uncovering new data sets,

new and effective drugs can be made available sooner, while also reducing the operational costs associated with the manual investigation of each compound.

But there's another reason why Novartis is at the top of our list. CEO, Vas Narasimhan is one of the forward-looking digital leaders in healthcare who is constantly advocating for the role AI, predictive analytics and big data can play in Pharma. David Shaywitz, in an excellent Forbes article summarizes all the challenges Novartis is facing in adopting AI - but also how the company is still pursuing AI with some notable results in clinical trials and finance.

Verge Genomics uses AI to predict the effect of new treatments for patients suffering from ALS & Alzheimer's

Verge Genomics develops drugs by automating their discovery process. They use automated data gathering and analysis to create solutions to some of the most complex diseases known today, including ALS and Alzheimer's. Cost aside, one of the reasons why drug discoveries fail is because they only target one disease gene at a time. Using the same technologies that power Google's search engines, Verge has discovered ways to map out the hundreds of genes responsible for causing disease and then finding drugs that target them all at once. Their platform is specifically designed for neurological diseases and can predict the effect of new treatments, while also reducing the cost of drug development.

Bayer and Merck & Co uses AI algorithms to identify pulmonary hypertension

Bayer and Merck & Co were granted the Breakthrough Device Designation from the FDA for artificial intelligence software that aims to support clinical decision making of chronic thromboembolic pulmonary hypertension (CTEPH). This form of pulmonary hypertension affects around five people per million, per year around the world. Its symptoms are similar to conditions like asthma and COPD, meaning it can be tricky to accurately diagnose.

The aim of the software is to help radiologists detect certain patterns faster, who are often on the frontline for identifying CTEPH patients. The AI would

analyze image findings from cardiac, lung perfusion, and pulmonary vessels in combination with a patient's clinical history and then pass the insights to the radiologists leveraging this technology. Both Bayer and Merck note that the development of their CTEPH Pattern Recognition Artificial Intelligence Software remains complex due to the nature of the disease they are attempting to better diagnose. However, should it prove successful, the tool will eventually be able to assist in diagnosing patients earlier and more reliably, leading to earlier treatment and better patient outcomes.

Cyclica & Bayer use AI to determine determine polypharmacological profiles faster & developer more affordable drugs

Cyclica is a biotechnology company that combines biophysics and AI to discover drugs faster, safer, and cheaper. They have partnered with Bayer to create an AI-augmented integrated network of cloud-based technologies, known as the Ligand Express.

The Ligand Express screens small-molecule drugs against repositories of structurally-characterized proteins to determine polypharmacological profiles.

From here, the company identifies significant protein targets and then they use artificial intelligence to determine the drug's effect on these targets. Finally, the AI produces a visual output of how the drug and proteins interact.

By understanding how small-molecule drugs interact with all proteins in the body, Ligand Express can produce the best solution, understand potential side effects, and determine new uses for existing drugs.

The use of artificial intelligence in pharma to tackle diseases previously deemed too difficult

AI in pharmacology can also be used to find cures for known diseases such as Parkinson's and Alzheimer's, as well as rare diseases. This is great news considering the fact that 95% of rare diseases do not have a single FDA approved treatment, according to Global Genes.

Traditionally, pharmaceutical companies don't focus their efforts on treatments for rare diseases because the return on investment doesn't warrant the time and cost it takes to produce the drugs.

However, with advancements in AI technology, there has been a renewed interest in rare disease treatments.

Tencent Holdings leverages AI to remotely monitor patients with Parkinson's

Tencent Holdings has partnered with UK-based Medopad to build artificial intelligence algorithms capable of remotely monitoring patients with Parkinson's disease and reducing how long it takes to conduct a motor function assessment from over 30 minutes to less than three minutes.

The AI will leverage smartphone apps that monitor how a patient opens and closes their hands. The smartphone's camera captures a patient's movement to determine the severity of their symptoms. The frequency and amplitude score the patient receives can determine the severity of their Parkinson's.

This will allow doctors to remotely monitor patients and set new drug doses. If a patient's treatment program needs changing, the AI will raise an alert to notify their doctor and arrange a checkup if required. The technology will also reduce the patient's costs of traveling back and forth to the clinic.

Mission Therapeutics uses AI to develop treatments for Alzheimer's

Mission Therapeutics, a drug creation company known for its chemistry and proprietary enzyme platform, and AbbVie, a pharmaceutical business known for its strong neurodegenerative disease research, have partnered to develop Deubiquitinase (DUB) inhibitors in the fight against Parkinson's and Alzheimer's.

Both Alzheimer's and Parkinson's patients have an abnormal accumulation of misfolded, toxic proteins, resulting in impaired brain functionality and the death of nerve cells. This is where DUBs comes in. They regulate the degradation of these proteins to maintain their health and stability.

By modulating specific DUBs within the brain, Mission Therapeutics is aiming to find potential treatments which will enable the degradation of these toxic proteins and prevent their accumulation.

Healx uses AI to help biotech companies find treatments for rare diseases

Healx is a promising startup focused on

accelerating treatments for rare diseases and artificial intelligence is at the center of their operations. Their AI platform HealNet enables scientists to increase production in disease drug discovery while simultaneously reducing time, cost and risk.

The company isn't directly focused on creating new drugs to cure these conditions. Instead, they use AI technology to examine existing drugs and repurpose them for curing rare diseases.

HealNet uses machine learning techniques to access data from a range of sources, including scientific literature, patents, clinical trials, disease symptoms, drug targets, multiomics data and chemical structures.

Drug adherence and dosage

Drug adherence is huge for pharma. In simple terms, to prove the success rate of a drug, a pharma company uses voluntary participants in clinical studies. If these patients don't follow the trial rules, they are either removed from the trial or they poison the drug results. As a result, having amazing drug adherence is crucial to any pharma company out there.

Another critical component for a successful drug trial is that participants take the necessary dosage of a particular drug at all times. For example, it's been reported that machine learning algorithms can cut incorrect drug dosage intake by as much as 50% for glioblastoma patients.

AiCure And AbbVie use image recognition to improve drug adherence

Traditional methods to measure drug adherence require patients to submit the data themselves without any evidence of them taking a pill or other type of treatment. They are also subject to tampering, such as deceptively removing pills to feign higher adherence.

AiCure, a New York-based mobile SaaS platform, has developed an image recognition algorithm that removes these issues. Using a mobile phone, AiCure tracks drug adherence by videoing the patient swallowing a pill. The facial recognition system then confirms that the right person took the right pill.

In 2016, they published findings from their study that confirms that the use of their AI platform significantly increases adherence in patients with schizophrenia, as measured by drug concentration levels. The results showed that cumulative

adherence was at 89.7% for those using the AiCure platform compared to 71.9% for subjects using modified Directly Observed Therapy (mDOT).

Even with the obvious advantage that this brings, AI will also decrease costs and accelerate drug development for clinical research and practices.

CURATE.AI built an AI platform to halt disease progression by optimizing drug dosage at an individual level

A research team led by the National University of Singapore (NUS) has used an AI platform called CURATE.AI to successfully treat a patient with advanced cancer and completely halting disease progression.

In this clinical study, a patient with metastatic castration-resistant prostate cancer (MCRPC) was given a novel drug combination consisting of an investigational drug, namely ZEN-3694, and an already-approved prostate cancer drug, enzalutamide.

CURATE.AI was used by the research team to continuously identify the optimal doses of each drug to result in a durable response, giving each individual patient the ability to live a free and healthy life.

Dynamic dosing in cancer therapy is not a commonly used technique; it's typically only used in oncology to reduce cancer's toxicity. The CURATE.AI technology can uniquely modify drug dosing to the required levels, increasing the efficiency and safety of the treatment.

AstraZeneca and Alibaba build AI to help patients with automated cancer diagnostics

The British drugmaker AstraZeneca has teamed up with Ali Health, a subsidiary of Alibaba, with the aim to grow the drug market in China and to help patients find and keep using the correct medicine with the help of smart health services and AI.

Because of China's aging population, the number of patients suffering from cancer and diabetes is increasing. This has led AstraZeneca to develop AI technology to improve ambulance pickups and smart cancer diagnostics.

Overall, this will allow patients to be diagnosed in ambulances quicker and more efficiently so they can be sent to the correct health institutions, where they can receive the right care.

The company is hoping that as new innovations develop, patients will be able to access AstraZeneca drugs far quicker and at a fraction of their current cost.

Using AI to make sense of clinical data and to produce better analytics

Clinical studies are still reliant on paper diaries instead of using modern, electronic systems. Patients are required to note the time they took a drug, record any other medication they took and describe any adverse reactions they experienced.

When it comes to the trial sites themselves, many biotech companies are still using fax machines to request and receive patient records from hospitals and have to manually extract relevant information from them.

A Cognizant study showed that around 80% of clinical trials fail to meet enrollment timelines, and one-third of all Phase III clinical study terminations are due to enrollment difficulties.

Extracting and making sense of clinical data from medical records is highly sought-after in the medical and pharma industries and AI can be the answer to it.

IBM Watson helps match patients with the right drug trials

IBM Watson enables clinicians to find a list of clinical trials for an eligible patient quicker and easier than through conventional methods. It also helps clinical

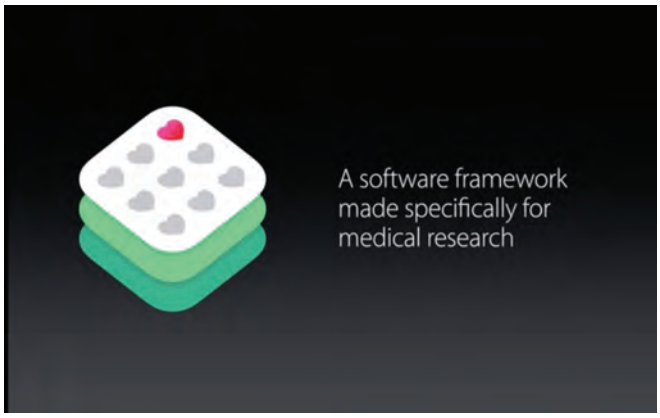
trial coordinators find patients that are potentially eligible for available trials.

Watson analyzes all of the structured and unstructured information from patients' medical records in real time, so the clinicians can see a summary of the characteristics that are most influential for narrowing down clinical trial options for a given diagnosis.

Watson has a deep natural language processing and reasoning algorithm which enables clinicians to look closer at symptoms and health status. Combined with doctors' notes, Watson can analyze a patient's health attributes against the clinical trial requirements uploaded in its database.

Watson will match the patient's records against suitable clinical trials as well as excluding any that are deemed irrelevant or unsuitable.

Apple uses AI to screen children



Technology giant Apple uses data collected from its iPhone and Apple Watch products to improve healthcare. Data is at the core of all AI applications and through their products, Apple can provide medical researchers with two streams of patient health data that were previously hard to access.

They have introduced an open source framework called ResearchKit that allows researchers and developers to create apps dedicated to medical research. It works in tandem with HealthKit, meaning researchers can access information such as heart rate and daily step count. For example, researchers at Duke University have developed an app that uses the iPhone's front camera and facial recognition algorithms to screen children for autism. Apple is also working with popular EHR companies, such as Cerner and Epic, trying to solve problems of interoperability. Data generated by patients directly through iPhones and iPads may result in the elimination of control groups for clinical trials and ultimately reduce recruitment bottlenecks.

GNS Healthcare and Genentech use AI to develop new cancer therapies

GNS HEALTHCARE

GNS Healthcare has collaborated with Genentech to leverage causal machine learning and simulations to help develop novel cancer therapies.

GNS's Reverse Engineering and Forward Simulation (REFS) technology can turn large and diverse patient data streams into mechanistic computer models. These models reveal new pathways, novel targets and diagnostic markers that may lead to the discovery of personalised cancer treatments.

The AI boasts a unique hypothesis-free approach that can reverse-engineer clinical models that cause cancer cells to evolve and insights that can help researchers develop responses to different drugs.

Combining AI technologies with Genentech's huge volume of patient data, the two companies hope to create a powerful tool to find and validate potential new drug candidates and develop patient response markers.

Artificial intelligence helps pharma companies find patients for clinical trials

While AI can be used to make sense of clinical trials data, another use of artificial intelligence in the pharmaceutical industry is to find the patients to take them.

Antidote uses Natural Language Processing to screen patients for drug trial enrollment

Antidote uses natural language processing to simplify the complexity of the inclusion/exclusion criteria in clinical trials. Patients just need to answer a few simple questions on its search platform and they will receive a list of suggested studies they may be eligible for.

Usually, when drugmakers submit details of their new trial, most of it gets entered as structured data in formats such as drop-down menus. This data is easy to record and analyze by computers.

However, patients' eligibility criteria get entered into free text fields where they can write anything they like. Traditionally, interpreting this data was near impossible for a computer to 'understand'. This is what Antidote does. It's AI can read this unstructured data so the computer can assign appropriate clinical trials.

Deep 6 uses AI to proactively find drug trial candidates

A staggering 86% of clinical trials fail to recruit sufficient patients. This leads to slower research and delays patients' access to life-saving drugs. Deep 6 use AI to analyze structured and unstructured clinical data, including doctors' notes and other free-text documents. Clinical data is separated into key elements while also protecting sensitive health information.

The AI then extracts thousands of these clinical data points to create a multi-dimensional profile. Doctors and researchers can then use these profiles to find suitable candidates for a clinical trial. As this is being done by a machine, the process is completely far quicker and with better precision. Deep 6 is only a startup business but with more investment, the technology is there to make a difference for medical professionals attempting to find patients for clinical trials.

The importance of what Deep 6 does cannot be understated. Today, the majority of drug trials are filled with referral patients. In simple terms, doctors refer patients to a trial. What Deep 6 is trying to do is simple and brilliant. They're trying to mine patient data to proactively identify perfect candidates for a specific drug trial. If successful at scale, this could redefine biotech trials as a whole.

Santen and twoXAR are using AI to develop drugs for glaucoma

Santen, a speciality ophthalmology company headquartered in Osaka, Japan, and twoXAR, an artificial intelligence-driven biopharmaceutical company have entered a partnership to focus on identifying new drug candidates for glaucoma.

twoXAR will use its proprietary computational drug discovery platform to discover, screen, and prioritise novel drug candidates with potential application in ocular indications.

Through the use of AI, big data and cloud computing, twoXAR has been able to build a drug discovery platform that is faster, cheaper, and more accurate than traditional methods.

These efforts will see the discovery of new therapeutic candidates to treat this particular disease, leading to the discovery of more effective treatments for those suffering from glaucoma.

Lessons & challenges to the adoption of artificial intelligence in the pharma industry

Even with all the benefits that AI has already brought to the pharmaceutical industry, a report by the HIMSS Analytics 2017 Essentials Brief shows that less than 5% of healthcare organizations are currently using or investing in AI technologies.

Most pharma companies' current IT infrastructure is based on legacy systems that were not designed with AI in mind. They lack sufficient data storing and often lack interoperability. The majority of data within medical systems is in free form so until systems like Deep 6 and Antidote are available, the information cannot be processed and used efficiently by health professionals.

Finally, machine learning and smart automations are still seen as a relatively new technology, even though both been available for a while.

However, with more information provided to the decision makers (such as through this article!), those in a position to influence organizational decisions around AI will hopefully get the ammunition they need to lead their orgs into the future.

AI is the future of pharma but the technology is available now. AI can cut costs down, create new, effective treatments and above all else, help save lives. So biotech companies should start leveraging AI today! ■

Codrin Arsene is CEO of Digital Authority Partners. He has spent over a decade creating successful digital strategies for both Fortune 500 companies and startups.Visit www.digitalauthority.me to know more

Drug Discovery in the Age of COVID-19

Isha Salian
NVIDIA

Drug discovery is like searching for the right jigsaw tile — in a puzzle box with 1060 molecular-size pieces. AI and HPC tools help researchers more quickly narrow down the options, like picking out a subset of correctly shaped and colored puzzle pieces to experiment with.

An effective small-molecule drug will bind to a target enzyme, receptor or other critical protein along the disease pathway. Like the perfect puzzle piece, a successful drug will be the ideal fit, possessing the right shape, flexibility and interaction energy to attach to its target.

But it's not enough just to interact strongly with the target. An effective therapeutic must modify the function of the protein in just the right way, and also possess favorable absorption, distribution, metabolism, excretion and toxicity properties — creating a complex optimization problem for scientists.

Researchers worldwide are racing to find effective vaccine and drug candidates to inhibit infection with and replication of SARS-CoV-2, the virus that causes COVID-19. Using NVIDIA GPUs, they're accelerating this lengthy discovery process — whether for structure-based drug design, molecular docking,

generative AI models, virtual screening or high-throughput screening.

Identifying Protein Targets with Genomics

To develop an effective drug, researchers have to know where to start. A disease pathway — a chain of signals between molecules that trigger different cell functions — may involve thousands of interacting proteins. Genomic analyses can provide invaluable insights for researchers, helping them identify promising proteins to target with a specific drug.

With the NVIDIA Clara Parabricks genome analysis toolkit, researchers can sequence and analyze genomes up to 50x faster. Given the unprecedented spread of the COVID pandemic, getting results in hours versus days can have an extraordinary impact on understanding the virus and developing treatments.

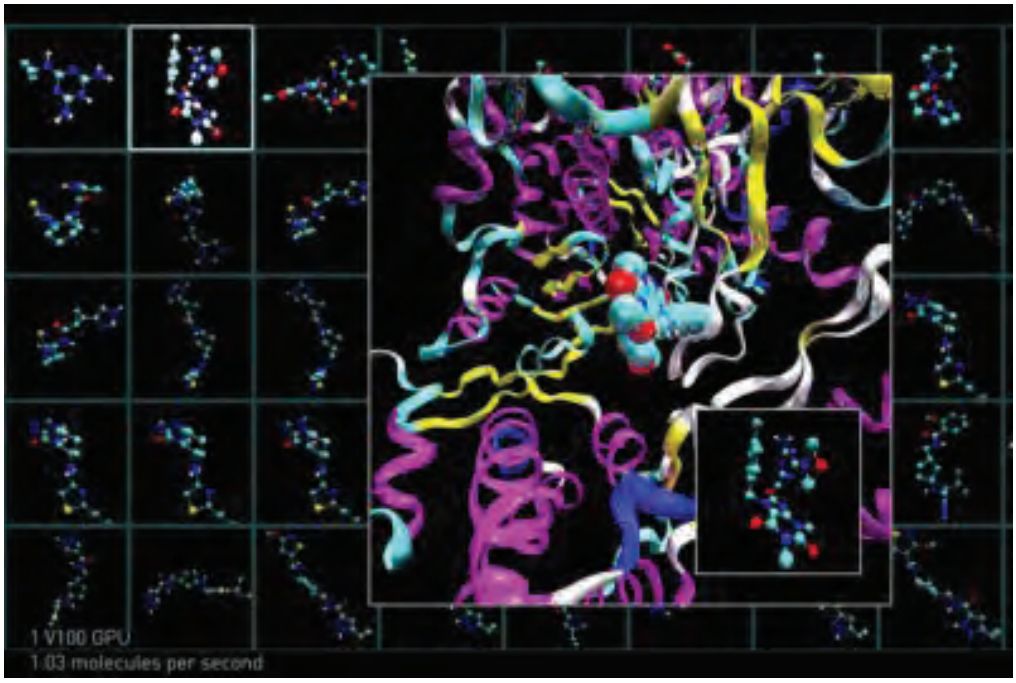
To date, hundreds of institutions, including hospitals, universities and supercomputing centers, in 88 countries have downloaded the software to accelerate their work — to sequence the viral genome itself, as well as to sequence the DNA of COVID patients and investigate why some are more severely affected by the virus than others.

Another method, cryo-EM, uses electron microscopes to directly observe flash-

frozen proteins — and can harness GPUs to shorten processing time for the complex, massive datasets involved. Using CryoSPARC, a GPU-accelerated software built by Toronto startup Structura Biotechnology, researchers at the National Institutes of Health and the University of Texas at Austin created the first 3D, atomic-scale map of the coronavirus, providing a detailed view into the virus' spike proteins, a key target for vaccines, therapeutic antibodies and diagnostics.

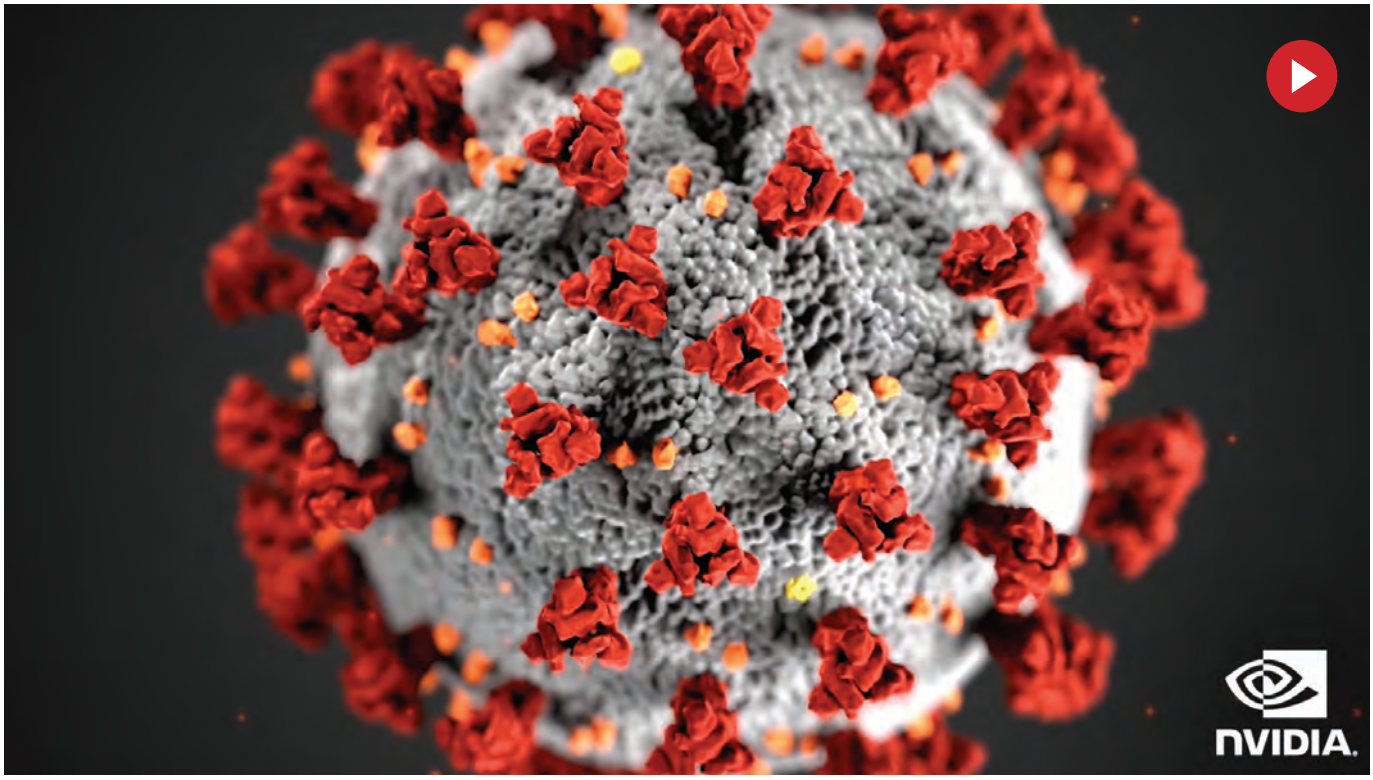
GPU-Accelerated Compound Screening

Once a target protein has been identified, researchers search for candidate compounds that have the right properties to bind with it. To evaluate how effective drug candidates will be, researchers can screen drug candidates virtually, as well as in real-world labs.



Drug discovery startup Atomwise, which joined the NVIDIA Inception virtual accelerator program in 2018, developed AtomNet, a convolutional neural network for small molecule drug discovery. The AtomNet AI technology can screen more than 16 billion compounds in less than two days using the scalability of NVIDIA GPUs hosted in the cloud. Virtual screening can accelerate the time it takes to discover potential drug candidates that may be promising for further testing and development, especially for challenging targets that were previously considered "undruggable."

New York-based Schrödinger creates drug discovery software that can model the properties of potential drug molecules. Used by the world's biggest biopharma companies, the Schrödinger platform allows its users to determine the binding affinity of a candidate molecule on NVIDIA Tensor Core GPUs in under an hour and with just a few dollars of compute cost — instead of many days and thousands of dollars using traditional methods.



Video LInk: https://youtu.be/b7QE32Pl6Cg

Generative AI Models for Drug Discovery

Rather than evaluating a dataset of known drug candidates, a generative AI model starts from scratch. Tokyo-based startup Elix, Inc., an NVIDIA Inception member, uses generative models trained on NVIDIA DGX Station systems to come up with promising molecular structures. Some of the AI's proposed molecules may be unstable or difficult to synthesize, so additional neural networks are used to determine the feasibility for these candidates to be tested in the lab.

With DGX Station, Elix achieves up to a 6x speedup on training the generative models, which would otherwise take a week or more to converge, or to reach the lowest possible error rate.

Molecular Docking for COVID-19 Research

With the inconceivable size of the chemical space, researchers couldn't possibly test every possible molecule to figure out which will be effective to combat a specific disease. But based on what's known about the target protein, GPU-accelerated molecular dynamics applications can be used to approximate molecular behavior and simulate target proteins at the atomic level.

Software like AutoDock-GPU, developed by the Center for Computational Structural

Argonne deployed one of the first DGX-A100 systems. Courtesy of Argonne National Laboratory.

on the DGX SuperPOD reference architecture. Argonne researchers are combining AI and advanced molecular modelling methods to perform accelerated simulations of the viral proteins, and to screen billions of potential drug candidates, determining the most promising molecules to pursue for clinical trials.

Biology at the Scripps Research Institute, enables researchers to calculate the interaction energy between a candidate molecule and the protein target. Known as molecular docking, this computationally complex process simulates millions of different configurations to find the most favorable arrangement of each molecule for binding. Using the more than 27,000 NVIDIA GPUs on Oak Ridge National Laboratory's Summit supercomputer, scientists were able to screen 1 billion drug candidates for COVID-19 in just 12 hours. Even using a single NVIDIA GPU provides more than 230x speedup over using a single CPU.

In Illinois, Argonne National Laboratory is accelerating COVID-19 research using an NVIDIA A100 GPU-powered system based

Accelerating Biological Image Analysis

The drug discovery process involves significant high-throughput lab experiments as well. Phenotypic screening is one method of testing, in which a diseased cell is exposed to a candidate drug. With microscopes, researchers can observe and record subtle changes in the cell to determine if it starts to more closely resemble a healthy cell. Using AI to automate the process, thousands of possible drugs can be screened.

Digital biology company Recursion, based in Salt Lake City, uses AI and NVIDIA GPUs to observe these subtle changes in cell images, analyzing terabytes of data each week. The company has released

an open-source COVID dataset, sharing human cellular morphological data with researchers working to create therapies for the virus.

Future Directions in AI for Drug Discovery

As AI and accelerated computing continue to accelerate genomics and drug discovery pipelines, precision medicine — personalizing individual patients' treatment plans based on insights about their genome and their phenotype — will become more attainable.

Increasingly powerful NLP models will be applied to organize and understand massive datasets of scientific literature, helping connect the dots between independent investigations. Generative models will learn the fundamental equations of quantum mechanics and be able to suggest the optimal molecular therapy for a given target. ■

To learn more about how NVIDIA GPUs are being used to accelerate drug discovery, check out talks by Schrödinger, Oak Ridge National Laboratory and Atomwise at the GPU Technology Conference. For more on how AI and GPUs are advancing COVID research, read blog stories and visit the COVID-19 research hub.

Pfizer and BioNTech's COVID-19 Vaccine Candidate

Pfizer Inc. and BioNTech SE announced that, after conducting the final efficacy analysis in their ongoing Phase 3 study, their mRNA-based COVID-19 vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints. Analysis of the data indicates a vaccine efficacy rate of 95% ($p<0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. Efficacy was consistent across age, gender, race and ethnicity demographics. The observed efficacy in adults over 65 years of age was over 94%.

Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose;170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group

There were 10 severe cases of COVID-19 observed in the trial, with nine of the cases occurring in the placebo group and one in the BNT162b2 vaccinated group. To date, the Data Monitoring Committee for the study has not reported any serious safety concerns related to the vaccine. A review of unblinded reactogenicity data from the final analysis which consisted of a randomized subset of at least 8,000 participants 18 years and older in the phase 2/3 study demonstrates that the vaccine was well tolerated, with most solicited adverse events resolving shortly after vaccination. The only Grade 3 (severe) solicited adverse events greater than or equal to 2% in frequency after the first or second dose was fatigue at 3.8% and headache at 2.0% following dose 2. Consistent with earlier shared results, older adults tended to report fewer and milder solicited adverse events following vaccination.

In addition, the companies announced that the safety milestone required by the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved. Pfizer and BioNTech plan to submit a request within days to the FDA for an EUA based on the totality of safety and efficacy data collected to date, as well as manufacturing data relating to the quality and consistency of the vaccine. These data also will be submitted to other regulatory agencies around the world.

"The study results mark an important step in this historic eight-month journey to bring forward a vaccine capable of helping to end this devastating pandemic. We continue to move at the speed of science to compile all the data collected thus far and share with regulators around the world," said Dr. Albert Bourla, Pfizer Chairman and CEO. "With hundreds of thousands of people around the globe infected every day, we urgently need to get a safe and effective vaccine to the world."

"We are grateful that the first global trial to reach the final efficacy analysis mark indicates that a high rate of protection against COVID-19 can be achieved very fast after the first 30 µg dose, underscoring the power of BNT162 in providing early

Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%

protection," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "These achievements highlight the potential of mRNA as a new drug class. Our objective from the very beginning was to design and develop a vaccine that would generate rapid and potent protection against COVID-19 with a benign tolerability profile across all ages. We believe we have achieved this with our vaccine candidate BNT162b2 in all age groups studied so far and look forward to sharing further details with the regulatory authorities. I want to thank all the devoted women and men who contributed to this historically unprecedented achievement. We will continue to work with our partners and governments around the world to prepare for global distribution in 2020 and beyond."

The Phase 3 clinical trial of BNT162b2 began on July 27 and has enrolled 43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate as of November 13, 2020. Approximately 42% of global participants and 30% of U.S. participants have racially and ethnically diverse backgrounds, and 41% of global and 45% of U.S. participants are 56-85 years of age. A breakdown of the diversity of clinical trial participants can be found here from approximately 150 clinical trials sites in United States, Germany, Turkey, South Africa, Brazil and Argentina. The trial will continue to collect efficacy and safety data in participants for an additional two years.

Based on current projections, the companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021. Four of Pfizer's facilities are part of the manufacturing and supply chain; St. Louis, MO; Andover, MA; and Kalamazoo, MI in the U.S.; and Puurs in Belgium. BioNTech's German sites will also be leveraged for global supply.

Pfizer is confident in its vast experience, expertise and existing cold-chain infrastructure to distribute the vaccine around the world. The companies have developed specially designed,

Safety data milestone required by U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved

The companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021

temperature-controlled thermal shippers utilizing dry ice to maintain temperature conditions of -70°C±10°C. They can be used be as temporary storage units for 15 days by refilling with dry ice. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment across their pre-set routes leveraging Pfizer's broad distribution network.

Pfizer and BioNTech plan to submit the efficacy and safety data from the study for peer-review in a scientific journal once analysis of the data is completed. ■

Pfizer & BioNTech's Disclosure Notice

The information contained in this release is as of November 18, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments. This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995.

Digital Transformation as Applied to Pharma Sector

Video Link: https://youtu.be/HH2x_pCdj-8

When thinking Industry 4.0, there is a sense of opportunities that are about to change the world for the better. What about its impact on the pharmaceutical industry specifically? How can the sector benefit from the Smart Factory technologies available today, and those that will be available in the near future? Implementing new industry 4.0-based manufacturing concepts in Pharma 4.0 requires alignment of expectations, interpretation, and definitions with the pharmaceutical regulations. It is therefore important to achieve not only an accepted understanding of readiness and maturity but also develop business cases to showcase which I 4.0 automation and digitalization technologies can be applied to pharma.

In this edition we have Pawan Kulkarni, a digital enthusiast and learner who has mixed exposure of pharma advertising, sales, marketing and strategy and is currently working as General Manager – Corporate strategy with a leading Pharmaceuticals organization In Conversation with Gauri Chaudhari, Co-founder of Brand Innerworld, a brand consultancy firm specializing in Healthcare and Pharmaceutical brands and author of 'The Perfect Pill: 10 steps to Build a Strong Healthcare Brand.' In this conversation they are exploring expectations, interpretation, and definitions of Digital Transformation as applied to Pharma Sector. ■

Five Key Tips to Enhance the Solubility of Your Oral Drug Products

Courtesy & Source: *Evonik Corporation*

In this discussion, Dr. Jessica Müller-Albers, Director of Strategic Marketing for Oral Drug Delivery Solutions at Evonik, shares some of the Company's top recommendations to enhance the solubility of poorly soluble drugs.

Dr. Jessica Müller-Albers
Director of Strategic Marketing for Oral Drug Delivery Solutions, Evonik

Poor solubility used to be one of the main showstoppers during the development of oral drug products. Advances in excipients, process technologies, equipment and predictive tools have fortunately all helped to substantially de-risk the process. However, while the risk of running into a dead-end may have reduced, market demand for solutions that can address the solubility challenges of complex drug products has skyrocketed in recent years.

Today, poor solubility affects around 40% of currently marketed drugs and the majority of actives in clinical development. One key factor behind this trend is a shift towards actives with a higher molecular weight and increased lipophilicity, which can result in a decrease in aqueous solubility.

"A vast range of factors can affect drug solubility, as well as overall bioavailability, based upon the product's inherent

permeability," said Dr. Müller-Albers. "In addition to drug concentration and disintegration time of the dosage form, it is also critical to understand the inter-relationships that can occur between properties including molecular weight, lipophilicity, solid state, particle size and surface area. To ensure reliable process development and scale-up, it's also important to review how these physical properties can be utilized with the right equipment and process technologies".

So how can pharma companies minimize project risk and development costs, select the right excipients, equipment and process technologies to complement their API and dosage form, and hopefully also enable higher drug loadings and improve stability? Dr. Müller-Albers listed five key factors that companies should keep in mind to help ensure their path to solubility enhancement is as seamless and as low risk as possible.

Understand the needs of your API, and select the right systems and excipients upfront

"It's most important to begin using best-in-class formulation and Quality-by-Design (QbD) methods as early as possible in the drug development process to not only maximize options to enhance solubility, but also increase stability, optimize physiological absorption and streamline downstream processes," said Dr. Müller-Albers. "One of the most important goals during these early stages of formulation development should be the selection of the excipient platform and process technology that will best serve the needs of your API and provide the highest probability of success".

Dr. Müller-Albers said that EUDRAGIT® polymers such as EUDRAGIT® L 100, EUDRAGIT® L 100-55 and EUDRAGIT® E have been used successfully in the market to dissolve APIs at the molecular level for stable, solid solutions, and have versatile processing opportunities comprising spray drying, hot melt extrusion, precipitation, granulation and layering. For spray drying, they are lightly soluble in common solvents and can be processed and scaled-up to an economic process by

balancing drying-gas inlet temperature, spray-solution polymer concentration, and solvent volatility. For hot melt extrusion, they have beneficial melt viscosity and show excellent extrudability.

Take advantage of predictive software and miniaturized screening tools

"It can be highly beneficial to take a systematic approach to the formulation development of solid dispersions to substantially reduce the number of experiments that may be required," said Dr. Müller-Albers. "Rather than relying on the random mixing of drugs and polymers, the use of predictive systems can help to select initial formulations for screening based upon physico-chemical properties such as solubility parameters and hydrogen bonding.

To identify the best polymer for a specific API and the potential drug loading, Dr. Müller-Albers said that Evonik utilizes MemFis®, a proprietary in silico tool. Afterwards, the most promising carriers can be evaluated in a miniaturized screening tool (solvent or melt based depending on the preferred technology) to determine the formation of stable amorphous solid dispersions and collect initial dissolution data in the relevant media. This fast, cost-effective development approach enables the creation of a comprehensive data package with only small amount of API.

Get your dissolution testing process right

A fundamental goal of pharmaceutical development is to optimize drug levels available in the body to match the therapeutic window, so that the desired therapeutic effect is achieved without adverse side effects. The effectiveness of any oral solid dosage form depends upon the intrinsic ability of the drug to reliably dissolve in the fluids of the gastrointestinal tract prior to it being absorbed into the blood stream. The rate of dissolution is a critical factor in this process.

"Dissolution testing is a standardized method for measuring the rate of drug release from a given dosage form to optimize the formulation," said Dr. Müller-Albers. "Tests must not only be robust and reproducible but be able to detect any key changes in product performance between different formulations or batches. It is also essential that in-vitro dissolution matches in-vivo conditions. If the dissolution procedure is well designed, it should help to accelerate drug development by an effective selection of prototype formulations and de-risk the clinical studies which are necessary in the drug product approval process," she continued.

Control your manufacturing process

Dr. Müller-Albers said that Evonik has found that stabilized amorphous solid dispersions (ASDs) are the most

effective and commonly used method of solubility enhancement that can result in higher bioavailability, especially when permeability is not the limiting factor.

"Most ASD formulations in the market are prepared from active and polymer solutions in organic solvents using spray-drying, or from polymer-drug high temperature mixtures cooled down to room temperature via hot melt extrusion. Identifying the ideal processing space and keeping control over particle and strand formation is important to cost-effectively manufacture the product at a reproducible quality. Undesirable effects such as fiber formation or additional down streaming steps can be avoided by properly adjusting and controlling process parameters and thus, particle formation," said Dr. Müller-Albers.

Select a single partner with decades of experience and a full range of services to guide you through the entire development process

Many large, commercial-oriented partners are focused more on clinical material manufacturing and production than formulation development. However, some smaller contract partners can lack the scale and process development expertise to help bring the customers' product all the way through to market. Dr. Müller-Albers said that for such complex ASD products, selecting a specialist with integrated capabilities across excipients, formulation development, analytical method development, process development and manufacturing would be the ideal scenario.

"At Evonik, we have a mix of competencies that can be tailored to the specific needs of a project, starting from functional ASD carriers up to phase II clinical manufacturing including high potency handling," said Dr. Müller-Albers. "These competencies have been leveraged by many customers over multiple decades to enhance the solubility and bioavailability of a range of API types and drug products. As a specialist for advanced drug delivery, Evonik brings together a range of material engineering and formulation and process development competencies. Additionally, we have a strong network to large scale commercial ASD manufacturing CMOs that supports a fast entry into late stage clinical trials and a secure transfer to the final production site." ■

Making the Medicine Go Down:
Specialized Oral Solids Delivery Technologies

Author: *Sandra Conway, Technology Lead, Pfizer CentreOne*
Courtesy & Source: Pfizer CentreOne

In this article, Sandra Conway, Technical Lead at Pfizer CentreOne discusses some of the drug development technologies that provide a more specialized approach to oral dose delivery.

The oral administration of drugs in tablet or capsule form is still the most common practice for taking medicines today and oral solids accounts for a large proportion of drugs in the development pipeline. Most oral solid formulations are designed to release the drug immediately after swallowing for rapid absorption into the bloodstream. However, some products have been developed to release the drug in a specific way following ingestion and provide a "controlled-release" of the drug products.

Why controlled release?

Controlled-release products are considered by drug developers for the following reasons:

- To provide improved pharmacokinetic profiles compared with the immediate release product (i.e. steady state plasma concentration resulting in reduced adverse events)
- Reduced dosing frequency for improved patient convenience and/or compliance and improvement in overall efficacy. Controlled-release products are often adopted for drugs with short half-lives which are used to treat chronic conditions

Many marketed controlled-release products are hydrogel-based tablets or capsules containing coated beads, which can be produced using conventional pharmaceutical manufacturing equipment. However, to achieve particularly demanding drug release criteria it is sometimes necessary to adopt more sophisticated pharmaceutics, such as the use of osmotic pumps, which require more complex manufacturing strategies.

Osmotic pump technologies

Osmotic pump tablets are coated with a semi-permeable membrane which is breached in one location by a laser-drilled port. Water permeates through the

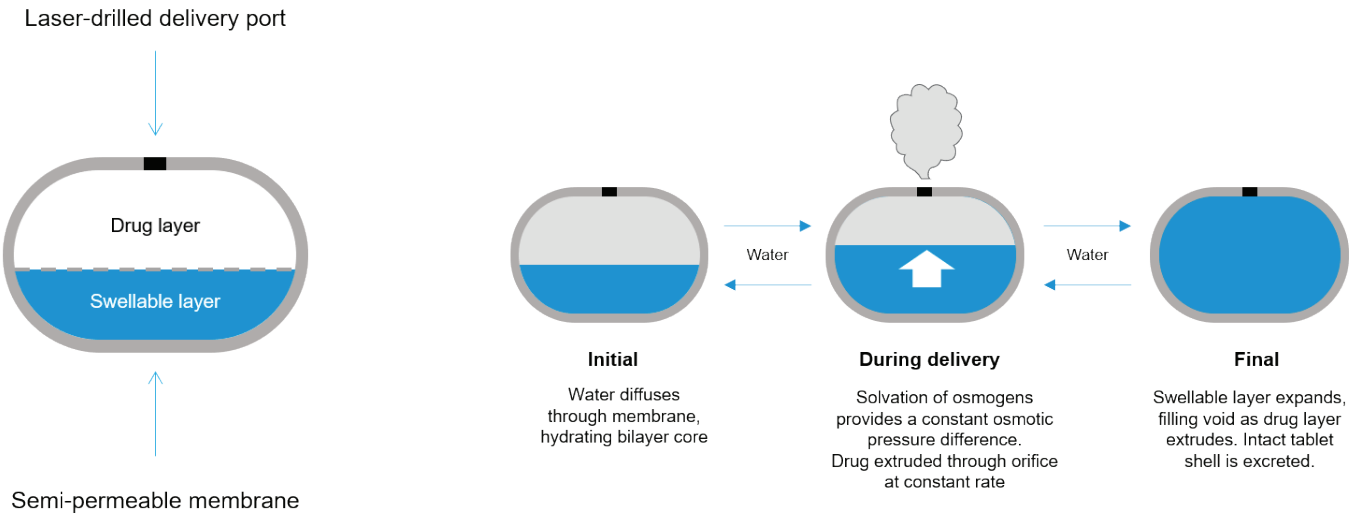


Figure 1. Schematic illustrating the working principle for the SCT. As water permeates the membrane the swellable layer expands, applying pressure on the drug-containing layer and hence forcing the drug through the port.

membrane, dissolving excipients in the core and thus raising the internal pressure. The raised pressure in the core causes the contents to be forced through the laser-drilled port at a constant rate.

The benefits of osmotic pump technologies for controlled drug release are:

- Zero-order drug release (i.e. drug is released at the same rate over a given period of time).
- The drug release rate is independent of the gastric pH
- The release rate from the delivery system is not affected by the presence of food (i.e. no food effect)
- High degree of in-vitro/in-vivo correlation with these kind of delivery systems
- Single daily dose is achievable

Pfizer CentreOne has two osmotic pump technologies within its Gastro-Intestinal Therapeutics Systems (GITS) portfolio. The Swellable Core Technology (SCT) consists of a round, bilayer core. One layer which contains the drug and a second layer which swells as water diffuses into the core, applying pressure on the drug-containing layer and thus extruding the drug through the laser-drilled port (Figure 1).

The Extrudable Core System (ECS) consists of a single-layer core containing both the drug and a polymeric viscosity enhancer. As water permeates the semi-permeable membrane the polymer hydrates and swells. The internal osmotic pressure increases and the viscous, drug-containing fluid is pushed through the laser-drilled port (Figure 2). The modified

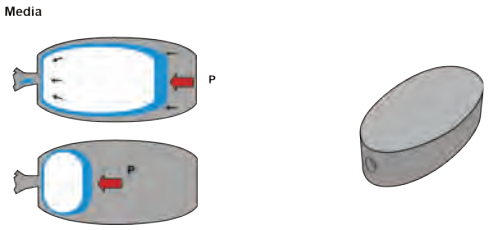


Figure 2. Schematic illustrating the working principle for the ECS. As water permeates the membrane the internal pressure (P) forces the drug-containing fluid through the port.

oval shape of the tablet helps control the release rate of the drug.

The single-layer design of the ECS allows higher drug loading compared with the SCT technology and the modified oval shape of the tablets make them easier to swallow compared with round SCT tablets. Single-layer ECS cores are also easier to manufacture compared with bilayer SCT tablets. The advantage of SCT tablets is that they deliver a more complete delivery of the unit dose from the tablet compared with ECS tablets.

For both the SCT and ECS osmotic pump tablet technologies, control of drug release depends upon the presence of a semi-permeable film with a laser-drilled port. The semi-permeable membrane is typically composed of a water-insoluble cellulosic polymer incorporating a water-soluble pore-forming agent. The permeability and thickness of the film are critical for achieving the required drug release rate. Film-coating of the tablet cores is therefore a critical process, particularly the intra-tablet coat uniformity to ensure coat integrity. Process analytical technologies (PAT) are employed to determine the process endpoint for

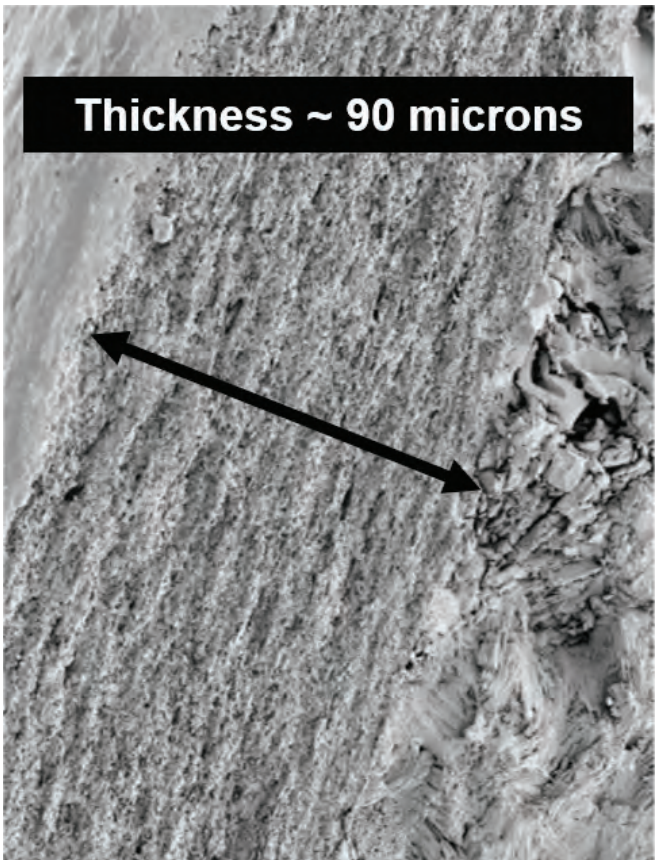


Figure 3. Cross-section of osmotic pump tablet showing semi-permeable film coat

coating and ensure the correct film thickness is achieved. A cross-section image of a coated tablet is shown in Figure 3.

The size of the port in the membrane is also critical for controlling drug release. Therefore, the laser-drilling process requires tight control. Vision systems are used for 100 per cent inspection of all laser-drilled tablets to ensure the presence, correct location and size of the port for all tablets produced.

Osmotic pump technologies have become popular for controlled drug delivery

Product	Drug substance	Dose (mg)	Indication	Manufacturer
Glucotrol® XL	Glipizide	5, 10	Diabetes	Pfizer
Minipress® XL	Prazosin	2.5, 5	Hypertension	Pfizer
Cardura® XL	Doxazosin Mesylate	4, 8	Hypertension	Pfizer
Procardia® XL	Nifedipine	30, 60, 90	Hypertension	Pfizer

Table 1. Commercially available SCT-type products

purposes and there are now many marketed products which utilise this approach. Some examples of commercially available osmotic pump products are given in Table 1.

Conclusion

Controlled release technologies provide versatile platforms for oral drug delivery. It is now possible to tailor drug release to match complex administration criteria in a single dosage form.

Osmotic pump technologies have become particularly popular due to their consistency of performance. In particular, the degree of correlation between in vitro versus in vivo performance is usually better with these osmotic controlled released forms than other conventional dosage forms. This is primarily due to the insensitivity of the release rate to food, pH and position in the GI tract.

There are now many marketed products that use this principle, for instance, they are used extensively for administration of hypertension drugs – providing accurate control of dose delivery and management of pharmacokinetics. They also offer the opportunity for extending the time between dosing intervals and thereby make life easier for patients on long-term medication, especially important for patients on multiple medications.

The use of controlled-release technologies in drug development will therefore certainly grow in popularity to meet patient needs. ■

Texture Analysis in Your Product Quality Testing

Brookfield is known for more than viscometers these days. Texture Analysis is another piece of the puzzle to help you solve your QC issues.

What is Texture Analysis? and Why Should it be Measured?

Texture analysis is primarily concerned with the evaluation of mechanical characteristics where a material is subjected to a controlled force from which a deformation curve of its response is generated. These mechanical characteristics in food can be further sub-divided into primary and secondary sensory characteristics.

A Texture Analyser is a texture measurement system that moves in either an up or down direction to compress or stretch a sample. The travelling arm is fitted with a load cell and records the force response of the sample to the deformation that is imposed on it. Force, Distance and Time data is collected and usually presented as a curve on a graph which, when analysed, indicates the texture of the sample.

Depending upon the chosen probe/ fixture, the Texture Analyser can perform compression, extension, cutting, extruding, bending and shearing tests – and in doing so, can measure properties such

PRIMARY CHARACTERISTICS	
Hardness	Soft → Firm → Hard
Cohesiveness	Crumbly → Crunchy → Brittle
Elasticity	Plastic → Elastic
Adhesiveness	Sticky → Tacky → Gooey
Viscosity	Thin → Viscous
SECONDARY CHARACTERISTICS	
Brittleness	Crumbly → Crunchy → Brittle
Chewiness	Tender → Chewy → Tough
Gumminess	Short → Mealy → Pasty → Gummy

as fracturability, chewiness, stickiness, consistency, bite force and springiness, to name but a few.

Textural parameters are very important to evaluate and control the quality of agricultural products and processed foods. Compared with conventional sensory evaluation, the instrumental evaluation method is able to characterize the many textural features of foods with strong reliability and high rapidity.

Texture measurements can be used for:

a) Research and Development: In longer term studies to understand micro and macro structures or in the development of new ingredients or unique products.

b) New Product Development: In faster moving and shorter term investigations to benchmark key attributes. The Texture Analyser would assist in the development of products with specific consumer markets in mind and monitoring of the effect of formulation and shelf life changes.

c) Process Development: The Texture Analyser would be used in an engineering approach to measurement to form an understanding of key stages in the product process. The effects of these stages and how they can be manipulated to maximise product quality would be observed. From each of these environments a technologist would learn and transfer information to its practical application at the factory level.

True quality control comes from the ability to use the Texture Analyser to measure manufactured products to desired quality standards and understand how you can alter the formulation or processing conditions should they deviate beyond acceptable tolerance levels.

Why Measure Texture?

Consumer products succeed in the marketplace in part because customers perceive which “textural characteristics” are desirable. This is certainly true with food products but also applies to cosmetics, pharmaceuticals, packaging, industrial materials and even adhesive type materials.

Why Choose Brookfield?

With over 40 years experience in texture analysis, from the Boucher Jelly Tester to the Stevens range of Analyzers, Brookfield's new Texture Division provides customers with a complete texture assessment service. We specialize in the development of novel and innovative test applications and accessories for solid and semi-solid materials, enabling our customers to maximize the practical value of their texture studies within all test environments.

Utilizing simple compression or tension forces, we are able to imitate almost all conditions imposed during the manufacture or handling of a wide range of foods, industrial materials and personal care products. Such measures provide a "real life" insight into the physical properties of a product, often invaluable in maintaining consistent quality manufacture while minimizing rejects in production.

The maximum load range you expect when testing your samples are as follows:

<= 100g (1N)
<= 1000g (10N)
<= 1500g (15N)
<= 4500g (45N)
<= 25000g (25Kg; 250N)

Type of testing
-Compression
-Compression and tension
-Multiple cycles

Type of result
-Single point load (force) value
-Graph of load profile during testing.

Physical properties of your sample you wish to determine:
-Hardness
-Adhesive force
-Cohesiveness
-Adhesiveness
-Chewiness
-Gumminess
-Springiness
-Brittleness
-Modulus
-Stress relaxation. ■

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Pentapharm® kpVantage® films

klöckner pentaplast

Klöckner Pentaplast delivers the next generation of films for pharmaceutical blister packaging with Pentapharm® kpVantage®. Now you can change to polyester without changing a thing. Pentapharm® kpVantage® are polyester-based films that can be processed on your existing equipment maintaining all critical package components – no need to change tooling, lidding or package design.

Available as mono films or can be integrated into barrier structures for products that require more protection from moisture and gas. Pentapharm® kpVantage® films are designed to support your social, economic and environmental sustainability goals while maintaining product integrity and production economies.

Benefits

- Process on existing packaging lines without investing in costly package redesign, new tooling or machinery
- Excellent sealability, work with existing lidding materials and structures
- Form at lower temperatures, decreasing energy use and increasing line speed
- Superior trimming and perforating performance with no angel hair
- Full range of barrier protection with common contact material
- Excellent machinability, higher yields for more good parts per pound/ kilo
- Outstanding lay flat for easier cartoning and handling
- Process consistently with no neck-in and precise index registration
- Brilliant clarity for superior optical and surface qualities
- Global availability for supply security

Applications

- Solid oral-dose packaging
- Ethical drugs
- OTC
- Generics
- Veterinary medicine
- Nutraceuticals ■

Contact Details

Website: https://www.kpfilms.com

UFlex Raises the Bar with its Innovations in Q2 FY20-21

UFlex Ltd, India's largest multinational flexible packaging company and a global player in polymer sciences, today declared its earnings for the quarter ending September, 2020. The company posted a strong performance with Consolidated Revenue rising by 19.2% YoY to INR 2234.5 crore, EBITDA increasing by 69.6% YoY to INR 472.9 crore and Net Profit jumping YoY by 136% to INR 221.8 crore in Q2 FY2020-21.The company has registered back-to-back successful quarters where they witnessed surge in demand for multiple lines of businesses while also adding newer clients.

Ashok Chaturvedi, CMD, UFlex Limited said, "We have been pivotal in providing packaged products to the end consumers during the pandemic period. To ensure that we are future-ready and have a better outreach of sustainable solutions to our clients located globally, we have been scaling up our international operations."

In Q2 FY 2020-21, UFlex introduced a host of new product innovations and developments to set a benchmark for the packaging sector:

Engineering Business:

1. Collar-type Form Fill Seal Machine for Snacks Packaging: In sync with 'Atmanirbhar Bharat' initiative, the Engineering Business of UFlex locally developed a higher speed Collar Type Form Fill & Seal machine CT 120 that has already been witnessing early success with a few big orders. CT 120 is completely servo driven with an operator friendly human interface. It facilitates efficient vacuum pulling, smooth-motion cross & vertical seal technology that delivers superior quality seal with high seal integrity. This machine runs at a speed of 120 PPM with a very low rate of on-line rejections on snack packaging applications. This is the first Indian continuous type VFFS machine running at this high speed with minimal rejection meeting the standards of any international machines.

2. Rotary Machine Foray into Spice Packaging: UFlex successfully forayed into spice packaging segment for the first time ever, thereby expanding its portfolio of Rotary machines. Spice is an ever growing market segment, and this success has opened up many new business opportunities for the company. With this new introduction, spices can be packed now at a speed of 300 to 400 packs per minute in pack sizes between 15 gms to 25 gms.

Holography Business:

1. Digital Foil for Ink & Varnish: Digital Foil has been created by the Holography business through process of applying hot stamping foil to an ink or varnish without the requirement of a die. These foils have been specifically manufactured to bond on ink, toner or varnish whilst still using heat and pressure. Digital foils have a huge potential in local and global markets and has already acquired its first customer overseas.

2. Registered Lens Label for Edible Oil Packs: Counterfeiting in edible oil segment has been posing serious challenges to the brand owners on account of sales and profit loss, brand dilution, unfair warranty and supply chain loss claims. To counter this menace faced by a famous edible oil brand, UFlex customised Registered Lens Label that helped the brand fight counterfeiting issues. This printing technology combines features of doing registration on holographic substrate and of doing precise re-registration printing on the same substrate which makes it next to impossible to replicate. The packaging of this customized holographic substrate is recyclable / biodegradable.

3. Labels for Hand-sanitizer: UFlex developed labels for a prominent alcohol brand that pivoted to manufacturing hand sanitizers as part of its social endeavour to promote hygiene and safe health practices to meet the sudden spike in demand for hand sanitizers,

triggered by the on-going COVID-19 pandemic.

Chemicals Business:

1. Toluene-free Inks for Food Packaging: The Chemicals business launched toluene free inks for vinyl, PU & polyamide based chemistries. Toluene free inks comply with revised guidelines issued by Bureau of Indian Standards (BIS IS 15495:2020). It is best suited for flexible packaging segments for food, pharma and hygiene applications.

2. Single Solvent-free Adhesives with Multiple Hardeners (OH): The company launched two component solvent-free adhesives range with one resin compatible with three different hardeners for general to medium to high performance applications. The new solvent-free adhesive is suitable for flexible packaging with hot filling application like ketchup, juice that needs sterilization. Solvent-free adhesives provide good heat resistance and are used to join layers of film and foils in medium to high-performance packaging applications. UFlex latest product also helps clients reduce their adhesives inventory.

3. Side & Bottom Sealing Adhesive for Paper Bags: A water based 'side and bottom sealing adhesive' for automated high-speed paper bag making machines was developed by UFlex. These bags are getting a lot of traction in the e-commerce space especially by players like Amazon & Flipkart, to achieve their sustainability goals.

Flexible Packaging Business:

1. Bespoke Packaging Innovation for Big Brands: UFlex created packaging formats for big brands like Nestle, AgroTech Foods and Olam Agro for its product variants.

a. For Nestle's launch of new Maggi Chilli Garlic Fried Rice Instant Spice Mix, UFlex designed a structure comprising of 10 micron polyester pack with 6.35 micron Aluminum foil and 50 micron EVOH Poly that provides excellent moisture and oxygen barrier to pack seasoning that needs the aroma to be retained till its consumption.

b. For Agro Tech Foods Sundrop Duo Twist Wrap, the requirement was to pack confectionary in a 23 micron metallized polyester pack with twist grade that allows surface printing and anti-static coating for smoother running of the pack through the

machine. Due to the combination of matted gloss printing, in which the product printed on the package looks glossy while the rest of the pack wears a matted look, the pack catches instant attention when placed on retail shelves.

c. For the launch of dry fruits, spices & rice of global food & agri-business brand Olam Agro, UFlex created laminates & pouches with a structure of 12 micron PET, 12 micron window MET PET and 90 micron PE to pack contents with requirement of a strong barrier to retain aroma, nutrients & taste within shelf life.

Films Business:

1. Metal Textured Film for Shelf-appeal: The Metal textured film is derived when textures are incorporated on a specially formulated BOPET substrate that is availed with the use of special polymers and nano materials, to impart good reflectance, depth and ease of processing. The films' two variants F-Brush-M and F-Lin-M are extensively used to produce labels and provide premium quality lamination on board, graphic and advertising banners, wall papers, automotive parts, sheet moldings and white goods. It is available in 23, 36 and 50+ micron thickness. F-Brush-M, available in silver, gold and rose colour, is used to achieve a fine brush like effect on a metallized polyester film to give a steel look on the shelf with excellent gloss and shine. Whereas, F-LIN-M is a special coated metallic linen textured polyester film that gives excellent gloss and design with seamless impressions. Both variants are compliant with the EU and FDA standards. The entire manufacturing of the film involves no use of solvents or UV radiation which makes the film sustainable.

2. Ultra-low OTR PET Film for Food Packaging – Patent pending film F-ULP is a coated transparent BOPET film with barrier layer coated on one side that provides an ultra-high oxygen barrier. F-ULP has the highest level of barrier achievement with one of the lowest OTR in the world. The standard film has the OTR values of less than 0.4cc/m2/day which can be reduced further down to 0.08cc/m2/day or even lesser depending upon the coating thickness. The coating has an excellent adhesion on the substrate which gives it good bond strength with all types of adhesive systems in multi-layered laminates. Besides, the film also offers strong barrier against moisture, supreme crack

resistance transparency and yields cost and environmental benefits, making it a preferred film by brands. The film is best suited to pack dry foods, confectionaries, snacks, dairy products, perishable products and processed foods.

3. BOPET Film for Printing & Lamination Application – UFlex launched F-MSH grade polyester film for multiple printing and lamination application. It is a mono-extruded matte finish polyester film that has high haze of more than 80% and low gloss with excellent muted and grainy surface. This grade of polyester film is also available with on corona treatment or chemically coated side and complies with FDA and EC regulations for food packaging. This film is highly beneficial for thermal lamination, label application, board lamination etc where one requires outstanding print quality and strong stiffness.

1. Sealable & Peelable BOPET Film with Water-based Coating for Lidding: F-TPS, a sealable and peelable polyester film with water-based eco-friendly coating, is a sustainable concept with low GSM instead of using solvent base coated product. This film offers higher optical clarity with 4-5% haze as against conventional haze product, and possesses anti-fog characteristics for hot and cold conditions. This film, that is USFDA and EU compliant, allows printed or metallized lidding on variations of PET like amorphous A-PET, recycled R-PET and crystalline C-PET, G-PET and PVC substrate.

2. High Oxygen Barrier BOPET Film for Dry & Chilled Food Packaging: Transparent high barrier polyester 'green' film F-PGS provides excellent barrier against oxygen and has chlorine free, water-based environment friendly coating technology. Additionally, the film offers excellent flex crack resistance unlike metal oxide coated film or Aluminium metallized film. Being optically clear and thermally stable with excellent processability, and due to it attribute to retain OTR at elevated humidity, this film is suitable for dry & chilled food and liquid packaging. ■

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Driving pharma & biotech manufacturers on their digital journey

The software experts of Körber's Business Area Pharma have established a new Principal Consulting & Client Advisory unit. Pharmaceutical and biotech manufacturers benefit from new, value-adding services by Werum Solutions on their digital transformation journey.

Many pharma and biotech companies today have either not digitized their production processes or only to a certain extent. If production data is available electronically at all, it is hardly contextualized, so that it can only be used insufficiently to increase production performance, quality or compliance. In most cases, it is challenging to setup

upfront clear, reliable and executable digital production IT strategies, where all necessary aspects in terms of people, processes, data and technology are carefully considered, planned and put into a context to drive production IT compliance and excellence.

The new Principal Consulting & Client Advisory services help drug manufacturers to develop and implement holistic digital manufacturing IT strategies utilizing the broad portfolio of Werum Solutions, that is tailor-made to the customer's circumstances and business targets. Customers will be advised and supported throughout the entire digitization lifecycle, from the very beginning of the digital strategic analysis and definition process to project/ program execution up to optimization potentials in operations. The new unit is headed by Zinaid Dzinovic, who worked for several years at a major pharma and biotech manufacturer in Switzerland in various positions.

"Turning pains into gains: with our new Consulting & Advisory services we address our customers' key pain points in business, quality, compliance and operational excellence," says Zinaid Dzinovic, Director of Principal Consulting & Client Advisory Software, Körber Business Area Pharma. "The new services are complementing our existing Werum Solutions consulting portfolio and help our customers in the strategic process towards fully digitizing their pharma operations."

Torsten Isenberg, Vice President Global Business Consulting Software, Körber Business Area Pharma, adds: "In discussions with our customers, we often find that the organizations are only insufficiently prepared for the digital transformation. We want to ensure an understanding for the disruptive potential of digitization. Together with our customers we develop and implement the right strategy for the successful journey to their digital pharma 4.0 factory of the future." ■

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The Evolution of Law & Ethics In Pharma Sector: ICMR & Improvements in Guidelines

In the last issue the author dealt about the role of various institutions and its functions, and biomedical research in the country. In this edition, the author expounds the role of revised guidelines that influenced policy formulation in pharma sector.

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

India is the largest producer of generic drugs. Around 20 percent of our global export is attributed to pharma industry. In order to be more focused on the quality of drugs, the government works relentlessly on formulating policies and revising existing guidelines. It is overall constructive for the healthcare sector. However, a minor section of people feel that frequent revision of guidelines create confusions in businesses and obscure drug manufacturers.

Indian Council for Medical Research Guidelines [ICMR] 2017:

The emerging ethical issues in the field of biomedical research in our country have posed several problems that warrant constant re-appraisal on the policy front. It also required strengthening of rights, the well-being and the safety of the participants. To address this moral conundrum, the ICMR came out with revised guidelines called the National Ethical Guidelines for Biomedical and Health Research involving Human Participants. This was in the year 2017. After several rounds of discussions with the stakeholders, it was decided to bring under its fold areas that hitherto remained unaddressed. They are:

- Public health research
- Social and behavioural sciences research
- Responsible conduct of research
- Research during emergencies and disasters

The 2017 revised guidelines gave an impetus to several other areas like seeking informed consent from the participants, the biomedical process and materials used, bio-banking, datasets and managing the vulnerability of participants.

Expansion of Basic Principles:

The four ethical principles of autonomy, beneficence, non-maleficence and justice came to be expanded to include the following twelve principles.

(i) Principle of Essentiality:

Humans as participants are essential.

(ii) Principle of Voluntariness:

The right to agree or not to agree to participate in any research, to withdraw from such research at any time is guaranteed to the participants. Informed consent must be honoured.

(iii) Principle of Non-exploitation:

Selection of research participants must be done equitably so that the benefits and burdens of the research are distributed fairly. Vulnerable groups must be adequately safeguarded.

(iv) Principle of Social Responsibility:

The research must not create or deepen social and historic divisions or disturb social harmony within communities.

(v) Principle of Privacy and Confidentiality:

Participant's records must be kept confidential and access must be limited to authorized personnel only. In case of alteration or edition on details, the Ethics Committee be consulted.

(vi) Principle of Risk Minimisation:

Due care must be taken by all stakeholders at every stage of research to ensure that risks are minimized. Care and compensation in case of any harm is mandatory.

(vii) Principle of Professional Competence:

The research must be planned, conducted, evaluated and monitored by people who are competent and have the appropriate and relevant qualification, experience and/or training.

(viii) Principle of Maximization of Benefit:

Due care must be taken to design and conduct the research in a way that it directly or indirectly maximizes benefits to the research participants and the society.

(ix) Principle of Institutional Arrangements:

The institutions where research is proposed to be conducted must have adequate policies and governance in place to sanction the research and aid it by providing required infrastructure, manpower, funds and training opportunities.

(x)Principle of Transparency and Accountability:

Research plan and outcomes emanating from the research must be brought to the public domain through registries, reports and scientific or other publications simultaneously guarding the participant's rightsof privacy.

The stakeholders must disclose conflict of interests. The research must be conducted in a fair, honest, impartial and transparent manner to ensure accountability. Records, data and notes must be protected for external scrutiny and audit.

(xi) Principle of Totality of Responsibility:

The stakeholders involved in the research must be made responsible for all their actions. This professional, social and moral responsibility is binding on all stakeholders both directly and indirectly.

(xii) Principle of Environmental Protection:

Researchers must be made accountable for ensuring protection of the environment and resources at all stages of the research.

Child Participants:

The above ICMR guidelines on biomedical research did not distinguish an adult participant from a child participant in generic terms. However, it talks about the vulnerability of children-participants and the measures required in safeguarding

them. It was rightly felt that research findings in adults cannot be adopted as applicable to children also.

To address special concerns pertaining to biomedical research involving the children, the ICMR came out with National Ethical Guidelines for Bio-Medical Research involving Children, 2017 for the very first time. At a global level, it is relevant to note that separate guidelines are available for paediatric biomedical research including countries such as USA, UK, and others in the European Union.

General Guidelines for Research in Children:

Following guidelines must be followed when research is conducted involving children:

- The research proposal must be scientifically sound.
- The proportion between potential benefit and potential harm should be skewed in favour of the former.
- The result must be beneficial to children in general and in most cases to the individual
- The need to study must be justified by thorough review of literature.
- The research has to be conducted by a team of investigators who have requisite expertise. One or more members of the team should be paediatricians and/or have prior experience in conducting research involving children.
- Research involving children must take into consideration their unique physiology, anatomy, psychology, pharmacology, social situation and special needs of children and their families.
- It must be conducted in a child-friendly environment as far as possible.
- Drugs must be tested for safety, pharmacokinetics and initial indications of efficacy are established in adults before they are tested on children.

The pharma industry should never be considered as a cash cow. The focus is always on improving quality of drugs and consequently the standard of life of people. The formulation and reformulation of policies by the government is a step in the right direction. There will always be 'ifs' and 'buts' but the government in its unique way is making an earnest attempt to adopt all or most of the international recommendations given by the Declaration of Helsinki (2013). ■

(The next column will talk about the statutory framework and role of courts in pharma sector).

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