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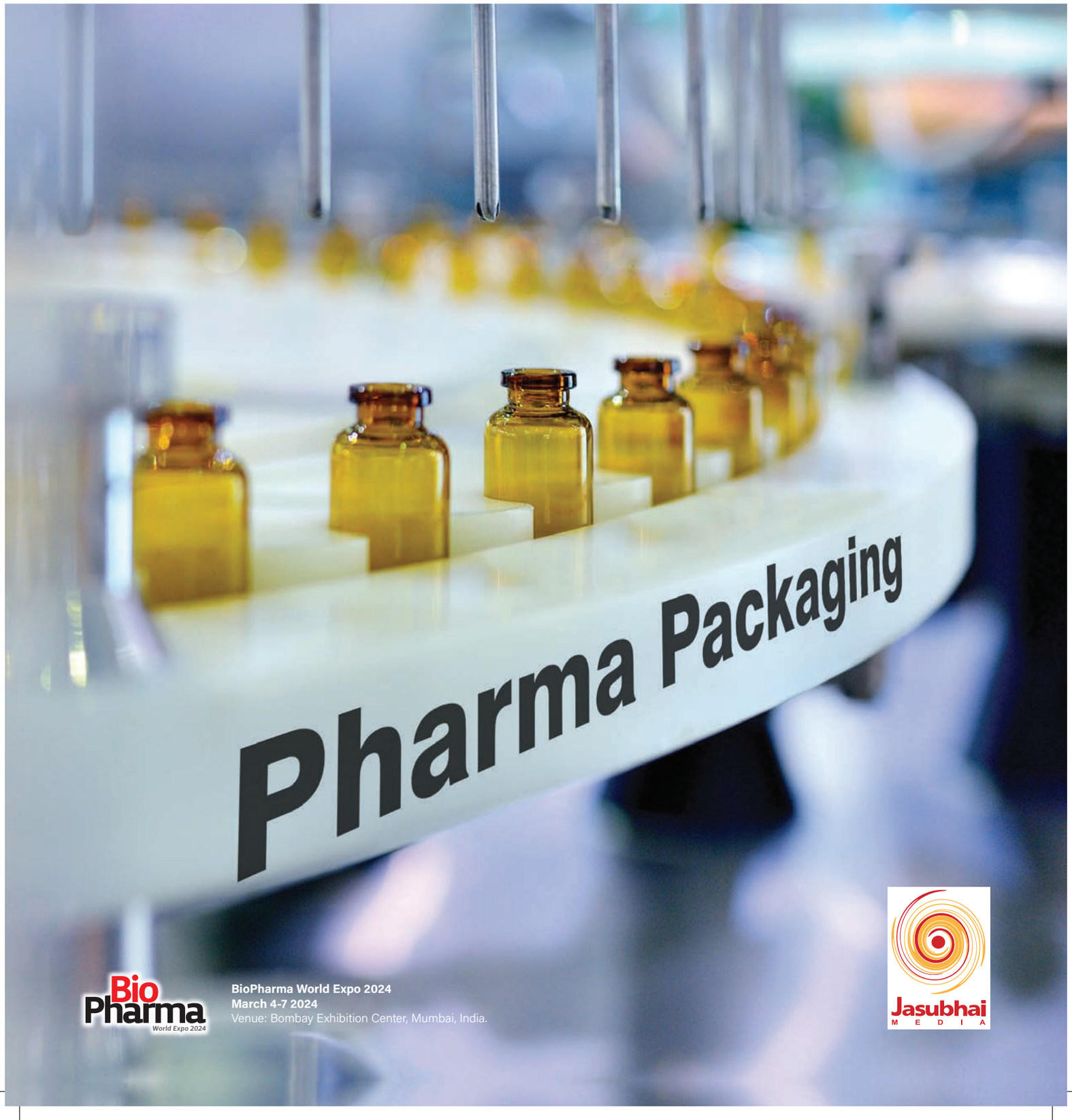

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Dr Mansukh Mandaviya addresses Global Vaccine Research collaborative discussion on Vaccine Research and Development

Dr. Mansukh Mandaviya, Union Minister for Chemicals & Fertilizers and Health & Family Welfare

New Delhi, India: Dr. Mansukh Mandaviya, Union Minister for Chemicals & Fertilizers and Health & Family Welfare stated that the COVID-19 pandemic has demonstrated the importance of global collaboration in vaccine research and development. As we continue to navigate this once-in-a-century public health crisis, we realize the importance of research to accelerate vaccine development, particularly for emerging pathogens, while addressing the Global Vaccine Research Collaborative discussion on "Vaccine Research and Development: Building Consensus for Future Health Emergencies Prevention, Preparedness, and Response' a co-branded event under India's G20 Presidency organized by Department. of Pharmaceuticals, Govt of India on the sidelines of the 3rd G20 Health Working Group Meeting, in Hyderabad.

Speaking on the occasion, Dr Mandaviya said that the Global Vaccine Research Collaborative could be a much-needed mechanism to advance vaccine R&D for emerging pathogens. "As we embark on this critical mission, we must leverage the collective expertise of our global health community and strengthen our pandemic preparedness efforts", he said. He further stated that "International cooperation is essential to advance vaccine development for emerging pathogens, and the G20 can serve as a vital platform to facilitate collaboration between governments, research organizations, pharmaceutical companies, and other stakeholders."

Highlighting India's leadership in vaccine R&D for several decades, with experience in developing, producing, and distributing vaccines for diseases such as polio, small pox, and measles, the Union Minister said that India, as a leading player in vaccine production and distribution, can play a critical role in building greater global collaboration towards this goal. "The development and deployment of effective vaccines can help to mitigate the impact of pandemics, and we must prioritize research efforts to achieve this objective", he said.

Elaborating on India's initiatives to boost vaccine production and distribution, the Union Minister stated that "the government has provided financial incentives and streamlined regulatory processes to encourage vaccine manufacturers to increase their production capacity. It has also taken steps to ensure the availability of vaccines in rural areas by leveraging the existing infrastructure of primary health centers and other healthcare facilities".

Government bans 14 fixed-dose combination drugs: Health Ministry

New Delhi, India: The government has banned 14 fixed dose combination drugs including Nimesulide and Paracetamol dispersible tablets and Chlopheniramine Maleate and Codeine syrup, according to Union Health Ministry notification. The banned drugs include drugs combinations such as Nimesulide + Paracetamol dispersible tablets, Chlopheniramine Maleate + Codeine Syrup, Pholcodine +Promethazine, Amoxicillin + Bromhexine and Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol, Paracetamol + Bromhexine+ Phenylephrine + Chlorpheniramine + Guaiphenesin and Salbutamol + Bromhexine for treating common infections. A combination drug or a fixed-dose combination (FDC) is a medicine that includes two or more active ingredients combined in a single dosage form.

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Indoco Remedies acquires 85% equity stake in US based FPP Holding Company, LLC

Aditi Panandikar, Managing Director – Indoco Remedies

Mumbai, India: Indoco Remedies Limited, a fully integrated, research based pharma company with a strong global presence has acquired 85% of equity stake of the US based FPP Holding Company, LLC for USD 4 Million from Contract Pharmacal Corp. The strategic investment by Indoco marks a significant milestone, solidifying its position as a key player in the US market. FPP Holding is the holding company of Florida Pharmaceutical Products, LLC ("FPP") which is based in Florida and engaged in marketing and distribution of generic pharmaceutical products in the USA. "This development will facilitate exchange of knowledge and best practices, further enhancing the overall competitiveness and growth potential of both organizations. Leveraging FPP's well-established distribution network, Indoco will have a greater reach and accessibility to a wider US customer base", said Aditi Panandikar, Managing Director – Indoco Remedies Ltd.

Sun Pharma enters into licensing agreement with Philogen

Mumbai, India: Sun Pharmaceutical Industries Limited and Philogen S.p.A announced that they have entered into a licensing agreement for commercializing Philogen's specialty product, Nidlegy (Daromun) in the territories of Europe, Australia and New Zealand. Nidlegy, currently in Phase III clinical trials, is a new anti-cancer biopharmaceutical which is being developed by Philogen for the treatment of melanoma and non-melanoma skin cancers.

Under the terms of the agreement, Sun Pharma will have exclusive rights to commercialise Nidlegy for indications of skin cancers in the territories of Europe, Australia and New Zealand. Philogen will complete pivotal clinical trials for the product in Europe, pursue Marketing Authorization with the regulatory authorities and manufacture commercial supplies. Sun Pharma will be responsible for commercialization activities. The two partner companies will share post-commercialization economics in about 50:50 ratio. Other financial terms were not disclosed. Philogen will retain the IP rights for Nidlegy for other territories and indications other than skin cancers.

Hellen De Kloet, Business Head - Western Europe and ANZ, Sun Pharma, said "We are delighted to partner with Philogen for Nidlegy, a close to market, new immunotherapy treatment in skin cancers. This collaboration is in line with our goal to bring innovative products to patients. With the expected addition of Nidlegy™ to our existing Odomzo™ franchise, we will be well-positioned to provide patient solutions across a broad spectrum of skin cancers in various disease stages."

Lupin receives USFDA approval for Diazepam Rectal Gel

Mumbai, India: Global pharma major Lupin Limited announced that its wholly-owned subsidiary, Novel Laboratories Inc., based in Somerset, New Jersey, has received approval from the United States Food and

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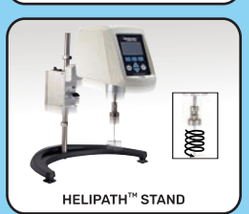
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Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Diazepam Rectal Gel, 10 mg and 20 mg, Rectal Delivery System, a generic equivalent of Diastat AcuDial Rectal Delivery System, 10 mg and 20 mg, of Bausch Health US, LLC. Diazepam Rectal Gel (RLD Diastat AcuDial) had estimated annual sales of USD 34 million in U.S. (IQVIA MAT Mar 2023). Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the U.S., India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions

AstraZeneca receives CDSCO approval for Tremelimumab combination in India

Bangalore, India: AstraZeneca Pharma India Ltd, a science-led biopharmaceutical company, announced it has received approval from the Central Drugs Standard Control Organisation (CDSCO) for its cancer drug Tremelimumab Concentrate to be administered intravenously. The approval for Tremelimumab in combination with Durvalumab is based on results from Phase III HIMALAYA clinical trial and is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC). The trial was conducted in 181 centres across 16 countries, including in the US, Canada, Europe, South America and Asia including India. This approval paves way for the launch of Tremelimumab solution of 20 mg/ml (25 mg/1.25 ml and 300 mg/15 ml presentations in single dose vials) in India for the specified indication. GLOBOCAN INDIA 2020 reports more than 30,000 new local cases of HCC are diagnosed every year, making it the 10th most common cause of cancer in India.

Dr. Sanjeev Panchal, Country President and Managing Director, AstraZeneca India, said: "As pioneers in science, we are united in our aim of improving the lives of patients. This approval is in line with our ambition of transforming patient outcomes and not leaving any patient behind. We have a breadth of scientific platforms to attack cancer while exploring the power of combinations, seeking to drive deeper and more durable responses." Dr. Anil Kukreja, Vice-President, Medical Affairs and Regulatory, AstraZeneca India, added: "Prognosis of patients with unresectable liver cancer is often limited and diagnosis is significantly delayed, with majority of the cases getting diagnosed in advanced and unresectable stage. Hence, novel treatment alternatives become paramount for improving long-term survival. The approval for Tremelimumab underscores our unwavering commitment of brining lifechanging medicines to Indian patients" The common causes and risk factors for HCC in India include- cirrhosis, hepatitis B infection, hepatitis C infection, alcohol, smoking, diabetes, NAFLD (Non-Alcoholic Fatty Liver Disease). The 5-year survival rate for HCC is about 18%; localised, regional and metastatic HCC have a 5-year overall survival (OS) of 33%, 10% & 2% respectively.

Venus Remedies consolidates its position in oncology space with Saudi marketing approval for Docetaxel

Saransh Chaudhary, President, Global Critical Care, Venus Remedies

Mumbai, India: In a decisive step towards making its entire oncology product portfolio available in Saudi Arabia, Venus Remedies Ltd, a well-known provider of affordable cancer drugs worldwide, has secured a marketing authorisation from the largest market in the Gulf Cooperation Council (GCC) region for Docetaxel, a widely used chemotherapy drug. The development comes three months after the company received good manufacturing practices (GMP) certification from the Saudi Food and Drug Authority (SFDA) for all its production facilities at its unit in Baddi, Himachal Pradesh.

The demand for Docetaxel has been steadily increasing the world over with the rising incidence of breast,

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prostate, stomach and non-small cell lung cancers, for which this chemotherapy drug is used as a first line of treatment. Docetaxel-based treatment has particularly improved the survival rate among men in castration-sensitive prostate cancers. The USD102-billion global Docetaxel market is projected to grow to USD184 billion by year 2030 at a CAGR of 10.22%. The marketing approval for Docetaxel from Saudi Arabia, a USD7.8-billion pharmaceutical market (as in 2021) which is expected to grow to USD13.1 billion by 2031 at a CAGR of 5.4 per cent, signifies a major step in the global expansion strategy of Venus Remedies in the oncology space.

Hailing the achievement, Saransh Chaudhary, President, Global Critical Care, Venus Remedies, said, "This approval will enable us to solidify our existing foothold in the GCC and Middle East and North Africa (MENA) regions by streamlining the registration process for our oncology drugs there, ultimately benefiting a large population in need of advanced cancer treatments." Venus Remedies is already a market leader for its key antibiotic products in Saudi Arabia, where it has nine marketing authorisations, including three in the oncology segment.

Aurobindo Pharma arm Eugia Pharma receives USFDA approval

Hyderabad, India: Aurobindo Pharma Limited announced that its wholly owned subsidiary company, Eugia Pharma Specialties Limited, has received a final approval from the US Food & Drug Administration (USFDA) to manufacture and market Carboprost Tromethamine Injection USP 250 mcg/mL, Single-Dose Vials, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Hemabate Injection, 250mcg/mL, of Pfizer Inc. Carboprost Tromethamine injection is indicated for the treatment of postpartum hemorrhage due to uterine atony which has not responded to conventional methods of management. Prior treatment should include the use of intravenously administered oxytocin, manipulative techniques such as uterine massage and, unless contraindicated, intramuscular ergot preparations. The product is expected to be launched in June 2023. The approved product has an estimated market size of around USD51.4 million for the twelve months ending March 2023, according to IQVIA.

Suven Life Sciences completes enrollment of patients for phase 2 clinical study of Samelisant

Hyderabad, India: Suven Life Sciences, a clinical stage biopharmaceutical company discovering and developing novel medicines to treat Central Nervous System (CNS) disorders, announced completion of enrollment for its phase-2 PoC clinical study evaluating the safety and efficacy of samelisant in adult narcolepsy patients with and without cataplexy. Data readout for the study is anticipated in second quarter of FY2024.

"We are pleased to have achieved this milestone with the development of samelisant in the narcolepsy space and look forward to the data readout in second quarter of FY2024". "Narcolepsy is a chronic disease characterized by the symptoms such as excessive daytime sleepiness (EDS) and cataplexy that impairs quality of life, Samelisant's mechanism of action increases histamine transmission in the brain which provides the scientific rationale for its potential clinical utility for the management of narcolepsy", said Mr. Venkat Jasti, Chairman & CEO of Suven Life Sciences." Samelisant is a novel, potent, selective, brain penetrant and orally active Histamine H3 receptor inverse agonist. H3 receptor blockade elevates histamine, norepinephrine and dopamine in brain, a potential for treatment EDS and cataplexy.

Glenmark Pharma reduces cost of Trastuzumab for Breast cancer

Mumbai, India: Glenmark Pharmaceuticals Ltd, an integrated, research-led, global pharmaceutical company, announced a price reduction of Trastuzumab for HER2-positive breast cancer, being marketed in India under the brand name ' Trumab.' A 440 mg vial of Trumab will be priced at Rs. 15,749, which makes it the most affordable option available currently in the country. Trastuzumab is a monoclonal antibody that has been the mainstay of HER2-positive breast cancer treatment for many years.

The cost of Trastuzumab treatment has been a major barrier for many patients in India. Most of the existing Trastuzumab brands in the market are priced in between Rs.40,000 to Rs. 54,000 per 440 mg vial. Considering that a patient needs to undergo a minimum of 18 cycles (12 months) of treatment, the average cost of treatment ranges from Rs. 4,00,000 to Rs.5,00,000 for early breast cancer and can exceed Rs.5,00,000 for advanced/

metastatic cases. This can be a significant financial burden for many families, especially in India, where out of pocket expenditures account for approx. 52% of the total healthcare financing.

Alok Malik, Executive Vice President & Head of India Formulations, Glenmark Pharmaceuticals Ltd. said, "At Glenmark, we believe that everyone deserves access to quality healthcare, regardless of their financial situation. Our company's move of reducing the cost of its life-saving drug Trumab is a major step in this regard. This will not only increase the accessibility, but also bring hope to over 75% of self-paying HER2-positive breast cancer patients in India."

USFDA completes inspection at JB Pharma's manufacturing facility at Panoli, Gujarat

Mumbai, India: JB Chemicals & Pharmaceuticals Limited announced that that the Company's formulations manufacturing facility- T20 located at Plot No. 4, GIDC, Panoli, Gujarat was inspected by the USFDA. The inspection was conducted from June 5, 2023 to June 9, 2023. "At the end of the inspection, the facility received "No Observations" and thus NO Form 483 was issued," the company said. The Company remains committed to producing quality products, embedding a quality culture across the organization and continuously investing in systems, processes & training of its employees so that it can maintain the highest standards of quality and compliance for all its markets.

Ind-Swift Laboratories Q4 turnover up 4%

Chandigarh, India: Ind-Swift Laboratories Limited (ISLL) posted financial results for the quarter ended 31st March , 2023. The company reported a turnover of Rs. 294.81 crores during the quarter ended 31st March 2023, as against turnover of Rs. 285.16 crores during the quarter ended 31st March 2022, registering a growth of 4%. The Company has however reported net loss during the quarter of Rs. 30.91 crores as against the net loss of Rs. 63.18 crores during the quarter ended 31% March 2022. The net loss is majorly attributable to the one-time loss on sale of investment during the quarter due to which the company recorded a loss of Rs. 26.64 crores. The Company however reported an EBIDTA of Rs. 61.72 crores during the quarter ended 31% March, 2023, which is very much in line with the performance of the Company for the last 6 to 8 quarters.

Commenting on the results N.R.Munjal, Chairman and Managing Director of Ind-Swift Laboratories Limited stated that © The year 2022-23 has been a significant year in the history of the Company as the Company reported lifetime high EBIDTA of Rs. 250 crores ; the performance of the company had been par excellence."

Alkem Laboratories launches World's first biosimilar for HNCs

Sandeep Singh, Managing Director, Alkem Laboratories

Mumbai, India: Alkem Oncology has announced the launch of Cetuxa, the world's first biosimilar of Cetuximab used for the treatment of head and neck cancer. This is in line with the company's endeavour to ensure affordability, accessibility, and availability while saving the lives of critically ill Cancer patients. Cetuxa has been researched and manufactured indigenously by Enzene Biosciences Limited, the biological arm of Alkem Laboratories.

Head and neck cancers (HNCs) are one of the most common cancers worldwide and in India too. According to the Global Cancer Observatory (GLOBOCAN) estimates, there were 19.3 million incident cancer cases worldwide in 2020 and India ranked third after China and the United States of America. Overall, 57.5% of global head and neck cancer cases occur in Asia and India accounts for 30% of these cases. Annually, in India, the prevalence of head and neck cancer is approximately

5,00,000 cases with over 1,25,000 deaths.

Cetuxa aims to increase the accessibility and affordability of a novel cancer drug for head and neck cancer patients. It is a biosimilar of cetuximab, a monoclonal antibody, and received DCGI approval on 16th January 2023 for this indication. Cetuximab binds to the extracellular domain of the epidermal growth factor receptor (EGFR), which is overexpressed in many human cancers, including head and neck cancer and colorectal cancer. This process prevents EGFR from binding with its endogenous ligand, blocking the receptor-dependent transduction pathway and providing many anti-tumour effects.

Cetuxa is administered as an intravenous infusion and is available as 100 mg (2 mg/mL) in a singledose vial. Initial dose is 400 mg/m2, follow-up of 250 mg/m2 per week. Cetuximab has a proven record in terms of better progression-free survival (PFS) and overall survival (OS) compared to chemotherapy alone for the management of head and neck cancer. "In India more than 76,000 patients are eligible for the use of cetuximab for the management of head and neck cancer. Currently, only 1,611* patients are managed by this therapy i.e., around 2% of eligible patients. Its reach in India is limited partly due to its high cost. To address this issue, we have launched an affordable biosimilar which is backed by indigenous research and production. We aim to ensure its availability in all parts of the country making it easily accessible to the Indian population," said Sandeep Singh, Managing Director at Alkem Laboratories.

"We are glad to announce Cetuxa drug as it will be a historic breakthrough in terms of saving the lives of cancer patients. We have developed Cetuxa as a goal to make cancer therapy more accessible and affordable to millions of patients suffering from head and neck cancer", said Dr. Himanshu Gadgil, CEO, at Enzene Biosciences Ltd(biological arm of Alkem Laboratories).

Zydus receives USFDA approval for Delayed-Release Oral Suspension

Ahmedabad, India: Zydus Lifesciences Limited has received final approval from the United States Food and Drug Administration (USFDA) for Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg and 40 mg (USRLD: Nexium Delayed-Release for Oral Suspension, 20 mg and 40 mg).

Esomeprazole is used to treat certain stomach and esophagus problems (such as acid reflux and ulcer). It works by decreasing the amount of acid your stomach makes. It relieves symptoms such as heartburn, difficulty swallowing, and cough. This medication helps heal acid damage to the stomach and esophagus, helps prevent ulcers and is expected to help prevent cancer of the esophagus. Esomeprazole belongs to a class of drugs known as proton pump inhibitors (PPIs). The product will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg and 40 mg had annual sales of USD 42 mn in the United States (IQVIA MAT April 2023).

Kilitch Drugs Q4 operating revenue rises 35%

Mumbai, India: Kilitch Drugs India Limited is a leading MSME multinational manufacturer of Injectable in India and Ethiopia, has announced its audited financial results for the Q4 & FY23. The company's operating revenue stood at Rs.43.28 crore, while EBITDA stood at Rs.8.12 crore for the fourth quarter. The net profit stood at Rs.5.13 crore, while net profit margin was 11.85%. Mukund Mehta, Managing Director of Kilitch Drugs (India) Limited said "We experienced a remarkable 69.87 % increase in net profit, which can be attributed to the splendid demand for our products during this period. I am particularly pleased with the results of our efforts to improve pricing and exercise rigorous cost control, which led to an impressive ~400 basis point jump in our EBITDA margin. This accomplishment reflects the dedication and hard work of our team.Looking ahead, we are confident that our positive momentum will continue in coming years. Our commitment to growth is evident through our ongoing capacity expansion initiatives, aimed at meeting the rising demand from both domestic and international markets."

University of Dundee secures £4.4 mn to advance Gene "Video Editing" for cancer and neurodegenerative disease drug discovery

Scotland, United Kingdom: The researchers at the University of Dundee have received funding of £4.4 million to explore how our genes can be 'video-edited' to develop new drugs for cancer, neurodegeneration, and other diseases. Genes are the pieces of DNA that contain the information required to make different types of proteins that build and maintain living organisms. Alternative splicing enables the production of different messenger RNAs and proteins from a single gene.

Professors David Gray and Angus Lamond, from the School of Life Sciences, University of Dundee will work with colleagues in Germany and Spain on the UNLEASH project. The project aims to produce drug-like small molecules that can control a process called alternative splicing (AS), known to play a key role in disease development. Both of the Dundee researchers have been awarded funding from UK Research and Innovation (UKRI) for UNLEASH, with their collaborators receiving a matching amount from the European Research Council (ERC).

The information in human genes is 'split', which allows a single gene to code for multiple proteins. If scientists can learn how to manipulate this process accurately, it will create opportunities to control how genes function and contribute to disease mechanisms. The team aims to precisely control this process to help pharmaceutical companies develop novel therapeutic approaches for treating human diseases. According to Professor Lamond, an analogy can be made with the more familiar process of video editing.

He further says, "The gene can be seen as the raw video footage that is captured, while the mRNA product that delivers the instructions for proteins is like edited video footage, where the editor has removed – spliced out – unwanted regions to form the final video story. Just as a skilled video editor can edit their raw footage in different ways to create more than one alternative video sequence, human genes can also be edited differently, thus creating alternative final mRNA products that code for different types of proteins. AS holds the key to understanding how our genes function and for the development of new therapeutics for a host of human diseases, many of which are known to alter the splicing process."

Caplin Steriles gets ANDA approval for Cisatracurium Besylate Injection

C. C. Paarthipan, Chairman, Caplin Point Laboratories Limited

Chennai, India: Caplin Steriles Limited (Caplin), a Subsidiary company of Caplin Point Laboratories Limited, has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Cisatracurium Besylate Injection USP, 10 mg/5 mL (2 mg/mL) and 200 mg/20 mL (10 mg/mL) Single-dose Vials; and 20 mg/10 mL (2 mg/mL) Multiple-dose Vials (Preserved)., a generic therapeutic equivalent version of (RLD), NIMBEX injection of AbbVie Inc. Cisatracurium Besylate Injection USP is a nondepolarizing skeletal neuromuscular blocker, indicated as an adjunct to general anesthesia to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgical procedures.

According to IQVIA (IMS Health), Cisatracurium Besylate Injection USP had US sales of approximately $35 million for the 12- month period ending December 2022.

C. C. Paarthipan, Chairman of Caplin Point Laboratories Limited commented "We have been consistent with our filings and also happy to receive approvals on time. We're creating a healthy portfolio of products that we will launch not only in the US but in global markets as well. This approval will augment our growth plans for Caplin Steriles this year and the years going forward."

Dr. Reddy's completes Phase I study of DRL_TC, a proposed biosimilar of tocilizumab

Hyderabad, India: Dr. Reddy's Laboratories Ltd, a global pharmaceutical company, announced that its tocilizumab biosimilar candidate, DRL_TC, successfully met its primary and secondary endpoints in a Phase I study. This Phase I study used an intravenous (IV) formulation to evaluate the pharmacokinetic equivalence, safety and immunogenicity of Dr. Reddy's tocilizumab biosimilar candidate in comparison to reference products. The Phase I study entitled 'A Phase I, Double Blind, Randomized, Parallel-group, Single dose, Three arm, Comparative Pharmacokinetic and Pharmacodynamic Study of Dr. Reddy's Tocilizumab (DRL_TC), USA sourced Reference Tocilizumab (Actemra) and EU sourced Reference Tocilizumab (RoActemra) Administered by the Intravenous Route to Normal Healthy Male Volunteers' met all primary and secondary endpoints.

Dr. Jayanth Sridhar, Global Head of Biologics at Dr. Reddy's, said: "Tocilizumab is an important antirheumatic agent that has a unique place in treating patients with rheumatoid arthritis and other diseases. By developing the formulation in both subcutaneous and intravenous formulations, we aim to reach more patients around the world. With our recent milestones in our proposed biosimilars of tocilizumab and rituximab, our partner's launch of pegfilgrastim in the U.S and Europe, we look forward to maintaining our momentum as part of our goal to serve over 1.5 billion patients by 2030."

Granules India receives ANDA approval for Metoprolol Succinate ER tablets

Hyderabad, India: Granules India Limited announced that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Metoprolol Succinate Extended-Release Tablets USP, 25 mg, 50 mg, 100 mg and 200 mg. It is bioequivalent to the reference listed drug product (RLD), Toprol-XL Tablets, 25 mg, 50 mg, 100 mg and 200 mg, of Toprol Acquisition LLC.Metoprolol Succinate ER Tablets are indicated for the treatment of hypertension in order to lower blood pressure.

Granules now has a total of 57 ANDA approvals from US FDA (55 final approvals and 2 tentative approvals). The current annual U.S. market for Metoprolol Succinate ER Tablets is approximately $321Million, according to MAT Mar 2023, IQVIA/IMS Health. Granules India Limited, incorporated in 1991 is a vertically integrated fast growing Indian pharmaceutical company headquartered at Hyderabad with best in class facilities and commitment to operational excellence, quality, and customer service. The company is among the few pharmaceutical companies in the world to be present in the manufacturing of entire value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs) and Finished Dosages (FDs).

Natco Pharma receives final approval for Tipiracil Hydrochloride and Trifluridine for US market

Hyderabad, India: Natco Pharma Limited announced the final approval for its Abbreviated New Drug Application (ANDA) for Tipiracil Hydrochloride and Trifluridine Tablets (generic for Lonsurf) from the U.S. Food and Drug Administration (USFDA). Lonsurf is sold in the US by Taiho Oncology Inc. Natco believes it is one of the First-to-File for the product and may be eligible for a 180-day exclusivity at the time of launch. Lonsurf is indicated primarily for the treatment of colorectal cancer. As per IQVIA data, Lonsurf had generated annual sales of $211 million in USA during the twelve months ending December 2022.

Natco Pharma Limited was incorporated in Hyderabad in the year 1981 with an initial investment of Rs.3.3 million. With a modest beginning of operations as a single unit with 20 employees, Natco has eight manufacturing facilities spread across India with dedicated modern research laboratories, capabilities in New Drug Development, etc.

Ipca Labs' Ratlam facility receives 11 USFDA observations

Mumbai, India: Ipca Laboratories Ltd announced that the US Food and Drug Administration (US FDA) conducted the inspection of the Company's APIs manufacturing facility situated at Ratlam, Madhya Pradesh from 5th June, 2023 to 13th June, 2023. "At the conclusion of the inspection, the US FDA issued a Form 483 with 11 (eleven)observations," the company said. The Company will submit its comprehensive response on these observations to the US FDA within the stipulated time and shall work closely with the agency to resolve these issues at the earliest. The Company takes the quality and compliance issues with utmost importance and remains committed to maintain the highest standards of quality and compliance across all its manufacturing facilities.

Ipca Laboratories is the leading API formulations manufacture & export with a reliable supply chain in over 120 countries. It is one of the world's largest manufacturers and suppliers of over a dozen APIs. These are produced from scratch at fully-automated manufacturing facilities, approved by the world's most discerning drug regulatory authorities like UK-MHRA, EDQM-Europe, and WHO-Geneva, among others. It produces theobromine, acetylthiophene, and p-bromotoluene as active pharmaceutical ingredients (APIs).

Biocon's API manufacturing facility in Bangalore receives EU GMP compliance certificate

Karnataka, Bengaluru, India: Biocon Ltd announced that Active Pharmaceutical Ingredient (API) manufacturing facility located in Bangalore has received a certificate of GMP compliance from the Competent Authority of Germany, following an EU GMP inspection that was conducted in February 2023. Biocon Limited is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US, Europe & key emerging markets.

Laurus Labs signs Memorandum of Agreement (MOA) with IIT Kanpur for novel gene therapy assets

Hyderabad, India: Laurus labs stated that it has signed an MOA with IIT Kanpur (IITK) to bring novel gene therapy assets to market. As per MOA, Laurus labs will in-license few gene therapy assets and will provide research grant for advancing these products through the pre-clinical development. Laurus will also provide funding for the clinical trials and will launch these products in India and emerging markets. Additionally, Laurus labs will establish a GMP facility at the Techno Park facility of IITK.

Department of Biological Sciences and Bioengineering (BSBE) at IIT Kanpur has been working on gene therapy for the last few years and have developed few gene therapy assets along with technology for novel Adeno Associated Virus (AAV) vectors. They have filed IPs around these products and few additional patent applications will be filed in due course. This partnership allows Laurus Labs to strengthen its presence in the promising Cell and Gene Therapy (CGT) space and allows it to become a leader in this space. These therapies are not available in India and emerging markets and this collaboration will help us in bringing these novel therapies to Indian patients at an affordable pricing. Additionally, this allows Laurus labs to offer CDMO services to cell and gene therapy companies.-

Commenting on this development, CEO of Laurus Labs Dr. Satyanarayana Chava said, "This collaboration exhibits our commitment towards Cell and Gene therapy (CGT) space. This partnership also provides a unique model for industry –academia collaboration and how can we leverage strengths from both the sections for the benefit of patients. IITK has a proven record of being a flag bearer for advancing research in India and this collaboration takes it to the next level". Founded in 2005, Laurus Labs is a research-driven pharmaceutical and biotechnology company with an aim to improve the quality of life for millions of people around the world. Laurus has a global leadership position in select Active Pharmaceutical Ingredients (APIs) including anti-retroviral, oncology drugs (incl High Potent APIs), Cardiovascular, and Gastro therapeutics. Laurus also offers integrated Contract Development and Manufacturing Organization (CDMO) services to Global Innovators from Clinical phase drug development to commercial manufacturing.

India's first mRNA based Omicron-specific booster vaccine from Gennova gets DCGI approval

Dr. Sanjay Singh, CEO, Gennova Biopharmaceuticals

Pune, India: Gennova Biopharmaceuticals Ltd, a Pune based company, announced that its mRNA COVID-19 booster vaccine – GEMCOVAC-OM - against the Omicron variant of SARS-CoV-2 received Emergency Use Authorization (EUA) from the office of the Drugs Controller General of India (DCGI).

GEMCOVAC-OM is the first booster COVID-19 vaccine developed in India against the highly transmissible Omicron variant. GEMCOVAC-OM has demonstrated robust immune responses in the phase 3 clinical trial conducted at 20 centers across 13 cities in India In Phase-II/ III trials, approximately 3000 individuals received GEMCOVAC-OM and the vaccine was safe and well tolerated.The currently approved vaccines used as precautionary/ booster doses are designed against the ancestral strain of SARS-CoV-2. Although these will increase the antibody titers, their ability to neutralize the circulating Omicron variant of SARS-CoV-2 is limited. Developing antibodies and memory immune responses specific to the Omicron variant would reduce the probability of infection and hospitalization and prevent future waves of the pandemic. The Made-in-India GEMCOVAC®-OM specifically addresses this gap.

GEMCOVAC-OM is a lyophilized (freeze dried) vaccine, stable at 2- 8 °C.It is delivered intradermally using a device called Tropis, developed by PharmaJet, USA. This is a needle-free device that obviates the disadvantages of using a needle, such as a needle phobia, sharps disposal, and needle-stick injuries, to name a few.

Dr. Sanjay Singh, CEO, Gennova Biopharmaceuticals Limited, said: "The Gennova team, as a part of the global scientific community's endeavour to meet unmet medical needs, is geared for dealing with health emergencies. There is a realization that the COVID-19 will remain and keep mutating, and therefore we need to be prepared with vaccines to deal with emerging variants, The mRNA platform, that was developed in association with the Department of Biotechnology, Government of India, provides an opportunity for a quick turnaround for vaccine development for any variants of concern in future, if any. Vaccines have remained the best shield for mankind against deadly diseases."

Reiterating Gennova's pursuit of research for finding solutions for better health, Samit Mehta, COO, Gennova Biopharmaceuticals Limited, said: "Gennova has successfully developed India's first Omicron-variant vaccine within a few months. Being aware of the accessibility challenges the world witnessed for the COVID-19 vaccines, we are happy that we are providing a vaccine based on a state-of-the-art technology, the mRNA. We are thankful to our stakeholders – medical fraternity, government, scientific community - for espousing confidence in our effort towards the mRNA technology and now the Omicron specific vaccine. The mRNA vaccine platform continues to remain a protective shield for India and the world against Coronavirus".

Neuland Labs receives 3 observations from USFDA for Jinnaram facility

Hyderabad, India: Neuland Laboratories stated that the United States Food and Drug Administration (US FDA) has inspected our Unit 3 manufacturing facility, located at Gaddapotharam village, Jinnaram, Sangareddy District, from 22nd to 26th of May 2023.The inspection has been concluded with 3 observations (minor) given under form 483, which are relating to procedures. The Company has already initiated corrective and preventive actions for the observations and is confident of addressing the same to the satisfaction of the US FDA within the stipulated time.

Neuland is a leading manufacturer of active pharmaceutical ingredients (APIs) and an end-to-end solution provider for the pharmaceutical industry's chemistry needs. The company provide solutions across the full range of the pharmaceutical industry's chemistry requirements, from the synthesis of library compounds to supplying NCEs and advanced intermediates at various stages in the clinical life-cycle, as well as commercial launch.

Strides Pharma Science Q4 sales stood at Rs.9,904 mn

Bangalore, India: Strides Pharma Science Ltd announced its consolidated financial results for the quarter (Q4FY23) ended March 31, 2023. The company reported quarterly sales of Rs. 9,904 million in Q4FY23, up 14% QoQ and YoY, while Q4FY23 EBITDA margins was at 16.1%.The company said that US business reported third consecutive quarter of $60+ million in revenues.

Arun Kumar, Founder, Executive Chairperson & Managing Director, Strides Pharma Science commented on the performance and said, "We are pleased to conclude FY23 on an encouraging note. The stated plan to return to growth, enhance profitability, and reduce debt has made significant headway. From FY22 to FY23, our total revenues increased by 20%, aided by performance in regulated markets. The US market, led by new product introductions and solid base performance, generated its highest-ever revenue of $232 million with significant margin expansion, in line with the management outlook. The other regulated markets also performed well throughout the year and reported their highest sales. The fro nt-end markets in the United Kingdom and the Nordics performed as anticipated, and the B2B markets grew further due to our renewed focus from the beginning of the year. On the operational front, we are delighted to announce that the USFDA has recently reclassified our Puducherry facility, giving all of our manufacturing sites a clear compliance status by the agency.

Bliss GVS Pharma receives Establishment Inspection Report from US FDA for Palghar unit

Mumbai, India: Bliss GVS Pharma Limited announced that United States Food and Drug Administration (US FDA) conducted a Pre-Approval Inspection (PAI) and Good Manufacturing Practice (GMP) at the Company's manufacturing unit at Plot No. 11, Survey No. 38/1, Dewan Udyog Nagar, Aliyali Village, Palghar, 401404, Maharashtra from Monday, March13, 2023, to Friday, March 17, 2023. Pursuant to above inspection by the United States Food and Drug Administration (US FDA), the Company has received the Establishment Inspection Report (EIR) indicating closure of the inspection through which the US FDA agency assigned the inspection classification of the facility as "Voluntary Action Indicated (VAI)".Based on this inspection and the US FDA VAI classification, this facility is in compliance with regard to current good manufacturing practices (cGMP).

Bliss GVS is a fast-growing Pharmaceutical Company with a proven track record of developing, manufacturing and marketing high quality pharmaceutical formulations at affordable prices for the global market. The company is among the world leaders in Suppositories and Pessaries dosage forms with one of the largest portfolios in this segment. Over the last decade, we have acquired definitive know-how in other dosage forms & therapeutic segments, which is exemplified by our ever-expanding product offering across more than sixty countries. ■

INTERVIEW

"We are investing through innovation and partnerships."

Alagu Subramaniam
Senior Director
Sales and Commercial Operations, Asia Pacific
West Pharmaceutical Services

Pharmaceutical packaging plays an important role in maintaining quality of product. ***Alagu Subramaniam*** *spoke about the company's footprint, global expansion strategy and shared insights about the growth drivers, and company's investment plans.*

What are your observations on changing market trends of containment solutions offered by West Pharmaceutical Services?

As today's medicines are changing with more complex and sensitive molecules, the drug delivery market will evolve. Injectable therapies are one of the fastest growing segments of the drug industry, which is mainly due to the growth of biologics. This is tied to the increasing demand for vaccines and other biologic medicines used in the treatment of chronic diseases like arthritis and diabetes. There is also a strong biologic pipeline led by cell and gene therapy, while radiopharmaceutical therapy is emerging as a safe and effective targeted approach to treating many types of cancer. There is also more focus on improving delivery of drugs, with the rise of the home-based healthcare market. This is beyond regular necessities like safety, efficacy, and quality – but looking at other benefits for patients such as precision and ease of administering the medicines. There is an increase in regulatory requirements for quality and control around the world. All of this translates into strong demand for high-quality and innovative containment solutions and delivery systems.

What is the market share of the company globally and in different markets?

Today, we have significant market share across the markets that we operate. In the Asia Pacific region, we boast a presence in Singapore, China, India, South Korea, and Australia. In Singapore, we have upgraded our Jurong facility with a combined team of almost 700, and in South Korea and Australia, West has strong connections and distribution networks with local suppliers.

Since the 1990s, West has also been serving the Indian and mainland Chinese markets – with strong sales teams of a combined 680 people across both markets. In 2019, West also established its first Digital Technology Centre (DTC) in India. As today's medicines are changing with more complex and sensitive molecules so does the drug delivery needs. With strategic growth plans and investments, West will continue to seek opportunities to reach the unmet needs of our customers around APAC by investing in our High Value Product capabilities to support the region's biotechnology growth and innovation, while nurturing the rapid pace of progress.

What is the rationale behind the upgrade and why did West pick Singapore?

The investment in our Jurong facility in Singapore comes at a critical time as the advancement of biologics is reshaping the way many diseases are prevented, diagnosed, and treated. This facility investment enables West to serve its customers' requirements by providing high-quality containment products for injectable drugs at one location, from start to finish, in the Asia Pacific region, helping to reduce overall lead times for customers. The Jurong facility in Singapore is the only one in APAC under the advanced manufacturing value stream for West. As a leading biomedical sciences hub at the heart of Asia, Singapore offers a high concentration of global players and clustering of industry leaders. It also offers a pro-business environment, infrastructure, talent, and innovation ecosystem. These external factors played a favorable role for Jurong site's selection for the upgrade.

Tell us about your Singapore facility? Please share insights into growth drivers and geographies that will drive the growth of these solutions?

The Singapore facility is part of our commitment to invest more than US$350 million globally in 2023 to ensure that our capabilities and capacity evolve in tandem with the needs of our customers. We are investing through innovation and partnerships. In 2022, West announced an supply and technology agreement with Corning Incorporated, that includes a multi-million-dollar investment to expand the Corning Valor Glass technology to enable advanced injectable drug packaging and delivery systems for the pharmaceutical industry. Earlier this year, we launched West Ready Pack containment solution with Corning Valor RTU Vials utilizing Stevanato Group's EZ-fill technology, the first of many containment solution products to come from West. We are also investing in strategic collaborations and early-stage funding through our Venture capital efforts to accelerate the development and delivery of new healthcare innovations.

How will the facility's enhancement benefit Singapore's thriving pharmaceutical and biomedical ecosystem?

With the upgrade, West will be able to manufacture advanced, high-quality containment products for injectable drugs from start to finish in a single location, significantly reducing overall lead time in production. This will enable us to offer a world-class supply chain to our customers across the region and help deliver life-saving drugs, life-enhancing solutions, and revolutionary medicines to patients more quickly. West has consistently built close partnerships with local and regional suppliers and partners over the years. This upgrade not only benefits our customer's businesses, but also support the growth of Singapore's pharmaceutical and biotech industry. With this manufacturing investment, we have reinforced our commitment to support the Singapore government's 'Manufacturing 2030' Plan and play a role in strengthening the country's advanced manufacturing industry. The investment will also support Singapore in achieving a complete supply chain manufacturing capability for future vaccines response.

What is West's business strategy in Singapore and APAC beyond the inauguration?

Asia is one of our most important markets, and West has been investing here for future growth. We look at APAC as a growth engine for us with one of the fastest drug discovery innovation speeds in the world. Singapore plays an integral role in strengthening West's footprint and manufacturing network in Asia Pacific.

Our focus is to continuously enhance our manufacturing capabilities to benefit the wider region, and the new plant is a step in the same direction which supports our strategy, while maintaining high quality and safety standards. In addition to facility expansion and modifications, expanding our talent pool of technical experts is also our goal. We also remain focused on supporting our talented workforce by offering career and upskilling opportunities that will benefit the wider region. Lastly, we will continue to seek our opportunities for collaborations with our valued customers, while engaging stakeholders to drive greater scientific insights and business capabilities within APAC. ■

INTERVIEW

"Advanced drug delivery, growing emerging economy and innovative packaging solutions drive the market for pharmaceutical packaging."

Rishad Dadachanji
Managing Director,
Dadachanji Group

Packaging is an integral part of pharmaceutical product as it ensures the quality and efficacy of these drugs are maintained throughout the supply chain. ***Rishad Dadachanji*** *spoke about the market dynamics, trends and future for Pharma packaging. He also shared insights about the regulatory framework for Pharma packaging and role of packaging in pharmaceutical industry.*

What are the new trends and future of Pharma packaging?

Pharmaceutical Packaging Market was valued at USD 99.9 billion in 2021 and is poised to reach USD 229.9 billion by 2027, growing at a CAGR of 14.9% from 2022 to 2027. Factors attributed to the rising demand for pharmaceutical packaging are burgeoning healthcare expenses and increasing consumer awareness regarding healthier lifestyle. Moreover, advanced drug delivery, growing emerging economy markets such as India, Thailand, China, and others, and innovative packaging solutions with higher patient convenience and compliance drive the market for pharmaceutical packaging.Sustainability is one of the trends currently. Companies globally want to reduce their environmental impact and save resources. Sustainability in the pharmaceuticals industry includes many facets, from decarbonizing operations by using renewable energies, to reducing or changing packaging materials. In this respect, recyclable and/or biodegradable solutions are pushing to the fore. Another trend is the increase in companies of all sizes working to marry connected

devices and sustainability goals. Companies both big and small are looking to widen networks and make supply chains more diverse and more secure.

A few more trends are Covid-19 and the risk of glass dependence, Rise of biologics and molecular diagnostics, Reduced Risk of Adverse Drug Reactions and Patient Accessibility. Advanced drug delivery, growing emerging economy markets such as India, Thailand, China, and others, and innovative packaging solutions with higher patient convenience and compliance drive the market for pharmaceutical packaging. The pharma companies globally would focus on strengthening research and resources to create drugs to save lives and develop packaging solutions. The future of drug packaging is bright for companies focused on glass alternatives.

What is the role of packaging in the pharmaceutical industry?

The role of packaging in the pharmaceutical market is crucial as it ensures the safety, integrity, and effectiveness of pharma products throughout their lifecycle, including storage, transportation, and usage. The pharma packaging industry complies with stringent regulations and standards to maintain the finest product quality, protect against contamination, and provide tamper-evident features.

According to a report by Evolve Business Intelligence, the global market for pharmaceutical packaging was worth USD 130.2 billion in 2022 which is poised to increase at a CAGR of 10.5% between 2023 and 2033. Another new report by Grand View Research (an India & U.S.-based market research and consulting company) states that the global returnable packaging market size is expected to reach USD 173.05 billion by 2030 which offers a humongous growth. This growth is attributed to the expanding key end-use industries such as healthcare, food & beverages, and others. The main purpose of packaging is physical protection, barrier protection, security, and patient convenience. Some of the primary packaging materials used in the pharma industry include ampoules, bags, blisters, bottles, cartridges, injection syringes, pressurized containers, tubes, and vials. During and post-pandemic, there has been a huge surge in demand for pharmaceutical products, a focus on patient safety, and the need for anti-counterfeiting measures. To achieve this, technological advancements in packaging materials are of huge importance.

The ministry has mandated a compulsory quick response (QR) code through its notification issued in January 2023. The National Pharmaceutical Pricing Authority (NPPA) had identified the list of 300 drugs including widely used medicines, such as painkillers, contraceptives, vitamins, blood sugar, and hypertension medicines. The QR code has been made mandatory at each level of packaging on Active Pharmaceutical Ingredients (APIs) to facilitate tracking and tracing of the products. This was the good move by the Centre given that over the years, there have been end number of reports of counterfeit drugs in the market.

What is your focus area going ahead? Brief us about the capacity expansion plan of KAISHA Packaging?

Coming from a background in injectable manufacturing and Type 1 glass primary packaging, we were the first company in India, to manufacture aluminum seals in controlled environments under positive pressure, while adopting several other pharma practices, such as GDP, PU flooring, HVAC systems, segregated man and material entry, linear material flow and EHS policies

amongst other positives. 100% compliance enables our customers to work closely with us.Our priority is to cater to the non-availability of solutions in Indian markets. Looking at what is available globally but not in India, we basically see a phenomenon where things gain attraction more easily in global markets but take more time in Indian markets. The company will continuously enhance its portfolio to offer the best solutions to its clients.

KAISHA Packaging has provided over two billion doses worth of flip-top aluminum seals used for packaging COVID vaccines. The seal is used as closures for injection vials during the vaccination drive and is an essential part of the vaccine package ensuring tamper-proof delivery. KAISHA Packaging is the biggest supplier for these seals to all the vaccines available in the Indian market and abroad. To ensure a consistent supply of vaccines and plug any shortages, we managed to arrange and stock a large volume of raw materials. Not only did KAISHA Packaging manage this challenge, it also expanded its capacity by over 450 million pieces to reach the overall capacity of 1.2 billion pieces per annum over the past year.

Brief us about the regulatory framework for Pharma packaging?

The government of India has a sound legal framework for the production supply and manufacturing of pharmaceutical products to ensure high quality and keep counterfeit products at bay. The pharma packaging sector in India gained the much-needed impetus to be considered the preferred packaging partner worldwide. According to India Brand Equity Foundation, India is the largest provider of generic drugs globally and is home to affordable vaccines and generic medications. The Indian Pharmaceutical industry stands at number three in pharmaceutical production by volume and is a thriving industry growing at a CAGR of 9.43% for the past nine years.

The Indian pharmaceutical sector supplies over 50% of the global demand for various vaccines and 40% of the generic demand in the US. India has the most pharmaceutical manufacturing facilities that follow the US Food and Drug Administration (USFDA) and has 500 API producers that make up around eight percent of the worldwide API market. It is true that pharma supply chains have become increasingly complex because of numerous issues. One of them is the cold chain issue. During the pandemic, there was a sudden surge in demand for vaccines and several losses were incurred by the manufacturers due to cold chain issues. Multiple layers in the supply chain involve several parties, making integration and communication difficult.

Consequently, the industry faces challenges in the quality distribution of biologicals, impacting the efficacy of the products delivered and raising health concerns for the end consumers. Such disruptions can ruin the pharma company's reputation, consumer satisfaction, and potential profit. Such undesirable things undermine the growth of the industry and require immediate attention. However, a lot of things have improved in the past few years as the government has been addressing the industry's issues and putting in a lot of effort. Resilience in the supply chain is one of the important things and pharma supply chains may adopt a string of strategies like crisis management, robust cold chain, and technological innovation, among others to meet consumer demands and reduce the risk of product and financial losses. Research and Development (R&D) at pharmaceutical companies has driven the growth of the pharmaceutical packaging market in India. ■

Securing Quality and Countering Counterfeit: Pharma Packaging Automation Revolutionizes the Industry

India faces a great risk of counterfeiting drugs in the pharmaceuticals industry. This article explores the role of automation in pharmaceutical packaging and Challenges faced by the pharmaceutical industry in combating counterfeit drugs.

In an era where patient safety and product quality are of paramount importance, the pharmaceutical industry is constantly seeking innovative solutions to combat counterfeit drugs and ensure the integrity of its products. One such solution that has gained tremendous traction in recent years is automation in pharma packaging.

Counterfeit drugs have emerged as a significant global concern, putting patients' lives at risk and undermining trust in the pharmaceutical industry. These illicit products infiltrate the market through various channels, often disguised as genuine pharmaceuticals. The consequences can be dire, ranging from ineffective treatments to severe health complications. Combatting this menace requires a multifaceted approach, and automation in pharma packaging to play a pivotal role in this endeavour.

Pharmaceutical packaging is designed to protect drugs from external factors such as light, moisture, and temperature variations. It prevents degradation and maintains the efficacy of the medication throughout its shelf life. Additionally, proper packaging helps in preserving the chemical stability of the drug, ensuring that patients receive the intended therapeutic benefits. The packaging also acts as a barrier against microbial contamination, safeguarding the product from harmful bacteria or fungi.

Moreover, pharmaceutical packaging provides critical information, including dosage instructions, potential side effects, and storage conditions. This information is vital for healthcare professionals to prescribe and administer medications correctly. Patients rely on packaging to understand how to take their medications safely and to identify any specific precautions or warnings. Clear and accurate labelling on packaging ensures that patients have the necessary knowledge to use the medication effectively and avoid any potential risks.

What are counterfeit drugs?

Counterfeit drugs are fraudulent medications that are intentionally mislabelled, contaminated, or contain substandard ingredients. They pose a grave danger to patients, as they may lack the necessary active ingredients, contain harmful substances, or have incorrect dosages. Counterfeit drugs not only jeopardise patient safety but also contribute to the proliferation of drug-resistant diseases. It is essential for pharmaceutical manufacturing companies to actively address this issue and protect patients from such counterfeit products.

Growing concern about counterfeit drugs and the need for robust solutions

The rise in counterfeit drugs necessitates robust solutions to protect patients and combat this issue effectively. While regulatory authorities and law enforcement agencies play a crucial role in enforcing regulations and prosecuting counterfeiters, pharmaceutical packaging is an essential tool in the fight against counterfeit drugs. Packaging can incorporate security features that make

it difficult to replicate, providing visible evidence of tampering and counterfeiting attempts. Additionally, advanced technologies such as serialisation, barcoding, and holographic labels allow for traceability and verification of product authenticity, enabling the identification and removal of counterfeit drugs from the supply chain.

The global impact of counterfeit drugs on public health and economies

Counterfeit drugs have severe consequences on public health and economies worldwide. From a pharmaceutical manufacturing company perspective, the impact includes:

- **Patient Safety:** Counterfeit drugs pose significant risks to patients who unknowingly consume them. Substandard ingredients or incorrect dosages can lead to treatment failures, adverse effects, or even fatalities. As a result, patient safety becomes a critical concern for pharmaceutical manufacturers.
- **Brand Reputation:** Counterfeit drugs bearing the name of a legitimate pharmaceutical manufacturer can damage the company's reputation. Patients may associate the subpar quality of counterfeit drugs with the genuine products, leading to a loss of trust in the company's brand.
- **Revenue Loss:** Counterfeit drugs result in revenue losses for pharmaceutical manufacturers. These losses occur due to decreased sales of legitimate products, as counterfeit alternatives may be sold at lower prices.
- **Regulatory Compliance:** The presence of counterfeit drugs in the market challenges pharmaceutical manufacturers to ensure regulatory compliance. Companies must adhere to stringent regulations and quality control measures to prevent counterfeiting and maintain compliance with regulatory authorities.

Challenges faced by the pharmaceutical industry in combating counterfeit drugs:

Pharmaceutical manufacturers encounter several challenges in their efforts to combat counterfeit drugs. These challenges include:

- **Global Nature of Counterfeiting:** Counterfeit drugs are a global issue, with networks extending across borders. Pharmaceutical manufacturers face the challenge of tracking and combating counterfeiters operating in different jurisdictions.
- **Evolving Counterfeit Methods:** Counterfeiters continually adapt their methods to evade detection, using advanced technologies and sophisticated packaging. This poses a constant challenge for pharmaceutical manufacturers to stay one step ahead and develop innovative solutions to detect and prevent counterfeiting.
- **Lack of Regulatory Harmonization:** Inconsistent regulations across different countries and regions

make it difficult for pharmaceutical manufacturers to implement standardized anti-counterfeiting measures. Harmonization of regulations would facilitate a more coordinated and effective global response to the counterfeit drug problem.

- **Supply Chain Vulnerability:** The complexity of pharmaceutical supply chains makes them vulnerable to counterfeiting. Counterfeit drugs can enter the supply chain at various stages, from raw materials to finished products. Ensuring the integrity and security of the entire supply chain presents a significant challenge for pharmaceutical manufacturers.

The role of automation in pharma packaging

Automation has revolutionized various industries, and the pharmaceutical sector is no exception. Automation in pharma packaging processes offers numerous advantages that directly contribute to fighting counterfeit drugs and ensuring quality:

- Enhanced Security and Anti-Counterfeiting Measures: Automated packaging systems enable the integration of advanced security features into drug packaging. Tamper-evident seals, holograms, and unique serialization codes can be seamlessly incorporated, making it difficult for counterfeiters to replicate or tamper with the packaging. This allows pharma manufacturing companies to provide visible evidence of product authenticity, thereby protecting patients and their brand reputation.

- Increased Efficiency and Accuracy: Automated packaging processes ensure the consistent and precise execution of packaging tasks. From filling and labelling to blister packaging and serialization, automation minimises the risk of human error, thereby improving efficiency and accuracy. This not only enhances productivity but also reduces the likelihood of mistakes that can compromise the safety and quality of the medication.

- Traceability and Supply Chain Integrity: Automation enables the implementation of track-and-trace technologies such as barcode systems and RFID (Radio-Frequency Identification) tags. These technologies facilitate real-time monitoring and traceability throughout the supply chain. By implementing automated serialization and authentication systems, pharma manufacturing companies can effectively track the movement of their products, detect any anomalies, and swiftly identify and eliminate counterfeit drugs from the market.

Collaboration and regulatory compliance

In the fight against counterfeit drugs, collaboration between pharma manufacturing companies, regulatory authorities, and technology providers is crucial. Regulatory bodies play a pivotal role in establishing guidelines and standards to ensure the integrity of pharmaceutical packaging. Pharma manufacturing companies must actively collaborate with these regulatory bodies to stay updated on evolving regulations and ensure compliance in their packaging processes. By working together, industry stakeholders can effectively address the challenges posed by counterfeit drugs and continually enhance the security and quality of pharmaceutical packaging.

Pharma manufacturing companies that have embraced automation in their packaging processes have experienced notable success in combating counterfeit drugs and ensuring quality. By integrating automation technologies such as advanced inspection systems, tamper-evident packaging, and serialization solutions, these companies have successfully minimised the risk of counterfeiting and enhanced patient safety. ' ■

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GUEST COLUMN

The Role of Cold Chain Logistics in the Pharmaceutical Industry

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The pharmaceutical industry plays a crucial role in safeguarding public health by developing and manufacturing life-saving medications. However, the effectiveness and safety of pharmaceutical products heavily depend on maintaining an unbroken cold chain. The cold chain refers to a temperature-controlled supply chain that ensures pharmaceutical products, particularly those that are temperature-sensitive, are stored, transported, monitored and delivered under controlled temperature conditions. Maintaining the integrity and efficacy of pharmaceutical products throughout the supply chain is paramount. Cold chain and cold chain logistics plays a critical role in ensuring their safe and effective delivery. In this article, we explore the importance of the cold chain for the pharmaceutical industry and how it contributes to the overall efficacy and quality of medications.

Preserving Product Integrity

Pharmaceutical products, such as vaccines, biologics, and certain medications, are highly sensitive to temperature fluctuations. Exposure to temperatures outside their recommended ranges can lead to a loss of potency, reduced efficacy, or even degradation of the product, rendering it ineffective or potentially harmful to patients. Cold chain ensures that these temperature-sensitive products are maintained within specific temperature parameters, typically ranging from 2°C to 8°C or even lower in the case of ultra-low temperature storage. By employing specialized refrigeration systems, insulated packaging, and temperature monitoring devices, the integrity of these products is preserved throughout their journey from production facilities to distribution centers, pharmacies, hospitals, and ultimately, to patients. The

cold chain serves as a protective shield, maintaining the integrity of these temperature-sensitive pharmaceuticals throughout their entire journey, from manufacturing to the end-user. By employing specialized temperature-controlled storage facilities, refrigerated transportation, and advanced temperature monitoring systems, the cold chain ensures that these products remain within the specified temperature range, preserving their quality and therapeutic value.

Ensuring Patient Safety

Patient safety is paramount in the pharmaceutical industry, and the cold chain plays a pivotal role in ensuring patient safety. Temperature excursions can compromise the safety and efficacy of pharmaceutical products, putting patients at risk. Proper temperature control during storage and transportation prevents product degradation, contamination, or spoilage that could compromise the safety and efficacy of pharmaceuticals.

For instance, vaccines, which are critical for preventing and controlling infectious diseases, require strict temperature control to retain their immunogenicity. Failure to maintain the cold chain during vaccine storage and distribution can lead to reduced vaccine efficacy and compromised immunization programs, thereby jeopardizing public health. By adhering to cold chain protocols, pharmaceutical companies can ensure that medications reach patients in optimal condition, maximizing their safety and therapeutic benefits.

Meeting Regulatory Requirements

Regulatory authorities, such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe and the India-based regulators, have stringent guidelines and regulations concerning the storage and transportation of pharmaceutical products. These regulatory frameworks aim to guarantee the quality, safety, and efficacy of medications.

The cold chain plays a pivotal role in meeting these regulatory requirements, as it provides the necessary controls and documentation to demonstrate that pharmaceutical products have been stored and transported within the required temperature range. Compliance with these regulations not only ensures patient safety, but also safeguards the reputation and credibility of pharmaceutical manufacturers.

Enabling Global Distribution

The pharmaceutical industry operates on a global scale, with medications manufactured in one location and distributed worldwide. The cold chain enables the global distribution of temperature-sensitive pharmaceuticals, allowing patients to access essential medications regardless of geographical location. By utilizing specialized temperature-controlled packaging, refrigerated containers, and logistics networks, pharmaceutical companies can ensure that their products maintain the required temperature conditions throughout the distribution process. This is particularly important for regions with extreme climates or remote areas with limited infrastructure, as the cold chain enables the safe and reliable delivery of medications to those in need.

Challenges and Future Developments

Implementing and managing an effective cold chain comes with its challenges. The cold chain infrastructure requires significant investments in temperature-controlled storage facilities, transportation equipment, and monitoring technologies. Additionally, maintaining a seamless cold chain network involving various stakeholders, such as manufacturers, distributors, and healthcare providers, requires strong collaboration and standardized processes. Overcoming these challenges necessitates continuous advancements in technology, increased industry collaboration, and regulatory harmonization.

Conclusion

The cold chain is an indispensable component of the pharmaceutical industry, ensuring the integrity, safety, and efficacy of temperature-sensitive medications. By preserving product integrity, ensuring patient safety, meeting regulatory requirements, and enabling global distribution, the cold chain plays a vital role in the pharmaceutical supply chain. Pharmaceutical companies, logistics providers, and regulatory authorities must continue to prioritize and invest in the cold chain infrastructure to ensure the safe and efficient delivery of medications, ultimately benefiting patients worldwide and advancing public health. ■

GUEST COLUMN

Artificial Intelligence accelerating pharma's growth

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The integration of Artificial Intelligence (AI) into the pharmaceutical industry has been a game-changer in recent years. AI technologies are revolutionizing processes, driving efficiency, and fostering innovation within the sector. The author explores various ways AI is accelerating the growth of the pharmaceutical industry and explore its potential for the future.

Artificial Intelligence in drug discovery

The traditional drug discovery process is a lengthy and costly endeavor. However, AI is transforming this landscape by leveraging machine learning algorithms and advanced analytics to analyze vast amounts of data. By mining extensive databases of chemical compounds, genomic information, and clinical records, AI can identify potential drug candidates and predict their efficacy and safety.

AI algorithms have the ability to sift through massive datasets, identifying patterns and relationships that human researchers may overlook. This speeds up the drug discovery process significantly, allowing pharmaceutical companies to prioritize their efforts on the most promising candidates. By reducing the time and cost associated with drug discovery, AI enables faster innovation and the development of new therapies to address unmet medical needs.

Artificial Intelligence in clinical trials

Clinical trials are a crucial aspect of pharmaceutical research, providing evidence of the safety and efficacy of new drugs. However, the process of conducting clinical trials can be complex and challenging. AI is bringing transformative changes to this area by optimizing patient recruitment, trial design, and data analysis.

AI algorithms can analyze patient data, electronic health records, and genetic profiles to identify suitable candidates for clinical trials. By considering various factors such as demographics, genetics, and medical history, AI can match patients with trials that align with their characteristics. This improves patient recruitment and retention, leading to more accurate and reliable trial results.

Furthermore, AI-driven algorithms can monitor patients during trials, detect adverse events in real-time, and provide valuable insights to researchers and healthcare professionals. This real-time monitoring enhances patient safety and enables proactive decision-making throughout the trial process.

Artificial Intelligence in manufacturing and supply chain management

AI technologies are also transforming drug manufacturing processes and optimizing supply chain management within the pharmaceutical industry. AI-powered systems can monitor and analyze manufacturing data in real-time, ensuring quality control and reducing errors.

By analyzing production data and identifying patterns, AI algorithms can predict and prevent quality issues, minimizing waste and increasing overall efficiency. This results in cost savings and improved productivity for pharmaceutical manufacturers.

In addition to manufacturing, AI is revolutionizing supply chain management in the pharmaceutical industry. By leveraging advanced analytics and predictive modeling, AI algorithms can optimize inventory management, demand forecasting, and distribution processes. This leads to improved product availability, reduced risks of stockouts or excess inventory, and enhanced overall supply chain efficiency.

Artificial Intelligence in patient care and personalized medicine

The integration of AI in patient care is revolutionizing healthcare delivery and driving the advancement of personalized medicine. AI-powered tools such as chatbots and virtual assistants can provide personalized healthcare advice, assist with medication management, and offer support for patients with chronic conditions.

These virtual agents utilize natural language processing and machine learning algorithms to understand patients' needs, provide tailored recommendations, and improve patient engagement. This not only enhances the patient experience but also frees up healthcare professionals' time for more critical tasks.

Moreover, AI algorithms can analyze patient data, including genetic profiles and medical history, to identify patient subgroups that may respond differently to treatments. This enables the development of targeted therapies and personalized treatment plans, maximizing effectiveness while minimizing side effects. Personalized medicine holds great potential to improve patient outcomes and transform healthcare practices.

Artificial Intelligence can help predict epidemic outbreaks

Machine learning models are being used to predict and prevent epidemics across the globe. According to a research conducted in Maharashtra, a data mining classification algorithm—Support Vector Machine (SVM), was used to successfully predict the onset of malaria in the early stages with a lower error rate. This type of AI/ML tool can empower organizations to engage in early preventive care and put the right measures in place to combat it.

Future of Artificial Intelligence in pharma industry

The recent surge in activity in deploying AI capabilities in the pharmaceutical industry shows no sign of slowing down. According to recent research, about 50 per cent of global healthcare companies plan to implement AI strategies and broadly adopt the technology by 2025.

Specifically, global pharmaceutical and drug development companies will invest more in discovering new drugs for chronic and oncology diseases. Some of the major chronic diseases that AI will tackle in the future include chronic kidney disease, diabetes, cancer, and idiopathic pulmonary fibrosis.

Artificial intelligence will also shape the future of pharmaceuticals by improving candidate selection processes for clinical trials. By quickly analyzing patients and identifying the best patients for a given trial, it helps to ensure uptake by providing trial opportunities to the most suitable individuals. This advanced technology also helps to remove elements that may hinder clinical trials, reducing the need to compensate for those factors with a large trial group.

In nutshell, AI and machine learning will continue to help further drug discovery and manufacturing. And as AI tools become more accessible over the years, they will become part of the natural process within pharmaceutical and manufacturing.

Artificial intelligence pharma market size and growth

The global artificial intelligence (AI) in pharmaceutical market was valued at US$ 905.91 million in 2021 and is expected to reach over US$9,241.34 million by 2030, poised to grow at a compound annual growth rate (CAGR) of 29.4% from 2022 to 2030. This growth is mainly due to companies resuming their operations and adapting to the new normal while recovering from the COVID-19 impact, which had earlier led to restrictive containment measures involving social distancing, remote working, and the closure of commercial activities that resulted in operational challenges.

The adoption of artificial intelligence and machine learning is rapidly growing across the pharmaceutical industry, as it offers technological decision making capabilities, improve production efficiency and it helps to improve efficiency of clinical trials.

Real time data output is an additional market driving factor in pharmaceutical industry. It has wider benefits in research and development for instance the machine learning algorithms helps to analyze the wider range of data which offers the real-time data output with respect to historical data. The application of data sciences and machine leaning helps to analyze the big data which enables the rapid development of new product.

Conclusion

Artificial Intelligence (AI)-based solutions in pharmaceutical sectors are gaining momentum, becoming the new competitive battleground for many manufacturers. The pharma industry needs digital transformation and new technologies to process vast amounts of health data efficiently. It identifies significant relationships between them, effectively decreasing time-to-market in drug manufacturing. ■

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