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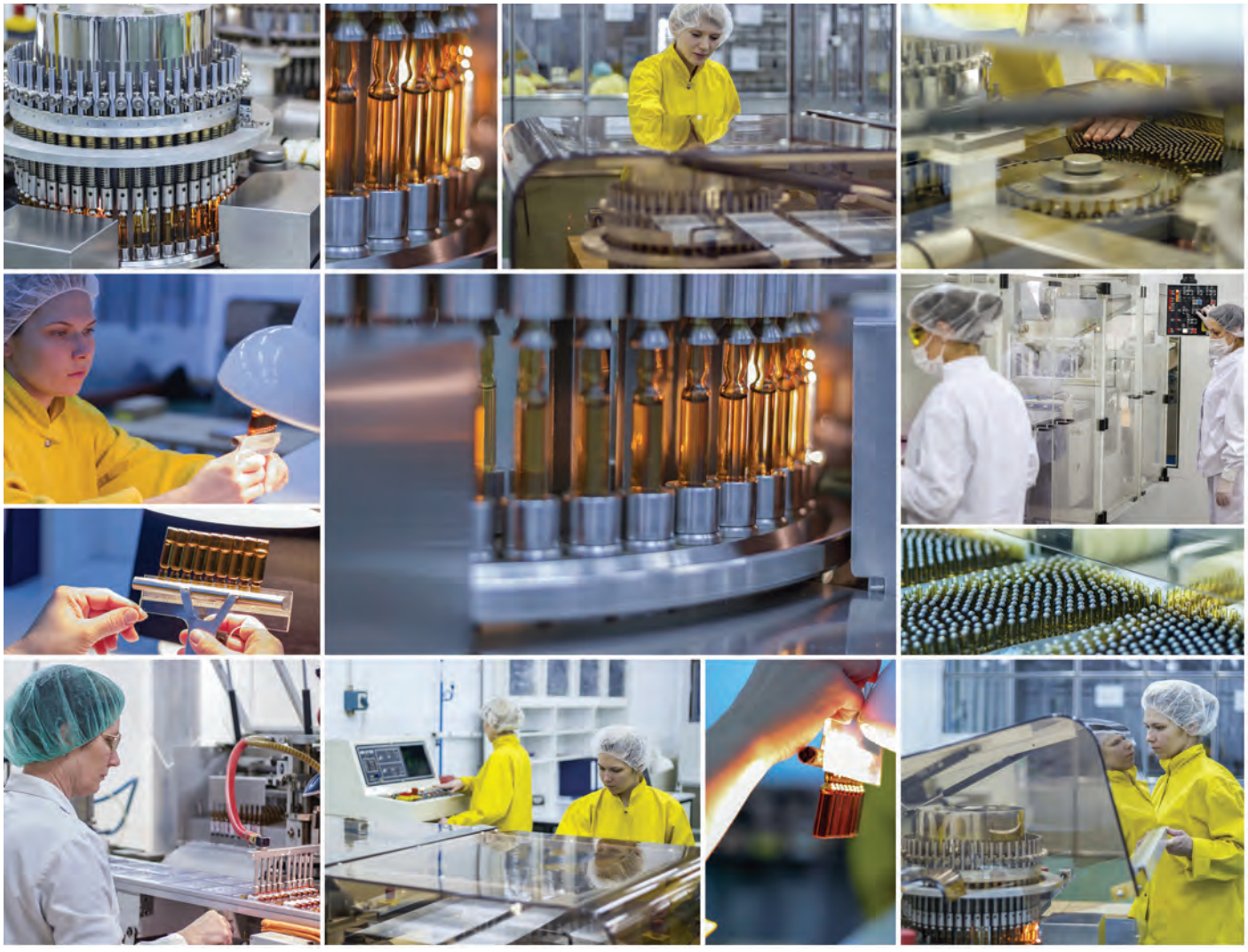
PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

Evolving Packaging Trends Across Pharma Value Chain



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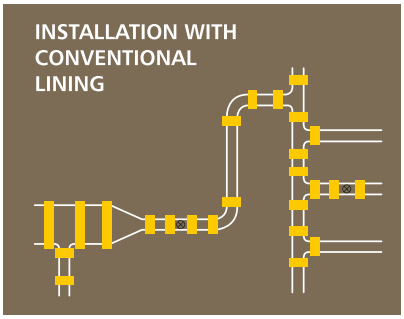

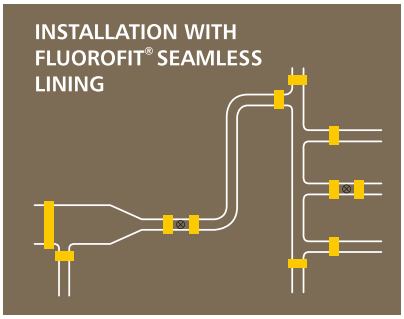

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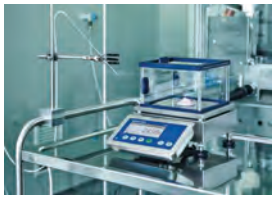

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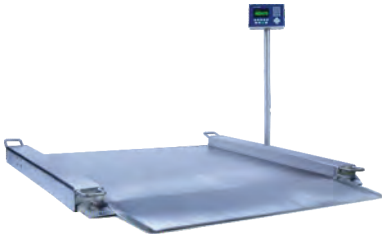

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BioMed X Institute and Merck Extend Collaboration Of Novel Research in Oncology and Autoimmunity

Christian Tidona, Founder and Managing Director BioMed X Institute

Heidelberg, Germany: BioMed X, a leading independent biomedical research institute, today announced the extension of its ongoing collaboration with Merck. Under the new agreement, Merck will start up to six additional research projects at the BioMed X Institute, building on ongoing research projects in the fields of oncology (DNA damage response and RNA splicing) and autoimmunity (intestinal epithelial barrier in autoimmune diseases). The next joint global crowdsourcing project will explore mechanisms of immune senescence and mitochondrial dysfunction in regulatory T cells and other T cell subsets that are shared in human autoimmunity and aging.

"We are very grateful for the trust and support we received from Merck over the past eight years since we started our collaboration," Christian Tidona, Founder and Managing Director of the BioMed X Institute said. "This new agreement with Merck is a great validation of our unique innovation model, showing that it delivers sustained translational value to the early R&D pipelines of our pharma partners."

Merck was the first pharma company to enter a partnership with BioMed X, beginning in 2013. Since then, the partnership has steadily grown and the previously initiated research projects have led to 25 scientific publications on topics such as in-silico design of selective kinase inhibitors, myeloid-derived suppressor cell activity, Golgi stress, and DNA damage, as well as several new potential drug target genes which have been further investigated in pre-clinical studies at Merck.

Aceto Expands Life Science Manufacturing with Acquisition of Finar Limited

Port Washington, United States: Aceto, a leading global provider of specialty materials for life sciences and advanced technology end markets, announced today the acquisition of a majority stake in Finar Limited. Finar is a leading manufacturer, supplier, and distributor of pharmaceutical excipients, lab chemicals, aquaculture inputs, and food grade additives. The acquisition complements Aceto's growth strategy, enhancing and expanding the company's manufacturing footprint, R&D capabilities, and quality expertise.

"We are excited to bring together Finar and

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Amit Maheshwari, CEO, Finar Chemicals

Aceto to give customers of both companies more solutions to support their supply chains globally," said Gilles Cottier, CEO of Aceto. "With the Finar team's help, we continue to strengthen our manufacturing expertise and expand our product offerings for the pharmaceutical, biopharmaceutical, and vaccine end markets."

Finar manufactures high quality pharma ingredients including GMP/Pharma grade solvents, advanced intermediates, and GMP excipients used in both small and large molecule applications. Finar provides customers complete regulatory & documentation support including Drug Master Filing and has a strong R&D team with expertise in developing specialized excipients for complex formulations. The company is based in Ahmedabad, India.

"We're weaving together an exciting story of growth with the acquisition of organizations that not only enhance our R&D and manufacturing capabilities but also align with our customer centric philosophy," added Gilles Cottier. "Finar's established reputation as a partner and supplier to the global pharma industry and commitment to producing high quality products, mirrors Aceto's guiding business principles and is complementary to our other recent acquisitions of Syntor, A&C and IsleChem."

"We live by our motto of consistently providing customers high-quality products and exceeding their expectations," said Amit Maheshwari, CEO of Finar Limited. "Both Finar and Aceto create long-term relationships with customers by providing best-in-class customer service and treating each customer with integrity and respect. These attributes are an important part of our company culture and we appreciate that Aceto shares this business philosophy. We look forward to providing our combined customers with access to our manufacturing expertise and diversified product portfolio."

Dr. Reddy's Laboratories Gets Emergency Use Authorisation for Sputnik V in India

Hyderabad, India: Dr. Reddy's Laboratories Ltd. announced that the first consignment of imported doses of the Sputnik V vaccine that landed in India on 1st May, 2021, received regulatory clearance from the Central Drugs Laboratory, Kasauli. As part of a limited pilot, the soft launch of the vaccine has commenced and the first dose of the vaccine was administered in Hyderabad.

Further consignments of imported doses

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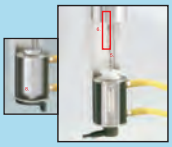
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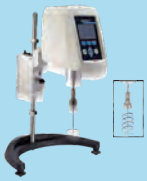
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RHEOLOGY VISCOSITY TEXTURE IN-LINE POWDER MOISTURE GAS

are expected over the upcoming months. Subsequently, supply of the Sputnik V vaccine will commence from Indian manufacturing partners. The imported doses of the vaccine are presently priced at an MRP of Rs 948 + 5% GST per dose, with the possibility of a lower price point when local supply begins. The Company is working closely with its six manufacturing partners in India to fulfill regulatory requirements to ensure smooth and timely supply.

Dr. Reddy's will work closely with stakeholders in the Government and private sector in India to ensure the widest possible reach of the Sputnik V vaccine as part of the national inoculation effort. This is a reaffirmation of the Company's commitment to explore every avenue in the fight against the COVID-19 pandemic in India.

G V Prasad, Co-Chairman and Managing Director, said: "With the rising cases in India, vaccination is our most effective tool in our battle against COVID-19. Contributing to the vaccination drive in India is our biggest priority right now to help Indians be healthy and safe."

Vectura And Inspira Pharmaceuticals To Develop Potential Inhaled Treatment For COVID-19

Chippenham, UK : Vectura Group plc, an industry leading inhalation CDMO, and Inspira Pharmaceuticals Limited, a new UK-based company focused on developing therapies for respiratory and infectious diseases, announced an agreement to develop an

Rory McGoldrick, CEO, Inspira

inhaled formulation of Inspira's lead drug candidate for the treatment of COVID-19.

Inspira's research focuses on proprietary IPX formulations, which are based on processed and purified extracts from a plant source. These extracts contain proteolytic enzymes that have been shown to rapidly inactivate the SARS-CoV-2 virus in vitro. The IPX technology platform has additional potential applications in other lung infections and treatment of biofilms associated with respiratory disease.

To date, Vectura has undertaken a feasibility study on Inspira's inhaled IPX formulation candidates with positive results. This new agreement will see the company perform further testing and development work, to prepare initially for Phase 1 clinical studies using its FOX® vibrating mesh nebuliser to deliver the IPX formulations directly to the lungs

"We are delighted to have partnered with Vectura, a company with a strong track

record in the successful development of pharmaceuticals for respiratory indications. Leveraging Vectura's expertise and network, Inspira is well placed to accelerate the development of our novel IPX formulations for pulmonary delivery. As we move from pandemic to endemic COVID-19 it will be ever more important to have new treatments that are cost effective, easy to distribute and easy to administer. We are targeting a treatment that has the potential to be effective at the early phase of infection, to minimise the risk of hospitalization and reduce the need for ventilatory support in intensive care. We hope that our human clinical trials of IPX formulations will prove as successful as our initial laboratory studies," **Rory McGoldrick, CEO of Inspira** commented.

Mark Bridgewater, Vectura Chief Commercial Officer commented: "The work carried out by Inspira demonstrates the potential to develop a highly-effective treatment for COVID-19, and our initial studies show that our FOX nebuliser offers an extremely efficient delivery method. We are excited to continue supporting Inspira on this lead programme's development towards the clinic, combining our expertise of formulation and device development with Inspira's innovative research to add to the treatments available to manage this global pandemic disease."

All studies will be undertaken at Vectura's Chippenham, UK facility, which is home to advanced pharmaceutical development laboratories, manufacturing suites and offices where the company's differentiated technology and skills are used to develop customers' inhaled products, from high quality generics to novel therapies.

Glenmark Pharmaceuticals Receives ANDA Approval For Single-Dose Prefilled Syringe

Mumbai, India: Glenmark Pharmaceuticals Limited (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Icatibant Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe, the generic version of Firazyr 1 Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe, of Shire Human Genetic Therapies, Inc. This marks Glenmark's first synthetic decapeptide injectable approval and will be manufactured in their North American manufacturing facility based in Monroe, North Carolina.

According to IQVIATM sales data for the 12 month period ending March 2021, the Firazyr Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe market2 achieved annual sales of approximately $223.4 million*. Glenmark's current portfolio consists of 172 products authorized for distribution in the U.S. marketplace and 44 ANDA's pending approval with the U.S. FDA.

In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

Dishman Carbogen Amcis Limited Records 3% Growth, 529 Crore Net Sales

Bavla, India: Dishman Carbogen Amcis announced the Net Revenue at Rs 5,293.2 mn in Q4 FY21 up by 3.4%. YoY CRAMS revenue declined by 1.9% YoY primarily due to -CRAMS India revenue decreased due to past EDQM observations but on account of certain successful customer audits and production of certain complex intermediates, this is expected to improve going forward. CRAMS Carbogen Amcis AG revenue increased by 23.1% due to increase in commercial revenue during the quarter. Marketable Molecules revenue increased 21.2% YoY primarily due to - Carbogen Amcis BV revenue increased by 12.0% due to increase in sales of cholesterol segment

EBITDA Margin at 16.7% in Q4 FY21 due to- Negative margins in CRAMS India due to decline in production on account of EDQM observations. Margins at Carbogen Amcis BV decreased in Q4 FY21 to 26.0% compared to FY21 average of 32.2% due to lower share of revenue from Vitamin D analogues

The financial results for QIV and full year FY 2021, contained two one offs -Deferred Tax Liability expense of Rs. 962.8mn on account of the change in Tax law relating to goodwill depreciation from 1.4.2020.

There shall not be any cash outflow on account of this and this liability will reverse in the future years. One time impairment of inventory of CHF 2.77mn due to one project cancellation at Carbogen Amcis AG. Capital expenditure for FY 2021 was approximately USD 49.31 mn, which includes majorly growth capex related to the planned expansion in Switzerland and France. Net Debt excluding lease liabilities was USD 101 mn as on March 31, 2021 against USD 100 mn as on March 31,2020.

Funds raised in the Offer for Sale undertaken by the promoter shareholder entity have already been infused in the company to the extent of Rs. 72 crores.

Some of the Business Highlights are pertaining to the issues raised by the European drug regulator (EDQM), the company received the Final Audit Closure Report from EDQM in October 2020, wherein the company's approach to remediate the deficiencies were considered as being appropriate.

The company has a strong basket of about 16 APIs in Phase III development. The company is focused on improving its capacity utilization at its manufacturing facilities by targeting small and mid-sized global biotech companies and diversifying across new geographies.

Recently, the company's Switzerland-based subsidiary, Carbogen Amcis AG, , announced a joint funding agreement with a longstanding Japan-based customer to build a site extension at the Bubendorf site in Switzerland.. Carbogen Amcis will produce exclusively for the signatory customer a complex highly potent drug component for a commercial antibody-drug-conjugate (ADC) API.

Concluded a commercial supply agreement to manufacture a Hypoparathyroid drug for one of our Clients, a compound that has been

in development for several years and will now be launched by the Client in the coming months. 12 of our 16 late phase projects are now being prepared for validation during FY 2021-22 which is a record in the 40-year history of the company. These projects span therapeutic areas such as Antibacterial Infection, Lymphoma, Multiple Myeloma, Myeloid Leukemia, Hypersimplex and Gastric related disease.

1 Additional early phase III project has moved into the late phase arena during Q4 FY2021.

The campaign to produce a highly complex GMP precursor for a commercial oncology product for a Japan based client has commenced. This product is manufactured every 2 years by CGAM.

Our development teams continue their progress on 3 new projects in the Synthetic Cholesterol, and Vitamin D2 areas that we are prioritizing across both India and Netherlands R&D teams.

Awaiting the imminent publication of the results of studies performed by Boston University with support and product from DCAL. The data has been collated, compiled, and prepared for publication which is anticipated during the next 4 weeks in the American Journal of Clinical Nutrition

Bavla facility successfully completed several virtual customer audits during QIV FY 2021.

Manufacturing of many CRAMS products underway at Bavla site. EDQM remediation plan being implemented and on track at Bavla site. ■

"Under current circumstances everyone is coming up with digital version. Even newsletters are coming out which are useful because their frequency is much more. We can even go for lesser pages and bring out information in newsletters. It's a yes for digital reading"

Dr. P. Reddanna
Executive President,
Federation Of Asian Biotech Associations

"Pharmabio World has been able to enable people by providing contemporary news and information from the healthcare discipline through education, knowledge-share, and more recently introducing entrepreneurs contributing their voice on novel latest technologies, research and development, and products that are altering conditions to lead better lives. The print magazine so far has been a visual treat for a wider audience. Although the rudimentary processes of hand-hold-magazine feel is missed, I completely endorse the electronic/digital alternatives for simple reasons and an optimistic view that the accessibility of the knowledge and information should be the contemporary life. I completely endorse the digital version of Pharmabio World with strong wishes to its success"

Dr. Sreedhara R VOLETI
CEO, ASPIRE-BioNEST

"One of the major consequences of this lockdown has been a shift of trend from conventional offline services to digital resources. Media has experienced the same trend as well. The shift from offline magazine and newspaper distribution to online stories publishing, I think digital media has got an extra point for covering every household even in the pandemic situation. That too without the fear of getting exposed to the virus "

Rajat Garg
CEO, Co-founder, myUpchar

ZUMUTOR BIOLOGICS INC

"Just gone through the digital edition, extremely professionally done, liked everything. Only one feedback, see if its possible to zoom page wise, I have seen it possible in other digital magazine.

Again, good job done on this."

Sunit Maity, PhD

Director , Product Development, Zumutor

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(a) Better content delivery – in digital edition, dense diagrams in smaller fonts, could be included, as readers could zoom in to read those. Therefore, it becomes possible to deliver more and precise content

(b) more creative in designing the book : the publishers would not be bound to keep the layout be fixed in A4, A3 format or so. They shall have the full flexibility to design the layout without trying to fit in the contents to the physical limitations of traditional boundary of print-edition once selected or of the font size. Each edition could carry the size needed to best deliver the message of the current content."

Aditya Sharma

Senior Vice President Asia | Boson Energy SA

"I really loved the magazine. It surprisingly delighted me by giving the experience of reading a paperback magazine. In fact, sometime back I had twitted tagging most publications saying, "Why don't you make newspaper PDFs easily available. We (the readers) are ready to pay for PDFs but not the typical e-paper which is so low on readability with multiple ads popping on the screen and causing major distraction."

You have taken that 'wish' of the readers to another height. So, I greatly enjoyed it.

I will also share the link through social media handles over the weekend and I am sure people will love it."

Gauri Chaudhari

Co-Founder Brand Innerworld

Evolving Packaging Trends across Pharma Value Chain

From the desk of Guest Editor

Chakravarthi AVPS
MD, Ecobliss India Pvt Ltd
Honorary Advisor & Director on Board
PHARMEXCIL, Govt. of India Guest Editor

It gives me immense pleasure to be the guest editor for the May edition of Pharma Bio world. I appreciate the team led by Ms. Mittravinda Ranjan and Jasubhai Media for choosing the theme 'Evolving packaging trends across pharma value chain' which is of great utility value for industry.

I thank Gautama Buddha, Prabir Das, Chandi Prasad, Sriman Banerjee, Santanu Chowdhury and Soumyanath Mishra for their valuable contributions. Each of them are proven leaders in their field and their insights will be of immense value. I complement PBW team for taking cognizance from the growing demand for various product innovations across drug delivery, dosing and dispensing of new products, sustainable packaging getting traction, smart packaging and labelling solutions gaining rapid ground and so on in this current edition.

The future of pharma packaging will be driven by two major factors the first one being 'User Centricity' and the other being 'Sustainability' at large. Every packaging development revolves around patient needs because it is the influencing factor to shape the market.

Under the current pandemic situation, consumer behavior has completely changed in every aspect. Physical interactions between patients and doctors are declining rapidly. With advanced digital communication being easily available every corner, consultations are happening remotely.

I would like you to recall my statement, "Packaging will be your second physician". It is really apt under today's situation. It is evident from the fact that ease of administration, dosage accuracy, dose monitoring, minimising (zeroing) medication errors have become the key factors, apart from safeguarding drug efficacy, providing product information while following regulatory framework in designing a pharmaceutical packaging.

At the end of the day, I sincerely believe that every innovation has to help mankind to benefit at large.

I once again congratulate team PBW and wish all the readers safe and successful days ahead. ■

Packaging will be your second physician

India is the pharmacy of the world and supplies 18 percent of global generic medicines, apart from the domestic market. Its position is unabated even under this pandemic situation. So, the packaging industry is expected to come up with these requirements too, along with a new set of challenges. The critical role of packaging cannot be undermined whether it is uninterrupted supply of essential drugs, expediting PPEs and testing kits, or supplying the vaccines which are critical in the current pandemic situation to several nations simultaneously meeting huge domestic demand. Pharmaceutical packaging is always designed to meet the safe use of medicines by patients and as we are aware, buying medication is extensively different from buying some consumables in a supermarket

The world has changed forever. This pandemic can probably be called the mother of all disruptions, at least for our generation. Life will never be the same even after it settles down. The industry which is surviving well under the current pandemic situation all over the world, despite a slew of hurdles and umpteen challenges, is pharma and healthcare. Obviously, the packaging industry, being an integral part of the pharma industry also is contributing to this pandemic situation. Packaging plays an important role in maintaining product quality and efficacy throughout the supply chain gamut. And it acquires even more relevance, given the lifesaving and life-sustaining nature of pharma and medical devices, Today, the healthcare industry is witnessing an unparalleled demand for personal protective equipment (PPE), diagnostic kits, medical ventilators and so on. This is in addition to the spurt in demand for critical medicines and hygiene products like sanitizers and hand rubs. Packaging plays a vital role in ensuring the safety and security of all the above items until they reach the hands of people who need them the most. And its role cannot be undermined in bringing the vaccines to across the globe.

We have witnessed an accelerated demand for healthcare-based packaging as a result of impulse buying in hygiene, healthcare, and critical medicines. In packaging, the top of the table were rigid plastics, blister foils, paper and paper board packaging that comprise the necessary labels, cartons and shippers. While paper board, paper, glass, plastic, metal, rubber and others come under basic raw material, the packaging products made out of all these materials meet a host of requirements viz. folding cartons, Display units, Paper Labels, Leaflets, Ampoules, Bottles, Vials, Syringes,

Cartridges, Closures, Bags, Tubes, Laminates with paper or foil aluminum, Collapsible tubes, Rigid cans, Needles, Gas cylinders, Pressurized containers, Closures, plungers among many others.

Role of Packaging in Time of Pandemic

Under the current pandemic situation, consumer behavior has completely changed in every aspect. Physical interactions between patients and doctors are declining rapidly. With advanced digital communication being easily available in every corner, consultations are happening remotely.

Packaging will be your second physician. It is apt under today's situation. It is evident from fact that ease of administration, dosage accuracy, dose monitoring, minimizing (zeroing) medication errors have become the key factors, apart from safeguarding drug efficacy, providing product information while following regulatory framework in designing pharmaceutical packaging.

I would like you to recall my statement, "Packaging will be your second physician". It is apt under today's situation. It is evident from fact that ease of administration, dosage accuracy, dose monitoring, minimizing (zeroing) medication errors have become the key factors, apart from safeguarding drug efficacy, providing product information while following regulatory framework in designing pharmaceutical packaging.

It is a fact that India is still a developing country and so affordable and efficacious drugs are in demand, but this does not deter the accessibility of technological advancements to the customers (ex. Revolution in mobile communication). The pharma and packaging industries always have great synergies and gregarious relationships. The innovation in each industry inspires the other to excel. The demand to optimize the drug delivery for healthcare professionals and patients in today's circumstances is much larger than ever before.

Sustainable Packaging

Packaging plays a crucial role in maintaining the quality, safety, and efficacy of all pharmaceutical products throughout the value chain. In pursuit of making packaging sustainable we also must realize the fact that any packaging that falls short of serving its defined purpose can never sustainable – no matter the amount of material reduced, recyclability,

or use of more recycled materials.

Designing sustainable packaging for pharmaceutical products is not an easy task. The packaging design must ensure that all product packaging must comply with the local packaging regulations and look for ways to reduce their environmental impact.

There are a lot of new sustainable packaging materials which can be reused or recycled are now available. Though it is not possible to use for every application (for example the primary packaging for a complex molecule) several sustainable materials like PCR plastic or recycled plastic and biodegradable material like recycled paper, paperboard, films derived from natural resources are also available for certain applications. The material that has a negative carbon footprint and easily recyclable eventually wins in the sustainability race. Pack that weighs less or occupies less space while fulfilling their purpose also contributes to the sustainability journey. The world health organization identified three directives to help reduce and eliminate waste: reducing packaging that is not essential to the protection of the drug, making as much of the packaging as possible recyclable, and making contaminated packaging incinerator safe.

In true sense, all packaging products must be designed keeping sustainability in mind paying attention to all components that include consumables like solvents, inks and adhesives.

Design Thinking in Packaging

Designing pharmaceutical packaging is a tad different from doing it for other products. While sustainability, protecting the environment must be taken into consideration several other issues like product safety and efficacy throughout the supply chain gamut, regulatory compliance, patient convenience must be given priority while designing a packaging. Well, if you think the drug for which you need to design the packaging is one of the most effective and efficacious, the packaging must not only safeguard those qualities but use all the factors that convey this message viz., the graphics, the colors, the text, and words in the labeling; on the packaging and of course the material used for the packaging itself.

The design thinking in pharmaceuticals must facilitate a better connectivity and patient-centricity.

The consumer must always have a feeling at the first instance that the product is well designed. If it's an OTC product its more important to consider several aesthetic factors to give the FMT feel to the customer. One must not forget the fact that your customer may or may not see the promotions in print, electronic or even in digital media. Invariably all the customers will see what is there in and on packaging.

This is the reason packaging is referred as a tool to extend your brand.

Now consider designing Child-resistant packaging.

The packaging must ensure an easy access to the needy (read the senior citizens or even people with arthritic hands) at the same time deter the child from accessing the product. So, it is essential to design a packaging that enables people an easy-open solution, simultaneously makes it difficult for children to access the medicines.

Similarly, a medical device or a prefilled syringe must be hermetically sealed to provide all the production, the medical staff or even the patient who needs to access it must have an easy opening option. User experience should always be in forefront while designing a product and it must communicate effectively and emotionally the objective to the consumer and in a nutshell the design thinking must elicit a meaningful experience to the patient in the simplest possible manner.

Future Trends

The future of the pharma market will be having a focused market approach rather than a saleable model. We started seeing these trends catching up in some segments already. The Pharma industry's approach today is more customer centric. Every development revolves around patient needs because it is the influencing factor to shape the market. Its noteworthy that, self-administered devices with advanced technology, especially for combination drugs are on the rise. Smart inhalers and nasal sprays will gain more demand. Transdermal patches are currently used for pain relief and normal healthcare. Similarly, a lot is happening in oral dissolvable films. This format is very useful for pediatric and geriatric patients. We have heard that Gilead Sciences is developing an easier-to-administer version that can be inhaled for the sought-after antiviral drug Remdesivir for COVID-19.

The use of Artificial Intelligence in every field will be on the rise. Concepts of smart packaging with advanced NFC components may become a norm for certain products. The evolution of ultra-thin ICs that can be embedded in any package has given scope for incorporating more features. Implantable medical devices gain ground as they are very appropriate for regulated drug delivery in certain cases. Wearable medical devices are another segment to watch. Many of them are already finding their applications, not just for diagnostics and monitoring purposes but also respiratory, therapeutic pain management and others.

At the end of the day, I sincerely believe that every innovation must help mankind to get benefited at large. ■

“Packaging industry is significantly changing the healthcare spectrum”

Gautama Buddha
Former Head Packaging Developoment
Dr Reddys Laboratories Ltd
Packaging Consultant

One of the major developments in the Healthcare sector is Telehealth which is a major outcome of IOT . It is now not limited to geographical boundaries. A doctor can see his patient from any parts of the world. The best example is in the current COVID treatment doctors are advising medication through audio-video mode and continuous engagement with the patients. Also, service offered from doctors abroad to patients across the globe.

Consumer Trends

Global markets see increased online retailing and continue to grow which is driven by internet penetration. This will see elevated demand for the right packaging solutions especially for secondary and

tertiary packs like CFB formats and cold chain packaging.

Consumer awareness and increased interest in their own health matters leading to a healthier lifestyle. This is boosting demand for packaged goods e.g., gluten-free, organic, nutritional supplements, etc.

E-commerce and globalization of international trade are also stimulating demand for RFID labels, smart tags, etc. to protect from counterfeits. The 21st-century consumer is less brand loyal due to the Internet and the availability of multiple brands. This is stimulating interest in customization or versioned packaging.

The above developments in the health care sector have a greater influence on the packaging. Packaging needs to gear up for customization and the online sale of medical devices and wearable devices that can monitor drug penetration and maintain health. Also, cold chain packaging to meet the drug requirements and to reach remote areas.

Critical Points of Failure

In terms of potential risk, the packaging and labeling process is one of the most vulnerable elements of a product's life cycle. The risks, ranging from incorrect or incomplete product information to translation errors or incorrect specifications and versions being used, all share the human element as the consistent point of failure. Any of these issues can lead to a regulatory breach, a delay in getting a product to market, a recall, or even a critical consequence for the patient.

Another important area is providing assurance to the customer on genuineness and safety and overcome the counterfeit issue.

Scale-up and packaging validation of primary, secondary, and tertiary packaging. Failures can happen largely if not focused on packaging validation. There is no scope for safe assumption even the packaging system may be the same for a new product or pack. It needs to be validated.

Global markets see increased online retailing and continue to grow which is driven by internet penetration. This will see elevated demand for the right packaging solutions especially for secondary and tertiary packs like CFB formats and cold chain packaging.

New innovations in pharma and biopharma packaging that you look forward to sustainable packaging solutions with minimum or reduced impact on the environment.

Compliance packs to adhere to the dosage regimen.

Medical devices which are patient-friendly and with safety features for administration. Overt counterfeit features for easy identification at the same time difficult to duplicate. Your expectations from a pharma packaging supplier. Packaging supplier or partner has an important role to play in new product or pack development. Continuous engagement from design to development till implementation to understand the customer requirements is very much necessary. Providing timely inputs in terms of processability and availability will help in decision-making.

Informing and updating customers on the changes in current process, input materials is necessary.

Support the customer with required data to meet regulatory requirements or amendments from time to time. ■

"New medicines require specialized packaging for shelf life"

Sriman Banerjee
Head of Packaging Development & CDE
R&D Pharma Science

Takeda Pharmaceutical Company Limited. The 19th century was focused on IT and the 20th century will see a focus on Healthcare. The trend started even before the pandemic and evolved as we strive to remain healthy and live longer. With advances in our lifestyles, the ecosystem of health becomes important. We see a lot of new medicines being developed enabled by Science & Technology leveraged by research.

The new medicines require specialized packaging for shelf life, cryogenic conditions, and delivery systems specifically in the areas of gene, cell, and plasma therapy. This is a new niche area of packaging being developed on material science and formats. While the packaging industry tends to manufacture based on volumes, there is a new opportunity to develop and manufacture custom products catering to the new age medicines. ■

The Necessities and Mandates of Packaging

Prabir Das
Head Packaging Technical Services
OSD India , VIATRIS

The necessities and mandates in the Category of Product Range include Physical, Chemical and Organoleptic properties, Shape, size, colour, Fragility, Sensitivity level, Bulk density, Viscosity, Flow properties.

In terms of Process, the Design, Flow, Scope of Automation, Standardisation and Harmonisation are observed.

In Branding, the Pack Design, Graphic Design, Use of Smart Features and in Logistics focus on Storage, Handling & Distribution, Mode of Transportation, Excursion, Study, Shipment Study are considered.

During the Customers phase, Domestic or Export, Demography, Convenience, Dispensing ease,

Disposal ease, Authenticity are followed.

In Regulator, the Local rules & Regulations, Environment friendliness, Child protection,

'Supply chain safety & security and in Competitors, the Bench marking, Cost sensitivity, Uniqueness (USP) and in Technology, Availability & Adaptability, Cost-benefit analysis, Feasibility for hybridizing, Sustainability is noted.

Future Development Strategy

- **Multi-Skilled Trained People:** Just like all-rounders in a team, this will bring flexibility, improve productivity level and help in any kind of crisis management.
- **Indigenisation:** In many areas we are still dependent on imports due to unavailability of suitable indigenous substitutes. Import substitution is needed to promote self-reliance, improve cost efficiency and procurement cycle time.
- **Automation:** It brings discipline at workplace, apart from enhancement in Quantity and Quality. It also helps in resource optimization in the long run.
- **Smart Features:** These are used on product-packs for multiple purpose like brand promotion and protection, prevention of theft, diversion and Cloning.
- **Track & Trace:** This brings traceability and transparency in supply chain operation with security and ensures customer safety.
- **Supply Network:** Well-knit strong connectivity is must for clear visibility of the goods in network. This helps to improve speed to market / customers and in customer services.
- **Awareness Building & Training:** This is one of the strong elements for building a good understanding to strengthen product-people connectivity through packaging. Understanding is a hybrid result from reading, writing, speaking, listening and watching.
- **Regulatory Guidelines:** Regulatory and statutory guidelines vary based on country / region, which indirectly generates varieties at workplace and all other activities, including supply chain. There is a scope of standardization and harmonization to optimize resources and efficiency.
- **Communication, Collaboration & Cooperation:** This is the final directive for seamless sustainability of the business. Internal or external, at each level this is must. Academy, Industry and Regulators need to ensure this for all. ■

"Packaging validation is still a nascent stage in the Indian Pharma industry"

Chandi Prasad Ravipati
Head - Packaging Development
Aurobindo Pharma Limited

Pharmaceutical Industry is a lifeline industry and forms an ecosystem with the healthcare industry that provides goods and services to treat patients with curative, preventive, rehabilitative and palliative care. It is one of the fastest-growing industries across the globe with a turnover of 390 billion USD at end of 2001 reached to 1.27 trillion USD at the end of 2020. The journey of the Pharmaceutical industry of India for the last two decades is phenomenal becoming one of the largest exporting countries of generic drugs to the world. The role of the packaging industry is equally outstanding in meeting the stringent demands of regulated and Emerging Markets.

Emerging Trends in Pharma Packaging

Change is constant. This applies to the pharmaceutical industry very aptly due to stringent regulatory changes from almost every importing country periodically. Child-Resistant and Senior-Friendly packs for blisters in the USA are becoming more and more strict. Compliance to requirements and developing a cost-effective pack desires lot of innovation in blister designing and packaging materials. The focus of the Indian Pharma industry for the next decade is more on developing specialty drugs, parenteral formulations, and novel drug delivery systems. All these necessitate special packaging.

User (Patient) Centric Packaging and Sustainability are two areas of focus and play an important role in the sustenance and creating a brand image for generic products in regulated and emerging markets. The packs besides meeting statutory and labeling requirements of the country they are consumed should facilitate pharmacist, administrator, and end-user convenience.

The advancement of the Internet of Things, digitalization, barcoding of data, and audio-visual presentation of usage can play role in making user-centric packs. While design a container-closure system for a product, packaging technologists should consider optimization in view of sustainability. Many packaging materials can be reduced using electronic media and reduce waste generation.

Dent the reputation of the organization. Technological development in the inspection and rejection of faulty packs on packing lines is still not robust to avoid packing and labeling errors. They may be due to human interference, bypassing inspection, or

Packing and labeling errors cause monitory losses and dent the reputation of the organization. Technological development in the inspection and rejection of faulty packs on packing lines is still not robust to avoid packing and labeling errors. They may be due to human interference, bypassing inspection, or failure of the inspection system

failure of the inspection system. There are frequent market complaints on missing tablets or capsules in blister, less count in bottles, missing labels, and or literature. Wrong labeling is very critical and it can happen from vendors of labels and foils or wrong dispensing which could not be detected on packing line by men or machine. It will be a joint effort by manufacturers and providers of hardware and software of packing lines.

Automation Of Packing Lines

Even though automation in the pharmaceutical industry is growing on the fast track, many secondary and tertiary packing operations are manual. Emphasis on developing efficient automation in primary packing operations and automation of secondary and tertiary packing operations will be a priority to increase productivity and avoid packing and labeling errors. It is very important that packing machinery manufacturers must concentrate on developing inspection system which is tested and validated for worst-case situations. They should make research and development a continuous program to overcome failures and provide foolproof inspection systems.

Packaging validation is still a nascent stage in the Indian Pharma industry. Both packaging technologists and production packaging personnel should prepare and implement packaging validation appropriate to their packing machinery and lines. This will greatly help in reducing market complaints due to packing and labeling errors.

Serialization (Track & Trace) Of Pharmaceutical Products

Serialization of packs of products at different levels, aggregation between these levels, and data submission to country of port became a global requirement now. The requirements slightly change from country to country. It is one of the best tools of track and trace to avoid spurious medicines in the market and provide authenticity of the medicine to the user. This is an example of the failure of pharma packaging solutions providers as the entire track and trace system is a combination of:

- Conveying the pack properly,
- Printing of barcodes and human-readable data with variable data on each pack with a unique serial number on each pack

- Inspection of printed data to pass correctly printed data with grading and rejection of wrong or illegible and non-readable packs.

Element of Information Technology is the backbone of entire serialization. No Indian hardware and software provider is efficient in all these fields and all have experimented. With a lot of deliberations between the pharma industry and service providers for almost a decade, it is now stabilizing.

Innovations Pharma & Biopharma Packaging

As the patents are diminishing, the need for new drugs and drug delivery systems is increasing, Indian Pharma industry started increasing their Research & Development and investing more funds for innovation in developing new medicines. Packaging of novel drug delivery systems requires innovative packaging systems to maintain the efficacy of the products. It is obvious that the Indian Packaging industry also focuses on Research & Development. The role of packaging institutes is very important for research and development and the packaging industry can benefit from their research as ours is a developing economy. ■

“Molecule entities are throwing up newer challenges in-terms of establishing product-pack compatibility”

Santanu Chowdhury
Sr. General Manager - Packaging Development, Sun Pharma

The changes in Healthcare sector vigorously influencing the packaging industry are molecule entities are throwing up newer challenges in-terms of establishing product-pack compatibility and stability during its long shelf life.

One such concern being surfaced out is oxygen & heat sensitivity. The dynamics of regulatory landscape ,government / insurance policies , stringent quality requirement are some of the contemporary that healthcare industry is gearing up to address while selecting the cost effective packaging options.

Critical points of failure for Pharma Packaging solutions providers in my experience and suggestions for improvement would be the absence of long term data availability on performance of said packaging material coupled with lack of interest to establish machine performance result are some of the low confidence factors that prevails in the mind of heath care user industry in connection with reliability/credibility quotient of packaging solution provider. ■

"Smart packaging can reduce supply chain losses & enhance environmental monitoring"

Soumyanath Mishra
General Manager & Head-Packaging Development, Mankind Research Centre

During the challenging days of the COVID-19 pandemic, as citizens around the world have moved into lockdown with limited movement, vast swathes have become reliant on technology for maintaining social connectedness or even obtaining essential supplies such as medicine. Products with names that had limited awareness have become household lifelines, such as Zoom®, Teams®, Uber eats and the plethora of other communication and delivery services.

Patients who previously considered the only way of receiving health care was by contacting their doctor, meeting them face-to-face, explaining their symptoms, being examined and ultimately getting diagnosed and treated have, in a few short weeks found other mechanisms to receive care. Patients have found themselves interacting via apps, online tools and video conferences, in many cases, with a more responsive approach. So, in the face of such disruption, there is a huge influence in Pharma packaging. Major changes can happen in the packaging industry.

Impact of Economic & Demographic Growth on Packaging

As the global economy grows & tends to incline towards sustainability, the packaging industry will address this issue alongside offer thrust to lightweight, patient centric and user friendly packaging.

- **Consumer (Patient) Trends:** The global pharma market is seeing an increase in online purchase of medicines which will drive the demand of specific type of packaging and self-demonstrating packaging.
- **Packaging Design:** We did not expect much demand from the healthcare/pharma packaging sector due to the regulatory environment. Moreover, pharma packaging is very different from other types of packaging due to strong emphasis on product functionality. Now the pharma & biopharma packaging solution providers are offering the manufacturers bold and innovative packaging solutions to enable them create differentiation in the market and improving bottom line sales.

In response to volatile raw materials cost & high cost of recycling of pharma packaging, companies could test new avenues for promoting the sustainability agenda—for example, by introducing truly biodegradable (compostable at home) packaging materials to reduce the leakage of packaging materials into the environment.

New Innovations Pharma & Biopharma Packaging

- **Device & Self-Administration:** Medical devices are taking a leading role in the health care sector. Changing hospital administration to the self-administration process is increasing rapidly in the market.
- **Connected Medical Devices:** A connected medical device can collect and store data about patient use and trace the effectiveness of a particular device and treatment to help them to do so.

In response to volatile raw materials cost & high cost of recycling of pharma packaging, companies could test new avenues for promoting the sustainability agenda—for example, by introducing truly biodegradable (compostable at home) packaging materials to reduce the leakage of packaging materials into the environment.

Utilizing connectivity in drug delivery devices such as injectors and inhalers, connected health solutions help pharmaceutical companies, healthcare professionals and patients by improving how people take their medication.
In addition to medication tracking, these systems support patients through reminders, incentives and peer communities to improve disease management, medication adherence and ideally the outcomes. Since patients are not ready to go to the hospital and want to connect with doctors or interacting via apps, online tools and video conferences then this data is very important for doctors to prescribe medication.

- **Smart Packaging & Intelligent Packaging:** Embedding advanced features into packaging such as sensing or wireless communication makes packaging "smart" which can provide significant functionality. The packaging then becomes not only a way to protect and provide information on medicines but can add a whole host of extra functionality. Smart packaging can reduce supply chain losses through the enhanced environmental monitoring and support improved patient adherence through smart adherence packaging.

- **Anti-Counterfeit Packaging :** Since online marketing or home delivery has demanded significantly high therefor the global anti-counterfeit packaging is having significant demand due to strong growth in the pharmaceutical & healthcare sectors. The growing pharmaceutical & healthcare industry and an increasing number of counterfeit products in the market are the major drivers of the anti-counterfeit packaging market. The upcoming decade would be more dedicated to overt Counterfeit options as the patient is the ones who will demand the genuine product

Packaging companies will have to address both sustainability and hygiene concerns alongside cost, performance, and convenience requirements. Moreover, volatile raw-materials prices and interruptions to recycling services could further disrupt markets. In response, companies could test new avenues for promoting the sustainability agenda—for example, by introducing truly biodegradable (compostable at home) packaging materials to reduce the leakage of packaging materials into the environment . ■

Spearheading Lipid Manufacturing To Produce Vaccines

Arun Kedia, Managing Director of VAV Lifesciences Pvt Ltd, *has often been regarded as an 'Entrepreneur with an expertise in manufacturing lipids for nanotechnology,' with over three decades of dedicated experience in the field. In an interview with PharmaBioWorld, Mr. Kedia talks about the company's hurdles, technological aspects, demand, and efficacies, regarding the antidote that the world awaits.*

Arun Kedia
Managing Director
VAV Lifesciences Pvt Ltd

Share with us the significance of gene-based lipid nanoparticles. How is this technology evolving for applications & in terms of scale across pharma and other industrial applications?

Covid-19 vaccines may have turned the spotlight on gene- based lipid nanoparticle (LNP) technology, however, it may be interesting to note that research on gene -based delivery actually started almost three decades ago. The Covid-19 vaccines, today, have proven that it was worth the effort. They have rekindled interest in mainstream pharma companies to adopt this technology. Several players are now keen to license and/or collaborate with mRNA-LNP manufacturers. The

technology offers tremendous potential as a tool for gene therapy across a wide range of therapeutic classes. The main hurdle in using mRNA, is systemic delivery, cellular permeation, and safety, to target cells. LNPs may provide a feasible solution to overcome this as it helps protect the non-stable mRNA, and delivers a large payload along with adjuvants. Highly purified synthetic Phospholipids like VAV's LECIVA range play a structural role in LNPs.

At a time where vaccines are the center of public and government scrutiny, what are your challenges often faced meeting the required demand?

The unprecedented increase in demand for lipids for the vaccine industry has created supply chain pressures. To keep up with the global demand, we have ramped up production. VAV is rapidly expanding its scale of manufacturing, as we speak. However, for pharmaceutical ingredients, this is not easy as there are regulatory procedures involved and processes are capital intensive.

In the last decade how has demand for this technology evolved in India and globally? Please share insights in context with market demand & barriers, regulatory challenges, techno

commercial feasibility, technology application, customers' concerns?

In the past decade, LNP technology has transitioned from a state of very low awareness and adoption in the initial stage, to rapid global recognition. Today, market demand for nano particle -based medicine is high due to its superior efficacy. However, being in a high technology space with specialized and dedicated manufacturing capabilities, it is not always easy for manufacturers of traditional pharmaceutical formulations. Biopharmaceuticals are relatively new and regulatory bodies are constantly evolving and redefining the standards and protocols.

VAV Life Sciences pioneers in lipid manufacturing in India for use in the mRNA- LNP technology-based vaccines, tell us about your market experience, initial struggles and how did you overcome these?

Lipids hold the potential to revolutionize drug delivery (NDDS), peptide therapies, and the treatment of genetic diseases. The risk involved in formulation research & development work and low success rates, makes interest limited to larger players or at academies. The market is still evolving and collaboration of multinationals with original mRNA research organizations can help bring such options in the market at a faster rate.

VAV's lipid development & production technology is a result of continuous efforts of our entire scientific team over 10 years. It involved close knit collaboration between chemistry, analytics, engineering, regulatory departments. Scientific interaction with customers by the marketing team played a critical role. The advanced knowledge of the domain acquired over the years was vital. Experimentation and ingenuity is built into the fabric of our organization which has resulted in novel products and processes increasing efficiency of our ingredients.

How far has VAV Life Sciences come from its starting point and now racing towards the end goal to manufacture the vital Lipids that make the antidote? Tell us more about-

Other specialized proteins and synthetic phospholipids used for NDDS and nanomedicine.

We have a comprehensive range of highly purified phospholipids for NDDS & nanomedicine under brand LECIVA & LIPOVA, besides our traditional products for nutrition and personal care. Our team works constantly to bring the very best in research technology.

Some of the notable projects so far and the ones in pipeline.

We work with top multinationals across the globe on different innovative & novel projects, protected under confidentiality agreements.

What are the future plans of the company?

Inspired by our commitment to improve the health and quality of people's lives worldwide, we are dedicated to being a leading provider of specialized products based on our technology. We have continuous development work going on in our R&D to develop novel ingredients in phospholipid space that can make an impact on human life. We are also aggressively expanding our range and capacity.

A report by Mordar Intelligence indicates Asia Pacific as the fastest growing region for lipid- based products. How do you see the competitive landscape evolving in the next few years in this region and in India? What would it require in terms of infrastructure, regulations for India to develop as one of the leading players in this domain?

VAV is looking forward to widening its reach by bringing innovative products and applications in the market and through strategic alliances to amplify its marketing efforts and grow globally. VAV has successfully completed capacity expansion in its existing product lines, to align it production capacity to meet the growing demands of the market. With constantly evolving R &D projects, VAV intends to tap new markets and opportunities in the pharmaceutical and nutritional industry in the coming years. Biopharmaceutical market is new and hence regulatory bodies are also constantly evolving and redefining standards and protocols. We have grown since 2003 and are a globally significant company in this domain. We retain the flexibility, and we need to keep on adapting and responding to the trends in society and technology. We are ready to embrace any new opportunities thus created. ■

How Covid-19 Brought A New Sphere of Pharmaceutical Packaging

Having previously worked as the Head of Packaging Department for Themis Medicare Limited, Plethico Pharma Limited, ***Jayanti Sawant*** *has been working in the Pharma Packaging, Procurement and Electronics industry for almost two decades. In an exclusive interview with PharmaBioWorld, she shared her views about how Covid-19 is ramping up the Pharma Packaging industry and various parameters that has changed the pharmaceutical industry's landscape.*

Jayanti Sawant
Packaging Development Consultant

COVID 19 has affected every aspect of our lives, personal and professional and threatened the global economy unlike any other factor has ever adversely the world till date. Small scale industries, businesses washed out, the life of daily workers was harder than before and meeting two ends was challenging for many people in rural part. Every industry, small or big , industrial , consumer and healthcare are no different.

Nevertheless, pharmaceutical has been on the frontline during the pandemic as there has been a huge demand of medicines globally.

Let's have a look at the demands of medicines when the pandemic started and physicians and scientists had no clue which medicine will work and how since it was a new virus.

Antimalarial, antiviral, antibiotics, steroids, cough and cold OTC products, multivitamins, antiallergic tablets, injectables, syrups have been in high demand. To maintain hygiene, disposables gloves , sanitizer , PPE kits , protective shields , syringes are in huge demand and will continue to be in demand post-pandemic. Packaging industry, especially pharmaceuticals, zoomed up rapidly during this crucial period.

Blister packs were in demand for tablets and capsule, demand for Vials and ampoules elevated never before since injectables were in huge demand. Plastics have been in continuous demand for almost all kinds of packaging and especially disposable products like PPE kits, gloves etc. Kraft paper and paper board industry faced shortages of raw material and hence it affected secondary packaging material supplies like cartons.

Impact on cost

The huge demand for packaging material resulted in hiked prices of paper boards and also shortages of packaging materials. It won't be exaggerated to say Packaging of pharmaceutical products has grown overnight along with the demand for medicines across the globe . Packaging of the products is the backbone of any operation and supply chain.

Packaging comes in contact with the person from manufacturing end to supply chain to consumer. Hence transmission of virus through packaging material is the biggest challenge to any industry - industrial, consumer and pharma .

Along with the huge demand of medicines, the consumption of packaging material increased enormously. This pandemic gave rise to new trends in packaging across the globe.

Trends in pharmaceutical packaging during pandemic

The biggest global concern during this pandemic has been, migration of the virus, through the packaging material. To arrest this migration packaging manufacturers

have been working in multidimensions to inhibit the growth of virus on packaging materials.

Here are some few trends that are Market-Driven and Consumer-Oriented

Antiviral or Antimicrobial Packaging

This packaging inhibits certain viruses or bacteria from the surface of the packaging material, thus arresting the entry of the viruses on packaging materials .

This innovation will capture the market anytime since these trends are being implemented in the food industry in countries like Japan. However, it may take a long time for pharmaceuticals to adopt this trend since using the antiviral package for medicine demands stringent stability studies and the effect on the packed medicine needs to be evaluated.

The reaction between the antiviral agent in the package and the product will have to be studied in multi directions. Regulatory compliances will also play a vital role in the acceptance and implementation of new trends and have to be passed by FDA and other regulatory bodies for safety to human beings. Interaction of product and pack compatibility will have to be studied through multi directions.

Touch less packaging

This sector of packaging material will involve automation of production lines like Auto labelling, Auto blistering, use of cartonator machines for packing to reduce human touch. it brings in role of robotics in production activities. Thus automation will reduce human touch in production activities thereby reducing migration of the virus on packaging materials.

Trends in Touchless Packaging

- **FFS technology -** Form fill seal technology which provides sterile product and pack without human touch.

- **Self-medication-** Prefilled syringes are in demand nowadays, where patients prefer to take injections on their own, nevertheless, this sector will require new setup of production .
- **E-Commerce packaging** - During the lockdown, more and more people are buying groceries, clothes, medicines online . This trend has given a boom to e commerce packaging. Secondary packaging like cartons and tertiary packaging like shippers are in demand. Products are directly packed in small shippers thereby eliminating extra packaging. This packaging also now has features like" frustration-free " packaging which is easy to open and made out of 100 % recycled paper.

Packaging of vaccines or cold chain packaging

The entire globe has focused on finding out solutions to this disease. Scientists have been working on the development of antivirals medicines, steroids, vaccines and many other fronts still unknown to many of us.

Vaccine development, manufacturing, and supply chain are long-term processes that involve a huge amount of economical investment for different solutions for the transportation of the vaccine and during storage in hospitals. Some solutions like Mobile fridges, Pallet shippers, Courier boxes and Carry bags are widely used globally for products which require cold chain packaging and supply chain.

Mobile or portable refrigerators offer perfect thermal insulation and stable temperature conditions with the lowest energy consumption. This will ensure the vaccine is transported to the patients from the vaccine manufacture at the right temperature, controlled throughout by the mobile or portable fridge.

Temperature data loggers play a very vital role in temperature and humidity monitoring. Loggers could be single-use or long-term use.

Smart packaging

Any new development is market-driven or customer-oriented. People tend to buy goods with good and attractive packaging. Thus smart packaging trends are in demand.

Tamper evident caps, anticounterfeit agents like holograms, RFID, QR code are necessary features of good packaging.

During this pandemic we all have heard and read about counterfeiting of life-saving injection REMDESIVIR. Without anticounterfeit measures it is easy for the counterfeiters to copy or remake the drug. With smart packaging the brand owner can make the brand difficult to copy by others though it cannot give a 100 % guarantee that the pack or the product cannot be copied.

Sustainable packaging

Reduce, Reuse and Recycle - are the three R's of Green Packaging.

Waste Management - The Circular Economy Model For Printers

It should be quality statement of every industry and not just Pharma Industry. The Healthcare industry is fighting to find medicines, vaccines for this disease which has suddenly demanded need of packaging materials There is a huge demand for antimalarial, antiviral, antibacterial injections/tablets. Medical devices like syringes, gloves, PPE kits are in demand and this trend will continue in the future as a safety and hygiene measure.

Thus blister packs, glass vials and ampules, rubber stoppers , seals , secondary and tertiary packaging is in very high demand. Plastics have become a first preference material for medical devices and disposable items.

When the pandemic started in 2019, no one had any idea where the scenario was heading to, affecting millions of lives globally and washing out the global economy. However pharmaceutical industry and packaging industry is growing even in this tough period.

On a positive note, the demand for packaging materials has grown enormously. It is estimated that the Pharma Packaging industry will grow by 20 % during the pandemic and the trend seems to be continuous in the future. ■

Regulations in Pharma Product Packaging

Adv. Gautam Panchal
Proprietor , Gautam & Co.
Advocates High Court, Bombay and IP Attorneys

Regulations related to Pharmaceutical packaging have been constantly evolving depending on the changes in relevant laws and market demands. The legal aspects to be borne in mind by the manufacturers before designing a packaging material involves various rules and regulations depending on whether the product is a tablet, vaccine, etc.

The packaging laws and regulations for drugs are mainly covered under:

- Drugs and Cosmetic Act, 1940;
- Drugs and Cosmetic Rules, 1945.

Rule 96 of the said Rules stipulates that the particulars of the label shall be either printed or written in a manner that cannot be removed, erased or washed away and

shall appear on the label of the innermost container of any drug and on every other covering in which the container is packed. The particulars should be as follows:

i. Name of the drug:

The generic name of the drug shall be printed or written in double the font size of the trade name and the trade name should be placed immediately below the generic name.

The generic name shall be specifically given depending on whether the drug is covered under;

- Schedule F or Schedule F(1),
- Indian Pharmacopoeia or the official Pharmacopoeias and official compendia of drug standards prescribed in rule 124; followed by the letters 'L.P',
- National Formulary of India; followed by the letters 'N.F.I.';
- for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

ii. Statement of Net contents:

Net contents of the drug in terms of weight, measure, volume, number of units of contents, number of units of activity shall be mentioned and should be expressed in Metric system.

iii. The content of active ingredients

- Oral liquid preparations - the content should be expressed per single dose of 5 millilitres. If the dose is below 5 millilitres, the contents may be expressed in terms of one milliliter and where the single dose is more than 5 millilitre, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the licensing authority,
- Liquid parenteral preparations ready for administration - the content should be expressed in terms of 1 millilitre or percentage by volume or per dose in the case of a single dose container,
- Drugs in solid form intended for parenteral administration - the content should be expressed in terms of units or weight per milligramme or gramme,
- Tablets, capsules, pills etc - the content should be expressed per tablet, capsule, pill or other unit,
- Other preparations - the content should be expressed in terms of percentage by weight or volume or in terms of unitage per gram or millilitre as the case may be.
  The above provisions shall not apply to a pharmacopoeial preparation and to a preparation included in the National Formulary of India;

iv. Name of the manufacturer and the address of the premises of the manufacturer:

If the drug is contained in an ampoule (small sealed glass capsule containing liquid), it shall be enough if only the name of the manufacturer and his principal place of manufacture is shown.

v. Batch number:

The figure representing the batch number should be preceded by the words 'Batch No.' or 'B No.' or 'Batch' or 'Lot No.' or 'Lot.'

Various ways of assigning batch numbers are prescribed depending on whether it is;

- Drug manufactured by a continuous process
- Powers, liquid orals, ointments, etc.,
- Tablet, capsule, lozenge, torches, etc.
- Parental preparations sterilized by steam under pressure,
- Container of parental preparations filled from one homogeneous bulk solution and sterilized in more than one sterilizer load
- Parental and other sterile products filled aseptically
- Medicinal gases produced by a continuous process of operation

vi. Manufacturing License:

The figure representing the manufacturing licence number being preceded by the words 'Manufacturing Licence Number' or 'Mfg. Lic. No.' or 'M.L.'

vii. Drugs specified in Schedule P and their preparations including combinations with other drugs:

It shall bear (a) date of manufacture and (b) date of expiry of potency. The period between the date of manufacture and the date of expiry shall not exceed that laid down in the Schedule 10.

Drug and their preparations not included in Schedule P:

It shall bear (a) date of their manufacture and (b) date of their expiry which shall not exceed sixty months from the date of manufacture. This period may be extended by the licensing authority specified if satisfactory evidence is produced by the manufacturer to justify such an extension.

viii. Drugs specified in Schedule C(1) and their preparations including combinations with other drugs:

It shall bear on the labels (a) date of manufacture, (b) date of expiry of potency fixed by the manufacturer, and (c) where such drugs are imported, also the number of license under which the drug is imported, preceded by the words 'Import License.'

The drugs in bulk form included in Schedule C(1) which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency.

ix. Drug intended for distribution to the medical profession as a free sample:

In addition to above requirements, it should further bear on the label of the container the words 'Physician's sample—Not to be sold' which shall be overprinted.

x. Contraceptive

- Mechanical contraceptive – contents shall be as specified in Schedule R.
- Contraceptive, other than a mechanical contraceptive - (a) the date of manufacture; (b) the date up to which the contraceptive is expected to retain its properties; (c) the storage conditions necessary for preserving the properties of the contraceptive For oral contraceptives, it is sufficient to display on the label the date of manufacture only.

xi. Export

xii. Prescription Drugs must have the symbol Rx on them and other drugs must include warning that the drug must be taken under medical supervision.

Penalties are also prescribed in the Act for non-compliance of the aforestated rules of labeling.

Further, one must also be vigilant in adopting a Trade Mark. The legal provisions pertaining to adoption of Trade Mark are given under The Trade Mark Act, 1999 and Trade Mark Rules, 2017. A Trade Mark must be distinctive and the one which is not conflicting with or similar to any other pre-existing Trade Mark. In view of the same, one must undertake trade mark availability search from the database of Trade Mark Registry before proceeding for registration of the same. Section 13 of the Act talks particularly about a pharamaceutical Trade Mark and thereby prohibits the use of name of chemical elements, compounds and international non-proprietory names (as declared by WHO).

Similarly, caution must be taken while adopting artistic label / packaging which consists of unique colour combination, placement of device etc. which is altogether different than any other label / packaging so as to be able to distinguish the same from the product of other. The legal provisions pertaining to adoption of Trade Mark are given under Copyright Act, 1957 and Copyright Rules, 2013. ■

The Evolution of Law and Ethics in the Pharma Sector: The Role of the Executive and Judiciary in India - II

An attempt to trace the evolution of law and ethics in the pharma sector without taking into account the various judicial pronouncements is nothing less than futile. This is because a large number of decisions have been instrumental in laying down its strong foundation. In the continuation of his series, the author explores the role of the Judiciary.

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

The World Health Organisation And Its Clout

All the international norms set down by the World Health Organisation (WHO) have a profound influence over our municipal laws. WHO's Indicatory Metadata Registry or the IMR acts as a data repository. It also provides indicators for the achievement of health standards at the national and at global levels. Its impact is felt from the expansive approach the Judiciary has taken towards public health.

The Developments Within Our Country

The Supreme Court's progressive approach with the liberal interpretation of Article 21 of our Constitution with an equal emphasis on the Directive Principles of State Policy gave the right impetus to healthcare being recognized as the fundamental right of every citizen.

Part IV of the Constitution of India featuring the Directive Principles of State Policy has become the fountainhead of power for the courts to interpret and to evolve principles relating to public healthcare policy.

The Relevant Principles From Part IV:

- Article 38 of the Constitution casts an obligation upon the State to secure a social order for the promotion of the welfare of public health;
- Article 39 (e) provides for the protection of the health of the workers;
- Article 41 pertains to providing public assistance by the State in special circumstances such as sickness, disability, old age, etc.;
- Article 42 intends to protect the health of the infant and the mother;
- Article 47 imposes a primary duty on the State towards the improvement of public health, the extension of benefits pertaining to sickness, disability, old age, and maternity benefits;
- Article 48A lays down the duty of the State towards providing a good and healthy pollution-free environment.

The Supreme Court On The Violation Of Clinical Trial Procedure

For the first time, the Supreme Court of India took note of the violation of clinical trial procedure in the decision reported in All India Democratic Women Association and others Vs. Union of India and another [(1998) 5 SCC 214]. It dealt with the use of Quinacrine as a method for the non-surgical sterilization of women. The government filed an affidavit that it was taking the necessary steps to ban the drug from use as well as ban its import, manufacture, sale, and distribution.

The Supreme Court On Law Of Informed Consent In Treatment

The leading authority on the law relating to Informed Consent is well laid down in the decision by the Supreme Court in Samira Kohli Vs. Dr. Prabha Manchanda & another [(2008) 2 SCC 1]. The court held that adequate disclosure of the information is one of the primary elements of informed consent when treating a patient.

Perhaps, it is one of the most significant contributions of the Supreme Court where it has deviated from the 'Canterbury Principle'. In Canterbury v Spence (464 F.2d. 772, 782 D.C. Cir. 1972), the court had felt that it was prohibitive and even unrealistic to expect doctors to discuss each and every risk about the proposed treatment with their patients. The decision gave huge leeway to doctors saying that they obviously could not disclose risks that they themselves were not aware of at the time of beginning the line of treatment.

The Supreme Court of India in the present case held that consent obtained from the patient should be 'real' and 'valid'. The patient should have the capacity and the competence to consent. The consent should be voluntary. And it should be based on adequate information about the nature of the treatment. In other words, the patient must fully understand what he is consenting to.

The Salient Points Of The Judgment

True consent requires complete disclosure of information by the doctors.

The physician must enable the patient to choose only after giving him all the required information along with the attendant risks.

An average patient has little or absolutely no understanding of medical procedures and therefore looks to the doctors for enlightenment to reach an informed choice.

The decision to undergo or not to undergo a medical procedure is the sole prerogative of the patient.

The duty of complete divulgence of information on the physician is based on the fiduciary relationship that he has with the patients.

Supreme Court On Illegal Clinical Trials And Malpractices

It is interesting to note that the issues of illegal clinical trials, malpractices, unethical clinical trials, deaths in clinical trials, and compensation in India were first flagged by the High Court of Allahabad. While hearing the writ petition filed by Rahul Dutta (W. P. No12280 of 2010), a Division Bench of the High Court of Allahabad, comprising Justice Umanath Singh and Justice Rituraj Awasthi took

cognizance of the fact that illegal clinical trials were rampant in India.

The court observed that it would award damages and came down heavily on pharmaceutical companies for flouting norms on informed consent and causing deaths of several participants in clinical trials.

The Role Of Social Movements

Social movements for public health and safety have also played a major role in shaping the policy and regulations governing clinical trials in India. The case of Swasthya Adhikar Manch vs. Union of India [(2014) 14 SCC 788] before the Supreme Court marked a watershed moment in matters relating to clinical trial in many ways. The order of the Supreme Court brought in several stringent measures like

- Enrolling research participants with informed consent;
- Audio-Visual recording of the informed process concerned;
- Contract research organizations to register with the government;
- Clinical trial proposal to share information to the participant about the benefits and risks;
- Preservation of documents while adhering to the principle of confidentiality.

Besides the above measures, the regulatory framework has been a work-in-progress with the Apex court striving to make significant changes. Even though the Supreme Court has observed in several cases that clinical trial contracts must by default contain a clause for compensation to its participants in case of injuries, little or no action has been taken towards it.

The good news however is that a committee has been constituted by the Ministry of Health and Family Welfare to look into the matters of compensation. Recently a formula to determine the quantum of compensation in the cases of clinical trials related to Serious Adverse Events (SAEs), including deaths occurring during clinical trials has been evolved by the committee under the Drugs and Cosmetics Rules.

What is intriguing to a lot of people is that the government has not thought it fit to bring a statutory amendment to the Drugs and Cosmetics Act, 1940 incorporating a provision for the award of compensation.

(The concluding article in this series will have the author throwing more light on the desired provisions relating to the award of compensation as well as other areas requiring more thought and action.) ■

How Single-Use Technologies Support Global Manufacturing Success

Narayana Rao, Vice President of Biopharma, Asia, Middle East and Africa, and Sean DeFusco, General Manager *– Single-Use Solutions & Fluid Handling, both from Avantor, in an exclusive interview with Pharma Bio World, talked about how single-use technologies are streamlining breakthroughs in biopharmaceutical manufacturing, ultimately supporting the advancement of regional and global healthcare needs.*

Narayana Rao
Vice President of Biopharma
Asia, Middle East and Africa

Sean DeFusco
General Manager
Single-Use Solutions & Fluid Handling

How has the market for single-use technology evolved over the past few years?

Sean: Over the last decade, single-use technologies have grown to become an intrinsic part of biomanufacturing, from upstream and downstream processing to final-fill. Single-use technologies offer both speed and flexibility in bioprocessing, from vaccines to mAbs production. A single-use facility take less time to commission and scale-up, whereas traditional manufacturing facilities can take many years to build even a small infrastructure. Another advantage of these technologies is that the manufacturers can eliminate protocols for cleaning and sterilization in place (CIP/SIP) that are required to reuse equipment.

Narayana: For these reasons, a significant shift has taken place in the industry towards adoption of these innovative technologies. Industry research is showing that single-use is expanding at CAGR of around 13% and projected to reach $33 billion (USD) by 2027. This trend will continue as new generations of therapies are developed and launched. COVID-19 vaccines are good examples, where single-use technologies have been used to offer greater speed and flexibility in manufacturing.

Sean: I would agree, Narayana. A significant market for these technologies was growing rapidly before the pandemic set in but COVID-19 has only fueled the demand. At Avantor, we are working rapidly towards expanding our global capacity to meet our customers' needs, wherever they are located around the world. The flexibility offered by single-use systems, components and technologies gives biomanufacturers the potential to develop innovative therapies like these in a shorter period of time.

What are the key parameters that one needs to consider when designing single-use facilities – from engineering and design, to running operations?

Sean: The fundamental approach to building single-use facilities is no different than building a conventional manufacturing plant. In terms of scale, when compared to manufacturing plants outfitted with stainless steel, single-use technology facilities tend to have smaller batches sizes but often more production lines. In some ways, it is also more of a "scale out" than "scale up" model. Single-use facilities are nimble and modular, in that multiple molecules could be produced in the same space and components reconfigured to do that.

Narayana: There is no one-size-fits-all approach when it comes to single-use. Standard designs and components do exist but are used to ultimately build

tailor-made solutions for customers. Even though we categorize drug molecules broadly into groups such as mAbs and vaccines, variations in the workflows do exist, from customer to customer or from molecule to molecule.

What is your level of engagement with customers when it comes to designing single-use systems?

Sean: A biomanufacturer needs to choose a partner that has in-depth knowledge and a strong understanding of the different processes, materials and components that go into a single-use manufacturing facility. We approach single-use system design collaboratively with our customers; we look to understand the workflow for their target molecules so we may design a single-use system to best meet their needs. This involves the engagement of our teams, from understanding the overall process, to specific needs of each unit operation, and desired outcomes.

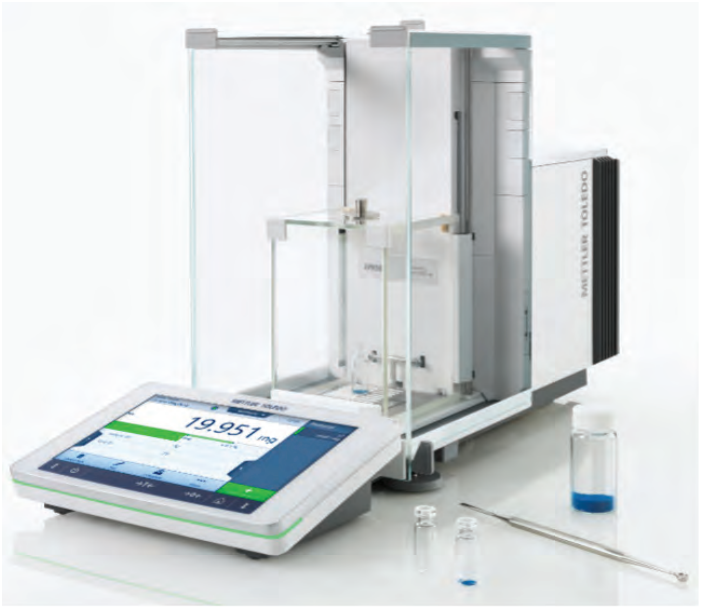
Narayana: Biopharma is a highly regulated, global industry. Our customers need high-quality products and services wherever they are located in the world. Avantor has innovation centers strategically within AMEA, where our applications teams perform customer trainings, technical assistance, troubleshooting, proof of concept studies and process development services. Also, they work closely with our global R&D team in developing the innovative technologies and solutions for future.

What is the future of single-use technologies?

Narayana: Globally, mAbs occupy a significant portion of single-use demand, followed by vaccines. We also see cell and gene therapy adding to the demand due to the batch sizes, personalized medicines and need of sterile handling. The trend is similar in AMEA as well.

Sean: In emerging areas like cell and gene therapy, the industry is adapting products that came from the medical device industry. There are shortcomings there, but they are the only materials/ approaches currently available. It's similar to where we were 15 years ago in biotech when we were using available industrial products and adapting them to the needs of the biopharma industry. But innovation led to big improvements – and the same will happen with emerging fields. ■

Exact Weighing Results Through Clever Ergonomic Design



Timely, efficient development of new medications requires accurate, fully compliant weighing data. The XPR Analytical and Micro-Analytical Balances are designed for ergonomic weighing and stable results, regardless of drafts or electrostatic charges. In addition, they benefit from connectivity options that support the audit trail.

A small footprint lets METTLER TOLEDO's XPR balances slot into any lab space; their ergonomic design reduces fatigue and the possibility of spilled samples. And SmartGrid™, an intelligently engineered weighing pan, lets spills fall harmlessly to the balance floor for faster and more stable results, even in turbulent areas such as a fumehood.

An up-to-date, intuitive touchscreen interface shows users all essential details at a glance, and can be navigated simply, even with gloves on. Addition of the powerful LabX® laboratory software helps to standardize results, with SOPs displayed on the screen(s) of the balance and other connected instruments so that operators can follow each step of a protocol to the letter. LabX immediately

captures, and securely stores, complete data in its central database, supporting compliance with 21 CFR Part 11. A range of inbuilt connectivity options allows further data backup as hardcopies or on local devices, as well as analysis in external tools.

The StaticDetect sensor and optional ionizing module eliminate electrostatic charges, reducing settling times regardless of local conditions or the substance's properties.

Infrared sensors permit handsfree operation, further streamlining weighing procedures.

With their clever construction, the XPR Analytical and Micro-Analytical Balances counteract typical weighing pitfalls to produce accurate, repeatable results every time. ■

Contact Details

Email us at: sales.sales@mt.com
Call us toll-free at – 1800 22 8884 & 1800 1028 460
Website: www.mt.com

An Accurate and Cost-efficient Pharmaceutical Industry Solution

Mettler Toledo's pharma checkweigher boasts a throughput of up to 300 packs per minute and an extremely high weighing accuracy thanks to high-performance conveyors. The weighing ranges from 0 to 300 g combined with numerous configurable options provides benefits for pharmaceutical production companies. Features include FDA 21 CFR Part 11 functionality, individual user profiles with password protection, advanced user management, and audit trails. Special handling options allow for the optimal transport of products – hand-in- hand with high-performance weighing conveyors this ensures increased weighing accuracy. Downstream production equipment is protected through a variety of product flow monitoring options. Security can be maximized by add-ons like the LogIn-Server for a complete access control protocol or Local Audit Trail for complete process accountability.

Some Major Features of the Checkweigher

Maximum Productivity: The transfer unit consists of top and bottom belts for smooth product transfer. The detection of open flaps and askew packages increases system availability and minimizes unforeseen production line stoppages

Up to 33% Higher Performance: The C-Series combines high throughput with utmost accuracy to promote tighter manufacturing tolerances in your production facility. Improved processes and increased overall equipment effectiveness maximize your profits.

Extensive Controls Maximize Process Reliability: A wide range of electromechanical and software options are available, ensuring that production processes are controlled precisely to ensure maximum safety and security.

Ease of Use: Process data is clearly displayed on a 12" multi-lingual high-contrast touchscreen guaranteeing ease of use. Our future proof system architecture ensures smooth processes and maximum uptime.

Global Service Support: The industry's largest, truly global service network ensures first class support – from professional installation to achieve compliance, over service contracts for maximum performance up to rapid delivery of spare parts to reduce downtime. ■

Contact Details

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West Ready Pack™ System

The Right Containment System for Sensitive Biologic

There is no doubt biologics and biosimilars will remain hot topics in 2021. This is due to the pandemic period of SARS-CoV-2 and the innovative treatments and vaccines that are under development at an accelerated speed.

Several questions arise frequently regarding the selection of the proper primary package system for a biologic/ biosimilar.

- If the biologic is very sensitive - can the system provide enough protection?
- If the molecules are very complex - can the system maintain stability?
- If the timeline for approval is very tight - will the system be approved?

These questions are especially challenging for a company that may have expertise in drug development, but not primary package systems.

West can help. Based on extensive knowledge and a history of market leadership, West offers primary packaging systems that can address these and other questions.

The Ready Pack™ system comprises NovaPure® stoppers, Flip-Off® CCS (clean, certified, sterilized) seals, and Schott adaptiQ® glass vials. NovaPure stoppers offer a FluroTec™ barrier film in areas that contact drug product, which can reduce:

- Migration of leachable from elastomer into drug product;
- Interaction of drug products with stoppers.

Each NovaPure stopper is vision inspected using the Envision™ verification process to ensure low and controlled particle levels. Ready Pack system components are offered in quantities that support every development stage – from concept through commercialization. The Ready Pack system provides you with a flexible solution at any stage of your drug development, with small quantities delivered when you need them. Components are suitable for the small-scale filling of high-value drugs and meet regulatory requirements from R&D through commercialization. West seamlessly supports your scale up to commercial production with larger volumes, while shortening your time to market with a proven containment system for your drug product.

Ready Pack System Benefits

- Integrated closure system proven to assure CCI, reducing your risks and testing efforts
- Provides a solution for risk mitigation and change control, assuring your drug product and its packaging maintain a consistent profile from clinical stages through commercial development
- Components are supplied sterile and can be directly introduced into your filling operations, eliminating component preparation from your process
- Supports scale-up and allows you to transition from early-stage pilot manufacturing to larger commercial-scale operations
- Available in small quantities, with the flexibility to buy the full system or only the components that you need, reducing waste associated with commercial volumes
- Dedicated technical support and access to scientific resources and content, aimed at helping you move your drug product to market. ■

Contact Details

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Visitor Access Control Systems with QR code scanner for TraceTogether / Safe Entry

Visitor Access control Systems

Marshal Systems introducing Visitor Access control Systems developed for visitor access control systems for Shopping Mall, Office Building, Government Building, Airport, Hospital, Schools, Supper Market, Gym Centre, and so on. It helps enterprises to save manpower and meet government COVID 19 regulation.

Some Key Features of the product includes Temperature scanning, Mask Detection.

Registering Trace Together or Safe Entry has benefits like Bar Code or QR Code scanner for IC, worker permit, Trace Together Token, Manual key-in by touch panel, Recognize the registering state by OCR module from visitor's mobile phone interface, People counting to control the crowd limits.

Other Key Specifications include Temperature accuracy: ±0.1 OC from 30~45OC, Detect Distance: 0.5~1.5 Meter, Mask Detection Rate: 99.99% and Flow rate: Min 25 person per minute

System Includes Industrial PC and 8-inch Monitor with Touch Panel, Bar Code and QR code scanner, Thermal Scanning module, OCR module (for mobile phone interface) and People counting module.

There are three types of Configuration, you may choose either one based on your requirement:

The set of devices, will scan the human temperature, facial recognition and allow the user to scan their QR code in the TraceTogether Token for check-in

The set of devices will scan the human temperature, facial recognition, allow the user to scan their QR code in the TraceTogether Token and allow the user to check-in through their hand phone screen if they already check-in to the building using a QR code pasted outside the building

The set of devices will scan the human temperature, facial recognition, allow the user to scan their QR code in the TraceTogether Token and allow the user to check-in through their hand phone screen and People counting Module.

Contact :

Marshal Systems

http://marshal-systems.com/

Predict The Failure, Prevent The Loss

B&R's real-time operating system, Automation Runtime, now automatically logs data about storage media's health to provide machine operators and service personnel early warnings of impending failure. Storage media can be replaced before a crash causes lost data and costly downtime. B&R is among the first to bring this commercial-grade feature to industrial embedded runtime systems.

Automation Runtime

"Failure of a storage device can be devastating," says B&R product manager Varad Darji. "Even with a backup, a certain amount of recently changed data and settings are always lost. It can even bring down the entire machine, resulting in expensive lost productivity until an engineer replaces the drive and restores the settings." The new Storage Health Data function is available with an easy update to B&R's Automation Studio engineering environment with its storage media health monitoring helping prevent costly downtime.

Without any additional programming, Storage Health Data can be viewed in B&R's web-based System Diagnostics Manager tool, allowing service personnel to recommend storage media replacement during scheduled downtime proactively. It is also possible to program HMI functions that notify operators directly on their HMI screen when a drive reaches a defined threshold, such as 80% of its lifespan enabling early warning for technicians and operators. When you can detect the signs of impending failure, you can replace storage media before a crash results in lost data and costly downtime

Contact :
B&R Industrial Automation
www.br-automation.com

PURO: A Scale Of The Digital Age

Weighing Solution Puro

Since the product launch, the Puro industrial scale series has been convincing not only because of its performance and affordable price: smart logistics, transparent processes, online tutorials and an improved ecological footprint make Puro a product of the digital age. The weighing solution Puro has a universally compatible menu layout, ensuring intuitive operation regardless of the device.

In times of Industry 4.0, customers expect more than just reliable weighing technology: the entire package must be right - not just the product alone, but the complete product cycle is important: from the ordering process to the service case, Minebea Intec and its partners are there to support the customer. With Puro, the customer also receives the strong quality of a leading supplier at a fair price. With Puro®, the global leader in weighing and inspection solutions offers a complete package of performance, quality, features and functions, enabling the broad and affordable portfolio that customers wanted.

In the beginning, the goal was to offer Minebea Intec's reliable weighing technology at an affordable price. However, it quickly became clear that Puro is not just an innovative industrial scale - but an overall digital concept. This starts with the smart logistics network: Registered dealers can conveniently obtain information on the Puro series via the online shop: Here, it is possible to see transparently what the availability of the respective models is and when the product is available. Such factors lead to precise weighing results, flexible in use and still affordable.

But even after delivery, the customer - and the environment - benefits from digital solutions: via the QR code enclosed in the packaging, customers can access the Puro website, which contains all the information material on the industrial scale series: Operating instructions, technical details and exciting best practices that show the Puro in use by customers. Minebea Intec places great emphasis on reducing its environmental footprint by not using printed information material. This concept, coupled with the company's own initiatives such as "Zero Waste", should also ensure better environmental sustainability in the future leading to Puro convincing as an expert digital solution.

Large front and rear displays with LCD backlighting guarantee optimal readability, stabilisation in seconds ensures immediate weighing results and the tactile buttons ensure intuitive operation. Depending on

the requirement profile, there are models that offer, for example, a rear display for readability on both sides, a traffic light LED for check weighing or non-slip feet for use in difficult environments assuring Intuitive operation and best possible customer comfort.

Smart portfolio continues to grow as Minebea Intec sees digital solutions for industry as a fundamental part of its portfolios. This is demonstrated by the latest additions: On the manufacturer's website, customers can find interactive offers to inform themselves: In addition to the free webinars with compactly conveyed expert knowledge, Minebea Intec also offers digital offers for other areas: The classic customer appointment can be replaced by a free appointment in the Virtual Showroom, practical online calculators help to calculate the return on investment.

Therefore, digitalisation is reflected in all areas of our company. In new products such as Puro, in production and internal processes, but also in services and offers for our customers. This can be seen particularly well in our virtual showrooms or webinars, which we use, among other things, to inform interested parties digitally about weighing in the digital age. "

Contact :

Minebea Intec gmbh

www.minebea-intec.com

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- Refining & Petrochemical products
- Biotechnologies
- Chemical & Pharma Processing Equipment
- EPC Services
- Automation Technologies
- Environment Solutions
- Water & Wastewater Treatment Technologies
- Pumps & Valves
- Pipes & Fittings
- Packaging Solutions
- Material Handling Systems
- Analytical & Laboratory Technologies
- Consulting Services
- Equipment Fabricators

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- Adhesives & Sealants
- Agrochemicals & Crop Protection
- Bulk Drugs & Intermediates
- Enzymes
- Colorants, Dyes & Pigments
- Cosmetics & Personal Care Ingredients
- Hygiene & Cleaning Chemicals
- Laboratory Chemicals
- Surfactants
- Water Treatment Chemicals
- Catalysts
- Electronic Chemicals
- Flavours & Fragrances
- Contract Manufacturers

FACTS & FIGURES - CHEMTECH WORLD EXPO 2019

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