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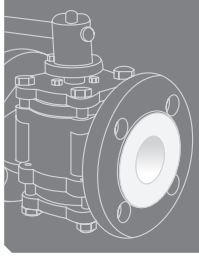

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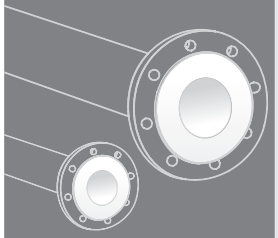

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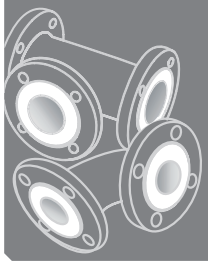

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R.N.I. No.: MAHENG/2002/08502

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Sanofi India Appoints Rodolfo Hrosz as the New Managing Director

Mumbai, India: Sanofi India Limited announced that its Board of Directors has appointed Rodolfo Hrosz as the Company's new Managing Director with effect from 1st June 2022, subject to regulatory approvals. He will transition from being Sanofi's General Manager, Consumer Healthcare business in Brazil to his new role in India as soon as the applicable regulatory approvals are in place. Rodolpho joined Sanofi as General Manager of the Consumer Healthcare business in Brazil in 2017 and has successfully led the organization through several transformative stages, right from the business unit's inception to its becoming a top growth contributor and a digital-acceleration reference point within the Sanofi Group.

Rodolfo brings with him a wealth of rich experience from commercial, marketing, and general management roles across several multinational companies. Prior to joining Sanofi, he has worked with Pfizer, LVMH, Heineken and Procter & Gamble in USA and in Brazil. Increasingly, companies are appreciating the value brought through diversity and inclusion. With Rodolfo at the helm as Sanofi India's new Managing Director, the Company is geared to mobilize energies, increase agility, and face the new challenges of our industry. His diverse global experiences, particularly in key emerging markets, are assets that will hugely benefit the Company's development.

Aditya Narayan Chairman of the Board, Sanofi India Limited "We are delighted to have Rodolfo Hrosz join Sanofi India as its Managing Director and look forward to his leading the team in the further development of the Company. His wide experience and diverse skills make him eminently suitable for this role and we wish him all the very best for every success in his new assignment."

Akston Biosciences Doses First Volunteers in Phase II/III Clinical Trial of Low Cost

Bangalore, India: Akston Biosciences Corporation, a developer of new classes of biologic therapeutics, announced that the first volunteers in Phase II/III clinical study of AKS-452, its low cost, shelf-stable protein subunit COVID-19 vaccine, were dosed in India. India's Central Drugs Standard Control Organization (CDSCO) approved the double-blind, placebo-controlled trial, initiated by Ahmedabad-based Veeda Clinical Research Limited, whose data will be submitted in an application for Emergency Use Authorization (EUA).

The multicenter trial will complete the enrollment of 1,500 healthy volunteers, age 18 and older, who will receive two 90 µg

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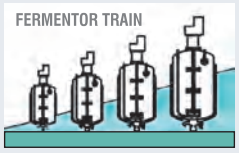

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doses 28 days apart. Under the supervision of six principal investigators (Pravin Dinkar Supe, M.D.; Krishna Giri, M.D.; Himanshu Pophale, M.D.; Prakash Shinde, M.D.; Shrikant Deshpande, M.D.; and Kuntal Shah, M.D.), the dosing of healthy volunteers will be completed by April 15, 2022.

Of the 1,500 healthy volunteers, 1,125 will receive the two-doses of vaccine, with the first dose including AKS-452 and an adjuvant, which primes the body's immune response, while the second dose will consist only of AKS-452. The remaining 375 will receive two doses of placebo with the first dose including placebo and the adjuvant, while the second dose will consist only of placebo. The primary objective of the study is to evaluate the safety, tolerability and humoral immunogenicity profile (i.e., SP/RBD-specific IgG titers) of AKS-452 at day 56, following a two-injection regimen in a combined bridging and a Phase II/III clinical study. Interim results of the Phase II/III trial in India are expected to be available in June 2022. This follows a successful 100-volunteer open-label bridging study by Veeda, which began in Nov. 2021.

AstraZeneca repositioning itself as a Global Innovation and Technology Centre in India

Chennai, India: AstraZeneca India Private Limited (AZIPL), the Global Capability Centre (GCC) of AstraZeneca announced that they have repositioned their Global Technology Centre (GTC) to focus on driving increased innovation, resulting in a rebrand of the centre to Global Innovation and Technology Centre

(GITC).

Siva Padmanabhan, Managing Director, AstraZeneca India Private Limited

Over the last eight years, the GTC in Chennai has consistently delivered market-leading IT services and capabilities for AstraZeneca's global business. Since inception, the centre has evolved its offering from that of traditional IT services, into a critical engine for AstraZeneca's digital journey and ongoing source of technology innovation. The Chennai centre has played a key role in driving productivity, simplification, technology delivery and innovation across AstraZeneca's business and in support of life-changing medicines delivered to patients worldwide. The rebranding marks the centre's evolution of capabilities, commitment to driving innovation and moving the company towards a digitally-enabled future.

Cindy Hoots, Chief Digital Office and CIO, AstraZeneca, said, "We live in an era where the possibilities of digital and technology to transform the lives of patients and

the healthcare sector, are limitless. Our centre in Chennai continues to play a strategic role in our digital transformation, working on Visualisation, Data & Analytics, Hyperautomation, XR/VR Capabilities, among other areas. These technologies and innovations play a key role in helping us to advance our science, anticipate patient needs, and work seamlessly across our organization. I am thrilled to see that the work delivered by the team in Chennai is being reflected in our transition from GTC to GITC."

Siva Padmanabhan, Managing Director, AstraZeneca India Private Limited (AZIPL), said: "The healthcare and life sciences industry is facing unprecedented challenges and opportunities. Over the last few years, we have successfully expanded our skillset and expertise from providing IT services, to becoming a pivotal global centre driving innovation and transformation. With close to 2,800 highly skilled employees, GITC is now one of the largest technology centres across the Life Sciences industry in the country. The strong collaboration we have been able to build between industry, academia and the government has helped us in our pursuit of enabling smart capabilities at scale across the company's value chain. Our GITC aims to bring the best of technology, innovation and people to the forefront, to address the ever-evolving healthcare and technology landscape. The rebranding is a powerful acknowledgement of the strategic importance our Chennai centre plays in our global operations."

Mankind Pharma Forays into the Agri-Tech Industry with the Launch of Mankind Agritech

Rajeev Juneja, Managing Director and Vice-Chairman, Mankind Pharma

New Delhi, India: Mankind Pharma, has announced the launch of Mankind Agritech Pvt Ltd. The company has entered into the ever-growing Indian agri-Input segment to use technological innovations in the field and bring its expertise to Indian farmlands and the Indian agriculture consumers, respectively. The decision behind foraying into this division is to assist Indian farmers by providing new-age technologies and helping farmers for the betterment of the rural sector.

With the launch of Mankind Agritech, the company will be providing crop care solutions to Indian farmers, including weedicides, insecticides, fungicides, plant growth regulators and biologicals. Mankind Agritech will work towards food safety for the country. The company will invest in the new

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technological tools and aims to deliver the same to the farmers to support them.

Announcing the launch Rajeev Juneja, Managing Director and Vice-Chairman, Mankind Pharma said, "We are happy to announce our launch in the Agritech domain with long-term investment plans with an initial 150 to 200 crore Capex infusion in the first two to three years. Mankind Agritech is committed to bring world-class crop protection technology to Indian farmers. Technology is playing a crucial role in ensuring the growth of the agriculture sector in India. Agritech has the potential to scale up the agricultural industry through technological intervention. If the farmers get the right products and tools they would be in a position to make an informed decision of using input and right technology. Mankind Agritech will ensure quality assurance to the farmers."

Sun Pharma to introduce its version of Vortioxetine in India

Mumbai, India: Sun Pharmaceutical Industries announced that one of its wholly-owned subsidiaries has entered into an exclusive patent licensing agreement with H. Lundbeck A/S ("Lundbeck") to market and distribute its own version of Vortioxetine in India under the brand name, VORTIDIFTM. The territory of the licensing agreement will only cover India.

Vortioxetine is a novel antidepressant with multimodal activity, which is approved to treat Major Depressive Disorder (MDD) in adults. The product is approved in over 80 countries1, including the US, EU, Canada and Australia. Kirti Ganorkar, CEO of India Business, Sun Pharma, said, "Sun Pharma is the leader in the neuro-psychiatry therapy in India and we always endeavour to bring innovative medicines that fill a need gap. MDD is a serious and complicated disorder and VORTIDIFTM will serve as an important novel treatment option for patients in India."

Canadian Jamp Pharma to invest ₹250 Cr in Hyderabad Facility

Hyderabad, India: Jamp Pharma Corporation, a Canadian generic drugs manufacturer, has commissioned its first overseas centre of excellence at Genome Valley in Hyderabad.

The company plans to invest ₹250 crore for the facility and generate 200 jobs locally. It has already invested ₹100 crore in the first phase and hired 80 workers. The second phase would be implemented over the next two years. The Hyderabad facility will contribute about 25 per cent of Jamp's total production in phase 1, the company said.

The centre of excellence is designed to manufacture pharmaceutical products as oral solids, powders, topicals, nasal delivery and oral liquids. The company plans to ready another manufacturing facility for nasal sprays within a year. "This major project would

never have been possible without the support and progressive government policies of the Telangana Government," Louis Pilon, President & CEO, Jamp Pharma Corporation, said in a release. "Jamp is committed to collaborate with the state of Telangana for future growth and activities', he added.

Avery Dennison Fortifies its Presence by Inaugurating Manufacturing Facility in Greater Noida

Gurgaon, India: Avery Dennison, a leader in global materials science and manufacturing, is to commence operations in its new state-of-the-art manufacturing facility in Greater Noida. Through this new facility, the company will be consolidating its manufacturing operations in order to better serve customer demands while optimizing the new technology and leveraging the improved efficiencies. A phased transition will take place for the facility and employees based out of Gurgaon plant over a period of time, as per business requirements. However, the corporate office of the company continues to be in Gurgaon.

Spread over an area of 12 acres, the new state-of-the-art plant will produce technologically-advanced, pressure-sensitive materials for the labeling and packaging industry and would incorporate best practices available across Avery Dennison globally. The new facility, whose land has been allotted by Yamuna Expressway Industrial Development Authority (YEIDA), will be equipped with the latest high speed coating technology and will have state-of-the-art coating and lamination lines, along with high speed sliters and sheeters.

Speaking on the occasion, Saurabh Agarwal, senior director and general manager, Label and Packaging Materials, South Asia for Avery Dennison said, "U.P. has emerged as a strategic business location, offering better connectivity and opportunities to serve key customers and markets. The new facility not only enhances our production capacity, but it further strengthens our company's position in the industry. This move is the culmination of the customer's increased demand as well as the potential India holds as a region. I'm extremely pleased that this achievement has taken place in the same year Avery Dennison is celebrating 25 years of doing business in India."

Speaking on this move, Mahesh Pathak, senior director, Operations, Label and Graphic Materials, South Asia Pacific and Sub Saharan Africa for Avery Dennison said, "This expansion is part of our long-term commitment to the Indian market, and our deep belief that it will offer enormous opportunities for the company and its ecosystem partners. The addition of this new greenfield facility in the North further strengthens our presence in the Indian market as well as in the Asia Pacific region." ■

The Evolutionary Drive of Biopharma Processing

Gaurav Kaushik
Managing Director & CEO,
Meteoric Biopharmaceuticals

Biopharma processing is a developmental series of steps to produce a biomolecule or biologics. This is the most accomplished form of modern biosciences which leads to the discovery and develop the most effective broad range of treatments for various diseases and disorders. This is more than a science rather than processing which designs and implement manufacturing process from a cell line to a milk drug substance. These are prescribed strategies of essential biopharmaceuticals which have let vaccine development on such a fast and large scale. Biopharma processing determines the quality exploration of a drug in a biotherapeutics arena. Reduction of cost and getting rid of over-dependency of equipment, improving quality & quantity, and handling large volumes up to tablets, pills, capsules, vaccines, pro-biotic development, biocatalyst, and antibodies have increased superior recognition of biopharma processing. Various FDA's

and regulatory institutions have also recognized that a well-defined biopharma has great potential to improve product quality and encourage the industry to come forward and intensify biopharma processing.

The biopharma process is the scientific production of a value-added material from a living source. The key component in the system is the source organism which is always alive and responding to the micro and macro environment. This way a well-defined biopharma adjusts the physiology of the source by maximizing efficiency in response to a comparatively minor change in its physical and chemical environment. A typical biopharma process is based on the controlled and optimized growth of microorganisms which encourages the production of a biological molecule that can be efficiently recovered at a high yield and economically beneficial format. Therefore, a well-defined biopharma process is considered as an evolutionary drive of an organism and its growing phase itself.

Biopharma process ability lies in the living organism to mutate and evolve, which also exists the potential of DNA molecules to change as per the biomolecule aspect of the organism. The mutational changes that arose in the biopharma process are beneficial to an organism and its favour to yield both quality and quantity, especially the characteristics of a quality biological.

Control of the environment is the key component of the biopharma process. More efforts are required in controlling the physical parameters therefore output in the biopharma process needs to be at greatest control considering the cost of the final product in the market. Secondary a well-defined quality control is required to be understood in the process therefore stringent controls and a more relaxed approach must be considered.

Inevitable operational challenges pertaining to machinery, equipment, its design, and other physical factors are essential to ensure performance in a consistent manner and its potential impact on bioprocess output. ■

3D Printing Methods Explored in Pharmaceuticals

Pankti Ganatra
Graduate Student, PhD (Tech.) Supervisor
Dr. Ratnesh Jain, Department of Chemical Engineering
Institute of Chemical Technology (ICT)

US FDA approved the first 3D printed pharmaceutical tablet Spiratam® in August 2015, which embarks a new era where the goal is to provide personalization through a digital platform (1). Historically, personalization was provided through compounding where drug ingredients are combined, mixed, and altered by the pharmacist to meet individual patients' needs (2). However, the trend completely shifted to bulk manufacturing and retail sales of pharmaceuticals post-1970. The major reason for the shift was to avoid compounding error and to set a standard process and quality parameters for pharmaceuticals with compounding limiting to specialized cases where commercial products were not available (2). With the advent of genomics in the pharmaceutical field, it is now clear that the "one-size-fits-all" approach of bulk manufacturing might not work as it is based on broad averages and does not consider critical factors like genetic profiles, age, race, gender, epigenetic and environmental factors (3). 3DP will enable pharmaceutical compounding to gain the lost ground in pharmacy practice with the pressing need for medication customization. It is a process in which the end product is designed using computer-aided software created in a layer-by-layer fashion. It delivers personalized precision medicines, along with the ability to choose optimal dose, appearance, flavor,

dosage form, and release profile, while also reducing the number of doses for each patient by custom-designed multi-drug dosage forms with customized release profiles of each contained drug (4,5,6). For example, patients with vision impairment can identify and choose appropriate medicine by either considering its shape and size or braille and moon pattern carved on the surface(6). In addition, the availability of various flavours, colors and shapes through 3D printing process makes the medication more attractive for paediatric patients and improves compliance (7). Opioids dosage forms with abuse deterring and alcohol resistant properties is possible with 3D which can be of great advantage(8). In addition, on-demand medicine printing prevents wastage to a great extent. It requires limited excipients and one or two manufacturing steps as compared to conventional bulk manufacturing where a variety of excipients are utilized for a multi-step process like mixing, sieving, granulation, drying, compression, coating, etc. to manufacture a tablet. Moreover, the cost of a 3D printer is lower as compared to other automated production technologies resulting in cost savings for the pharmacies while making medications safer for patients in special population groups (3). Since the entire process is digitally executed, it is possible to consistently achieve high accuracy, precision, and drug uniformity throughout dosage forms. Changes in formulation can be easily incorporated by changing the digital design (3D model) or ink deposition instructions. It is possible to 3D print quick response (QR) codes directly to the dosage forms which are known as data enriched edible pharmaceuticals. It conveys information such as drug dose, use, directions, side effects, pharmacy, patient, and date printed. This ensures that once a drug is removed from the packaging it still has the necessary information needed to prevent misuse or counterfeit production (10).

There are a few 3D printing methods that are widely explored in the pharmaceutical field viz. material extrusion, binder jetting, selective laser sintering, and stereolithography. The main challenge of the 3D printing technique is to convert the starting materials (drug and excipients) into a “curable ink” or a printable material (1). Thermoplastic polymeric filaments, pellets, hydrogel etc. are utilized as starting material based on the type of 3D printing method. Once the raw material is transformed into a suitable ink formulation, the next step of manufacturing a 3D object involves designing a digital model of the desired 3D product by special CAD software. The digital design is exported to the 3D printer in a readable format which is mainly a stereolithography (STL) file. A slicer (3D printing software) transfers the

Table 1: 3D printing methods used in pharmaceuticals.

Sr. no.	3D printing method	Mechanism	Pros	Cons
1.	Fused deposition modelling	Polymeric filaments or powder is melted by application of heat and deposited layer by layer	▪ Affordable-Suitable to prepare modified release dosage forms ▪ Requires minimal post processing	▪ Not suitable for thermolabile drugs ▪ Requirement for accessory equipment to make polymeric filaments
2.	Semi solid extrusion	Hydrogel is extruded through thin nozzle with the help of pressure in a layer-by-layer fashion.	▪ Preparation of ink is convenient and easy ▪ Attractive dosage forms like mouth dissolving film, chewable tablets, gummies, liquid filled jellies can be prepared	▪ Requires drying as post processing step ▪ water sensitive drugs are not suitable
3.	Binder jetting	Binder liquid is sprayed on the thin powder bed. The process is repeated with each layer	▪ Suitability in current FDA approved 3D printed medicine ▪ Minimal or no heat in processing ▪ Porous fast dissolving tablets are formed ▪ High amount of drug can be loaded	▪ Requires drying as post processing step
4.	Stereolithography	It involves exposing liquid resins to ultraviolet or other high-energy light source to induce polymerization reactions. It is also known as photopolymerization	▪ Faster method with highest resolution	▪ Limited raw materials suitable for this method
5.	Selective laser sintering	It involves sintering (partial surface melting and congealing) or binding of high-melting-point particles with a low- melting-point binder.	Rapid method	▪ Involves heat, not suitable for thermos labile drugs

STL file into a series of thin layers with the instruction tailored to generate the 3D object. In the end, the 3D product may require post-processing like removal of solvent residues, excess powder, polishing, sintering, etc. 3D products can be made from a single material or a combination of materials, where each material may be deposited by a separate print head or another deposition method. Drug dose and its release rate can be precisely modified by manipulating printing parameters such as the number of layers, fill density, print area, etc. Table 1 summarizes widely adapted 3D printing methods in the pharmaceutical field (3,11).

Similar to compounded medications, printed dosage forms require analysis to ensure that the intended product characteristics have been successfully printed through established standard formulation procedures. The need to analyze each custom dosage formulation/ medicine could delay the much-needed widespread implementation of on-demand 3D printing technology in pharmacy. Convenient analytical and predictive tools will need further development to fully enable customized medications with efficient timing relative to customized prescription receipt. Development of 3D printers and related programs specific to pharmaceutical compounding, comprising of built-in predictive and analysis tools, will improve the acceptability of 3D printed dosage forms. This will aid in revising the USP-NF preparation standards for printable 3D pharmaceutical dosage forms. (3). ■

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11. A new chapter in pharmaceutical manufacturing: 3D printed drug products

Borosil 'Enabling the Future of Science' by Leveraging Market Opportunities

Vinayak Patankar
Chief Operating Officer,
Borosil Limited, Scientific and Industrial Products
Pharma Packaging, Laboratory Equipment

What has been your strategy to establish Borosil as a Pharma packaging company and tell us about the latest technologies and strategies?

It started way back when we began by entering into the space of analytical vials. The analytical vials looked promising in terms of business growth if we entered as a structured player. We decided to partner with Klasspack Private Limited and today, we are the major stakeholders with around 85% of the stakes being held by Borosil. The ampoules and vials used in pharmaceutical injections grow at a pace of around 12% - 13%.

Since 2016, we focused on getting into key areas. The aim was to connect with all the major pharmaceutical players. The second thing was improving the capabilities in terms of infrastructure, machines, etc. The demand for the latest manufacturing machines gave rise to the need for inspection machines. We procured European machines as the conventional ways of inspection are humanized which leads to errors. Advanced technologies were cleared by most of the pharmaceutical industries and became a paving stone towards our success. For the last 3-4 years a 25% growth was observed that has laid down our plans for 2025. We

plan to execute aggressive strategies in terms of CAPEX for our pharmaceutical primary packaging business.

What is the current share that Borosil holds in this particular domain in India, vis-à-vis other international players and local players?

For our pharma packaging business, the current market size in India is around Rs 1000 crore. We aim to acquire 10% of the domestic market share and become 3rd largest in India by the next financial year. We are well prepared for the competition to drive the growth with a highly motivated sales and marketing team supported from the backend by experts in automation to achieve our goal.

What are the major challenges in this business?

Tubes are the basic raw material for this packaging industry that we have to procure from vendors. Schott Glass is one of the largest manufacturers of these tubes. This not only offers them a monopoly but also drives the pricing which becomes a major challenge for manufacturers like us who have to depend on the tubing vendors. One needs to understand that this is a low-margin business and requires effective skills to manage efficiencies at the backend to minimize wastage. This makes the selection of technology a critical point for consideration to maintain the tube to final product ratio.

Initially, we did face challenges to make inroads into this domain to qualify as a new vendor. We relied on world-class technologies & installed state-of-the-art machines to improve efficiencies & quality. We focused on delivering the best services in terms of both quality and service and are already working with some of the large brand names like Sun Pharma, P&G, Mylan. This industry thrives on word of mouth, we are quite confident with our journey ahead.

You are also busily expanding the business and operations of Pune and working with young engineers. Tell us your experience with that.

In SIP division verticals, the first is laboratory glassware which has been our business for the last 54 years. Another is in the Laboratory Instrumentation. In lab glassware, we have around 67% to 70% of the market share in India.

Our Greenfield project, Borosil Technologies Limited is aligned toward laboratory equipment & instrumentation. In 2018, we were hardly a team of ten engineers, moving to 75 in a few months, and today we have 150 engineers. We are focused on this particular project and aggressively investing in human talent. The brand LabQuest is for our Laboratory Instrumentation. The philosophy is when the Americans, Germans, Japanese, do their work they have a very set quality but for customers in India, that particular price point becomes expensive. We will maintain that quality and offer economical prices.

Give us an overview of the international markets, your stance in the markets in terms of this division, SIP division, Lab Products, and Lab Installments.

We started the export journey in 2012 with a focus on the international market with our available products and in 2013-2014 started exporting Laboratory Glassware to around 10 to 15 countries. Today, we export to around 70 countries in the world and have distributors appointed in these countries. Our export revenue has increased by 15-20 for the last 7-8 years. The price point is one of the reasons which gives us an edge because the Americans have an expensive price point but here they get the same quality at an economical price. This has been one of the reasons for manufacturing Laboratory Glassware, to create an infrastructure as good as the Germans. We follow the same German manufacturing quality standards and our backend engineers and employees at the Plant, are trained as per the German standards. We also had some German visitors and they could resonate the experience with their own which made us attain standard certification.

"We started the export journey in 2012 with a focus on the international market with our available products and in 2013-2014 started exporting Laboratory Glassware to around 10 to 15 countries. Today, we export to around 70 countries in the world and have distributors appointed in these countries."

What is Borosil's future road map, from Lab Instrumentation, and now with this primary Packaging facility, what are the plans for the next level?

Our major verticals of Laboratory Glassware, Pharmaceutical Packaging, and International Markets have been highly rewarding for the last four years. Pharmaceutical Primary Packaging has an interesting roadmap to get into prefilled syringes as many application-based people might start taking these injectables over the counter.

We are going to invest more in our export markets in terms of some strategic places to expand further. We wish to enter the two big markets of Europe and the US and establish a good customer base. We eventually plan to start our Warehousing and Logistics operations as part of our roadmap for 2025. In our last town hall meeting in December which brought together all general managers and heads, Mr. Shreevar Kheruka, Managing Director, Borosil Ltd, laid down the goal of becoming a sizeable company of around 4000 Crores by 2025. ■

mRNA Vaccines: UV/Vis Spectrophotometric Analysis

During the outbreak of the coronavirus disease COVID-19, mRNA (messenger RNA) vaccines evolved as efficacious vaccines. Research and development of these vaccines relies chiefly on their quality and equivalent action to a traditional vaccine approach, which can be assessed with advanced analytical techniques.

METTLER TOLEDO's UV/Vis spectroscopy is one such simple and widely used technique that can help determine the presence and quality of nucleic acids, one of the key components of mRNA vaccines. This document describes promising mRNA vaccines and the potential for UV/Vis spectro¬photometry to assist in the accurate and fast characterization of both raw materials and finished products throughout the R&D and manufacturing process.

Researchers across the globe are always working on new vaccines. However, this development process is long and complex. It may take several years to reach a point where a vaccine is determined to be efficacious and safe.

In the case of an emerging disease such as COVID-19, several years may be too long to wait. Therefore, all technologies and processes that can help shorten time-to-availability need to be considered. As you will see in the following pages, UV/Vis spectroscopy is a technology that can provide a solution for characterization of vaccines, their components, and raw materials.

Mettler Toledo FastTrackTM UV/Vis Spectrophotoscopy

UV/Vis spectrophotometry is a well-established analytical technique used in life science and pharmaceutical laboratories.

Spectrophotometers are popular due to their simplicity and ease of use, as well as the quality of information they provide. The use of these reliable tools has become a standardized analytical method in pharmacopoeias, and they are used daily in analytical laboratories around the world.

Usage of UV/Vis Spectrophotometer in Quality Control of mRNA Vaccines

The nature and composition of mRNA vaccines make them inherently difficult to characterize. Characterization of vaccine components is also a challenge in R&D, pilot production, manufacturing, quality control, and control pre- and post-sale.

UV/Vis spectrophotometric determination is considered a standard method for determination of nucleic acid content. In addition, it can be used in the analysis of bacteria, enzymes, proteins, nucleotides, plasmids, as well as for purity/impurity profiles of raw materials such as ethanol and sucrose. This flexibility along with ease of analysis has made it an analysis of choice for characterization of both final vaccines and various vaccine com¬ponents across the development chain.

COVID-19 vaccine manufacturers and quality control departments are sharing information about the analytical techniques that are helping them to standardize vaccine quality. According to international pharmacopoeias including the European Pharmacopoeia (Ph. Eur.),

United States Pharmacopoeia (USP), Japanese Pharmacopoeia, and the British Pharmacopoeia, UV/Vis spectrometry is a classical method for physicochemical characterization of vaccines that is being put to use in COVID-19 manufacturing research.

The METTLER TOLEDO UV/VIS Excellence spectrophotometer series (UV5, UV7, UV5Bio and UV5Nano) can assist with in the synthesis and characterization of vaccine and raw materials. The advantages of METTLER TOLEDO UV/VIS Excellence spectrophotometers are as follows:

UV/VIS Excellence spectrophotometers can determine all chemical components of a vaccine or vaccine raw material if:

- The sample absorbs or transmits distinctly within the UV or Vis region (spectral range 190–1100 nm)
- The sample is a clear and transparent liquid or a transparent creaseless solid
- The sample is turbid but needs to be measured for its absorbance
- The color sample & dye based analysis also performed ■

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New Age Evaporation System (Natural Evaporator) For Zero Liquid Discharge* an Environment Friendly Solution for Liquid Waste Disposal

Makarand A. Chitale, Director (Technical), Mist Ressonance Engineering Pvt. Ltd.

We all know that Industrialization is very much essential for our economy and growth of the society. However, it is also necessary to keep balance of nature & maintain a pollution-free environment. Hence, A few years ago, Government of India declared Zero Liquid Discharge Policy for process industries. This means that any process industry, which is using water as its auxiliary must consume or reuse the water in its process. Any form of liquid which can pollute our rivers/water source should not be discharged outside the premises.

This mandate forced the process industries to use the conventionally known Zero Liquid Discharge Technologies, which use large Multiple Effect Evaporators that consume high amount of steam/ coal. Their capital expenditure is also very high & at the same time their OPEX is also enormously high. So it was not possible for the small/medium sized industries to adopt this technology. Many industries still throw the dirty effluent water/ RO reject to open water sources/rivers thus polluting precious water or harm aqueous life.

Hence it was necessary to find a technology which will be affordable to all size of industries and environment friendly.

MREPL is glad to announce that they have developed New Age Evaporator System (Natural evaporator) for Zero Liquid Discharge of RO Reject / Effluent, which

use minimum utilities like steam/coal/ electricity. Effluent/RO reject is naturally evaporated by their unique patented technology of Mist creation with or without help of waste heat available in the plant. This helps the industry to adopt this system at minimal OPEX

compared to conventional system & even its first investment is about 50% or less in comparison to MEE.

In the year 2016, MREPL received the prestigious "G. S. PARKHE INDUSTRIAL MERIT AWARD" given by MCCIA for Innovation in Entrepreneurship. The Award was received for our Technology of Mist Creation & its application in Zero Liquid Discharge of RO Reject / Effluent. Since then the system has been successfully implemented at many process industries.

Technology of New Age Evaporator System

NEW AGE EVAPORATOR SYSTEM is a high efficiency system, which works on our Mist Cooling Technology which induces water to intensive atomization i.e. water particles are subdivided to around 5 microns. The atomized particles shoot out of MIST-CREATOR NOZZLES at immense speed and rise to a height of 6 meters above the nozzles.

This ensures extensively large surface area for a longer interval and at high velocity providing a mist formation. Surface evaporation is very fast, faster than the time needed to reach equilibrium. This ensures faster evaporation of water and the effluent water starts concentrating.

It is very important to note here that, this evaporation is carried out inside a closed chamber in most cases & hence pure water vapor goes away from top through Mist Eliminators thus achieving Zero Liquid Discharge.

Mist creator nozzles operate with a choke-less design as mist formation is achieved when water comes out in whirling motion through its bore of size more than 16 mm in diameter. Hence, NAES can easily handle RO/Effluent water of TDS up to 40% concentration without any choking.

Mist Evaporation Effect:

As effluent water passes through Mist Evaporation System at very high velocity due to our patented nozzle design, it atomizes the water particles to fine mist to the size of 5 micron. As these fine mist particle come in contact of large air surface area, they tend to absorb heat available in ambient air and hence evaporate instantaneously to a large extent. We have observed this natural evaporation is appx. 18% in a day (Annual Average). This is additional evaporation due to natural mist evaporation effect combined with solar evaporation. This natural evaporation reduces actual heat required in heating tank.

New Age Evaporation System for Zero Liquid Discharge:

Based on our MCS technology, we have developed a unique Mist Evaporation System for Zero Liquid Discharge for effluent water. Here we use special Mist creator nozzles of patented design to create Mist of size 5 microns. We heat up the effluent water in a tank with waste heat available in the plant/Solar heat source and is evaporated by our Mist creator Nozzles and cooled down and is again heated. This heating and cooling cycle continues and thus in every cycle part of water is evaporated and balance quantity is taken in the tank. In the cyclic way we can evaporate up to 40% concentration. Final balance sludge can be taken out for any drying process viz. filter press, decantor, ATFD etc.

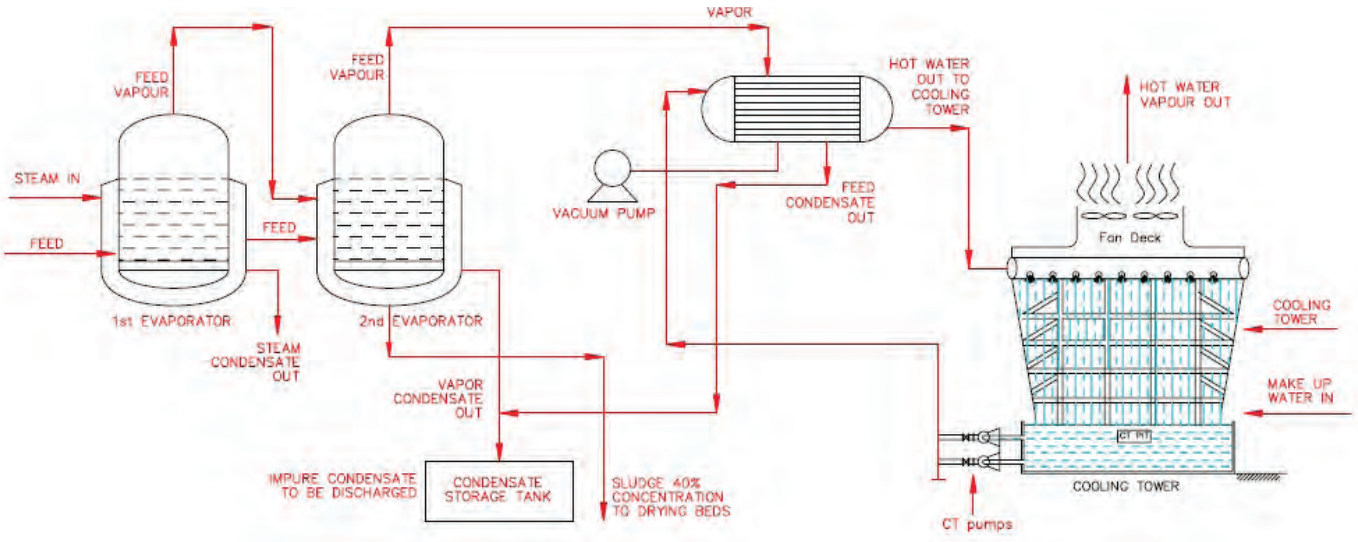
It must be noted here that the above operation is entirely carried out inside a closed chamber where air is taken through louvers from sides & pure water vapor escapes from top through a canopy with mist eliminators.

Salient Features of Naes Over Conventional Systems (Mee/Mvcm):

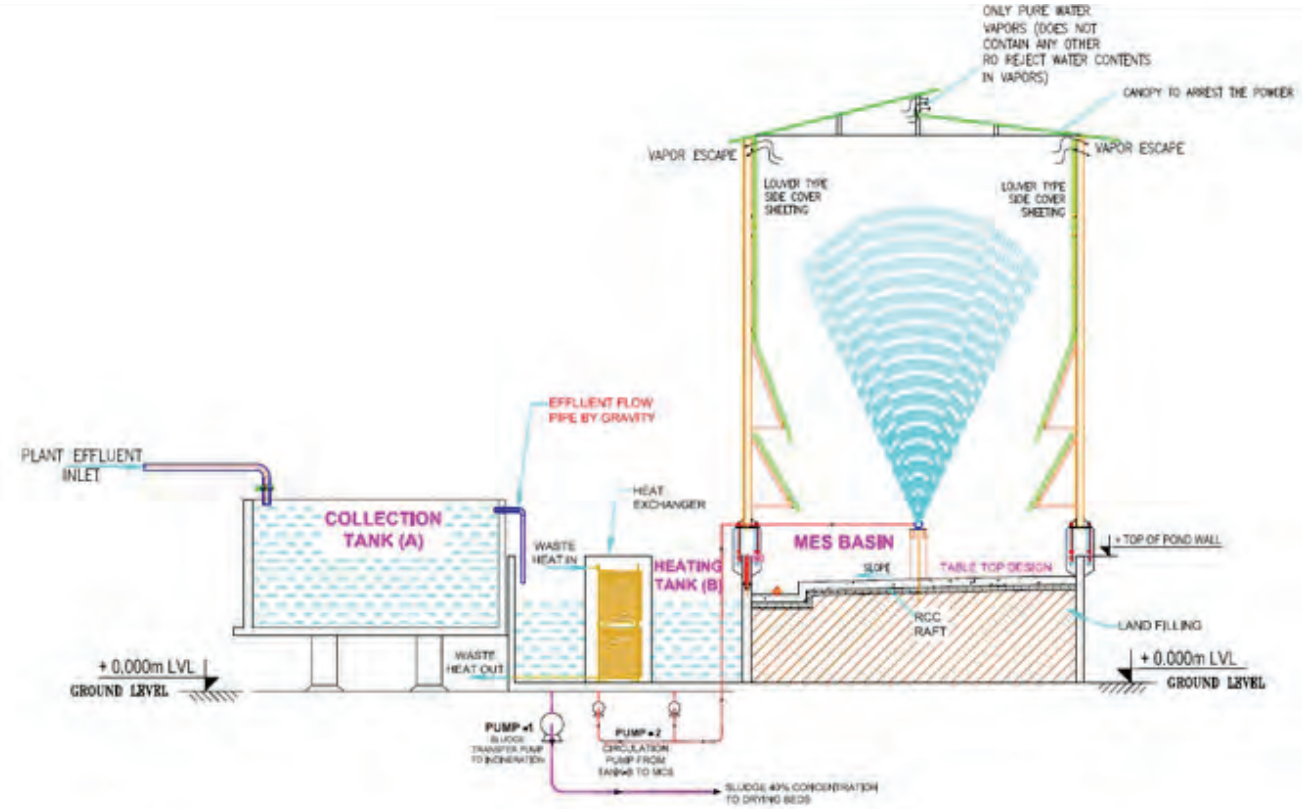
- Minimal OPEX due to Natural Evaporation.
- Lower CAPEX.
- Entire operation happens inside a closed chamber only allowing pure water vapour to escape thus acting as a Natural evaporator.

Comparative Diagram of Conventional Mee System & New Age Evaporator System For Zero Liquid Discharge

A) Schematic Drawing For Conventional Multiple Effect Evaporator (Mee) System



B) Schematic Drawing For New Age Evaporator System For Zld



Naes V/S Conventional Multiple Effect Evaporators with Various Options

Sr. No.	Description	Conventional MEE System	MES with natural evaporation – without using any heat source	MES with waste heat source viz. Hot air, hot water, flash steam, flue gas etc.	Mist Evaporation System with live steam as heat source throughout the year
1	Capacity (KLPD)	10	10	10	10
2	Salient features a) Water Consumption b) Waste Water Generation c) Civil Work d) Maintenance	a) Make up required for CT b) Impure 50˚C condensate generated is to be disposed. c) Heavy due to static and dynamic load d) Very high	a) No Make up required b) No excess /impure condensate generated. c) Simple due to table top construction with static load. d) Negligible	a) No Make up required b) No excess /impure condensate generated. c) Simple due to table top construction with static load. d) Less	a) No Make up required b) No excess /impure condensate generated. c) Simple due to table top construction with static load. d) Less
3	Operational Cost/KLPD	Rs. 1000/KLPD	Rs. 100/KLPD	Rs. 80/KLPD	Rs. 500/KLPD
4	Saving on OPEX	Nil	Rs. 900/KLPD	Rs. 920/KLPD	Rs. 500/KLPD
5	Initial Cost	High	Low	Low	Low
6	Plot size	3 m²/KLPD	10 m²/KLPD	6 m²/KLPD	6 m²/KLPD

- Negligible maintenance due to choke less design of nozzles.
- Vacuum and cooling system is not required.
- No make-up water required.
- NAES achieves complete zero liquid discharge as the process does not produce impure condensate which is generated by conventional MEE which is to be disposed.
- Easy to operate.

Types of New Age Evaporator System (Naes):

Open Type NAES:

Where area is available, MREPL can guarantee complete Natural evaporation of effluent/RO reject by our high efficiency Mist Creation System installed in Open basin.

Totally enclosed NAES for Salt concentration/ Zero Liquid Discharge:

NAES is closed from all sides up to 7 meter height by louversand by canopy/ mist eliminators at the top.Entire operation happens inside a closed chamber with top covered with Canopy/ Mist Evaporators. This allows only pure water vapour to escape from top & avoid carryover of any mist particle or impurities and also arrest entry of rain water.

This technology will now help any size of industry to adopt Zero liquid discharge policy easily and preserve nature. ■

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When Renting is the Best Option

Capital expenditure and investment in water infrastructure are critical to maintaining an ongoing high-quality supply, but when might it be better to rent equipment instead of purchasing it?

The pharmaceutical sector is a major water consumer and relies on treatment processes to ensure a safe and secure supply of purified water that meets and exceeds stringent quality and quantity demands. The industry is highly regulated by supervisory bodies such as the United States and European Pharmacopoeia, and every manufacturing facility has a User Requirement Specification (URS) defining feed-water quality, volume of water and necessary purification steps. Purified water is used in a variety of applications, from production to cleaning reactor vessels and facilities require a continuous, reliable supply that mitigates the risk of microbial growth and the deterioration of water quality.

The US and European Pharmacopoeia highlight three key measurable variables in water treatment: conductivity, Total Organic Carbon (TOC) and bacteria levels. Water purification for pharmaceutical manufacturing is a multistage process, with reverse osmosis (RO) and continuous electrodeionization (CEDI) forming the two core processes to reduce conductivity and TOC. Invariably, pretreatment is required for most raw water to protect the RO and CEDI units. This usually includes softening and some form of free chlorine removal. Some customers may choose to install an additional post-treatment process, such as ultrafiltration (UF) steps to remove endotoxins from the water or an ultraviolet disinfection unit as an extra precaution to kill any prevailing bacteria that may have passed through the system.

Further pretreatment purifications steps may also be necessary, depending on the hardness of the raw water supply. For example, water from Suffolk and Norfolk in the UK has a very high conductivity — around 1,000 µS compared with 80–120 µS in Scotland. The US Pharmacopoeia calls for water conductivity to be less than 1.3 µS at 25°C, requiring significant pretreatment of the raw water supply prior to RO and CEDI.

Finally, preventing dead legs and ensuring that water is kept moving, as well as using hot sanitizable equipment, are key steps to ensuring that the quality of water is maintained, and bacterial

growth is minimized. Once a plant has been installed, the U.S. Food and Drug Administration, European Medicines Agency or other equivalent region-specific agency audits the facility to see that drug production complies with regulations, and that companies are meeting the day-to-day monitoring and sanitization procedures.

It is essential that a facility can rely on the quality of water from its purification system, as a single product batch voided by impure water can represent a loss in revenue in the region of one million euros. The potential disruption and financial impact caused by out-of-specification water quality means that planned equipment maintenance is extremely important. The arrival on the market of rentable, skid-mounted mobile water systems can offset this disruption and provide a source of pharmaceutical-grade water during planned maintenance or a facility upgrade to support continued production.

Plants for hire

During the last decade, an increasing number of companies have created a demand for long-term equipment rental, particularly in cases when the return on capital investment will not be met during the lifetime of the project, and especially if it is a period of less than five years. A multi-year "pay-as-you-go" scheme may be the most suitable option, providing a more cost-effective approach to water purification, and enabling the water system to be covered by the operations budget, leaving the capital available for core investments.

In cases when capital investment is the most sensible route, a mobile system can still meet the additional requirements in the interim period between increased demand and a permanent solution being installed. A complete turnkey project can take up to 10 months from initial installation to completion, followed by validation, including performance qualification steps that can take up to six months depending on the size of the system. Mobile water systems are already fully validated and can be introduced into the main water purification supply in a two to three-week timeframe.

A final benefit afforded by the rental market is the opportunity for companies to conduct production trials as they monitor the effect of water quality on their manufacturing processes. Temporary treatment plants provide a cost-effective means of finding out whether making a substantial capital investment is worthwhile.

In practice

In one instance, a client needed to increase production in response to market demand, and its existing water infrastructure could not meet the water requirements and necessary validation. In another example, a supplier of

pharmaceutical-grade plastic foam needed to improve water quality and validation in response to the demands of a multinational client.

Flexible hire periods and a pay-as-you-go system, combined with full service and maintenance support, provided an ideal solution in both situations.

New way of thinking

The rental model may be new to the water technology market, but there is a solid business case for many pharma companies to opt in, whether to cover planned maintenance, deal with an increase in production or simply as a more cost-effective solution during shorter-term projects. Increased options and flexibility in the water technology market can only help to provide the reassurance pharmaceutical companies need that their supply of pharma-grade water is safe, secure and can reliably support continuous production as recognized by the International Society for Pharmacoepidemiology (ISPE). ■

Contributed by:
Veolia Water Technologies

Rigorous Thermal Analysis for cGMP Data Integrity Compliance

AMRI, an analytical service provider with a global footprint, has responded to industry demand for its cGMP services by adopting METTLER TOLEDO's thermal analysis instruments — to meet recently updated regulatory data integrity standards.

Over the past 25 years, AMRI, SSCI have provided comprehensive research and current Good Manufacturing Practice (cGMP), analytical services to characterize solid forms, particularly pharmaceutical APIs and drug products. AMRI trusts METTLER TOLEDO TGA and DSC instruments for its analyses. Proper calibration of these instruments and validation of the results follows the ultra-modern state of art of the cGMP. Mettler Toledo provides an exceptionally helpful tool for the study of active pharmaceutical intermediate and ingredients under cGMP conditions. Mettler thermal analyses (TA) produce highest quality data for quantification of polymorphic drugs and excipients as well as represents a solid platform for the development of thermal methods to obtained correct information concerning the thermodynamic relationships between phases, for the proper selection of salt and crystal forms.

"Our scientists solve highly complex solid-state problems for our clients using techniques like TA. These new instruments give us the ability to develop high-quality, cGMP methods that meet current data integrity regulations," said Jon Selbo, Ph.D., General Manager and Site Head (AMRI,

West Lafayette, IN, USA).

Built-in 21 CFR Part 11 functionality

A major focus in modern GxP laboratories is ensuring that electronic media meet updated regulatory data integrity standards. AMRI employs METTLER TOLEDO's STARe TA software for this purpose; STARe's CFR option is designed to help companies achieve compliance with 21 CFR Part 11 or related EU regulations by affording users the following mandatory technical controls.

- Password-protected access to the application
- User management and user rights
- Change log and system history captured in an audit trail
- Electronic signatures to indicate the status

A secure and integrated database

Even with the appropriate technical controls in place, data integrity issues frequently arise from inadequate data storage, such as files in operating system directories; these are vulnerable to deletion outside the application, and if the audit trail is contained in the data file, it cannot monitor its own deletion.

The STARe database system avoids such data integrity breaches by automatically storing and linking all records in a secure, protected data archive. In addition, electronic records have been protected against modification since the software's initial introduction in 1993.

"The database structure and updated STARe software, and the close working relationship between METTLER TOLEDO and AMRI, streamlined computer systems validation activities," said Susan Bogdanowich- Knipp, Ph.D., Director of Analytical Technologies at AMRI's West Lafayette site. "The software meets the current criteria for 21 CFR Part 11 data integrity compliance and enables us to continue to provide high-quality, cGMP-compliant thermal data to our clients." ■

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AI Advancements Promising Agility, Accuracy & Efficacy in Drug Discovery

Dr. T.N.G. Sharma
Manager
Federation of Asian Biotech Associations (FABA)

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

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

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

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

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

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

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

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

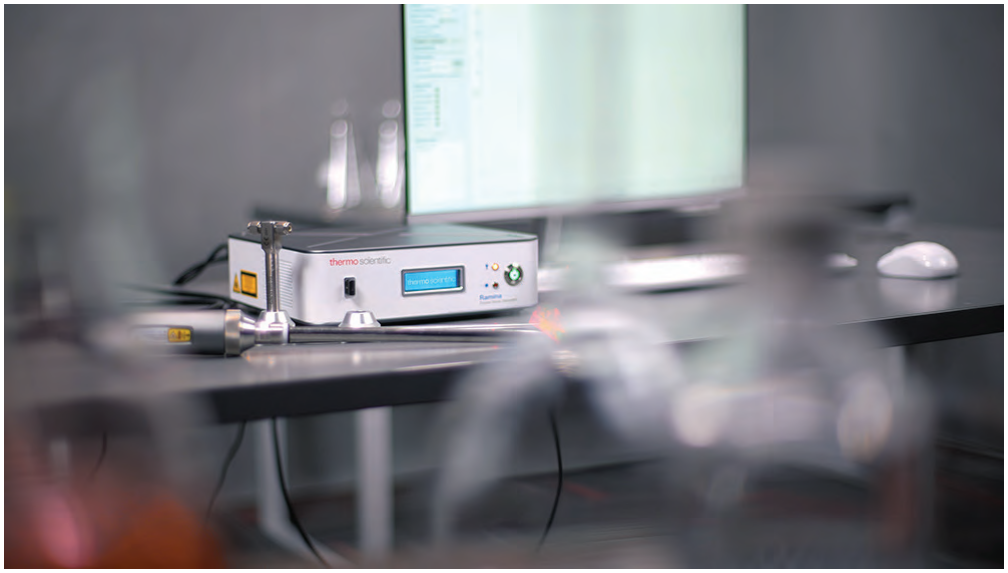
As regulatory agencies mandate improved traceability of data, enhanced quality of the complex processes and supplier networks within the industry creates pressures that manufacturers must address, for which they require new or more advanced technologies which can fulfill unmet analytical needs, ranging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

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

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

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

Thermo Fisher Scientific Launches User-Friendly Raman Spectroscopic Analyzer



Thermo Fisher Scientific Inc. announced the release of a new Raman spectroscopic analyzer for process monitoring for a variety of applications, including biopharmaceutical manufacturing. The Thermo Scientific Ramina Process Analyzer offers non-destructive and continuous analysis without the need for sample preparation, with rapid system setup and deployment in as little as 15 minutes to generate spectral data on target analytes within seconds.

This easy-to-use system is designed to eliminate the complexity of performing Raman spectroscopy measurements, making the technique accessible to all levels of user experience while maintaining high precision and accuracy. The compact system utilizes a range of patented probes to maximize the speed and sensitivity of results, enabling fully automated in situ measurements to calculate concentrations in a reaction vessel.

The Ramina Process Analyzer offers a rapid and easy-to-use alternative to offline manual or automated wet chemistry testing, and is simpler to install and use compared to traditional Raman process monitoring systems. Ramina comes with everything the user needs to start collecting data, including a Raman spectrometer and fiber optic probe, as well as a portable monitor, mouse, keyboard and laser safety goggles. Factory calibration ensures the Ramina system is ready to use without delay, and its solid-state construction offers long-term stability, meaning users can enjoy continuous, highly accurate measurements without frequent calibration. Users can also use multiple systems in parallel to test different reaction vessels simultaneously, or combine a number of probes in one vessel. ■

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R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month.

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