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Union Health Ministry issues Advisory to States in view of Zika virus cases from Maharashtra

New Delhi, India: In view of some reported cases of Zika virus from Maharashtra, Dr Atul Goel, Director General of Health Services (DGHS), Ministry of Health and Family Welfare has issued an advisory to States highlighting the need for maintaining a state of constant vigil over the Zika virus situation in the country.

As Zika is associated with microcephaly and neurological consequences in the foetus of the affected pregnant lady, States have been advised to alert the clinicians for close monitoring. States are urged to instruct the health facilities in the affected areas or those catering cases from affected areas to screen the pregnant women for Zika virus infection, monitor the growth of the fetus of expecting mothers who have tested positive for Zika and act as per Central Government Guidelines. States were also instructed to advise health facilities/hospitals to identify a nodal officer to monitor and act to keep the premises Aedes mosquito free.

States have been emphasized on the importance of strengthening the entomological surveillance and intensifying the vector control activities in residential areas, workplaces, schools, construction sites, institutions and health facilities. States are also urged to promote awareness through precautionary IEC messages in social media and other platforms to reduce panic among the community, as Zika is like any other viral infection with most cases being asymptomatic and mild. Though, it is reported to be associated with microcephaly, no report of any Zika associated microcephaly has been reported in the country since 2016.

For timely detection and control of any impending upsurge/outbreak, State authorities have been advised to be vigilant, prepared and ensure availability of appropriate logistics at all level. States were also urged to immediately report any detected case to Integrated Disease Surveillance Programme (IDSP) and National Center for Vector Borne Diseases Control (NCVBDC).

Zika testing facility is available at National Institute of Virology (NIV), Pune; National Centre for Disease Control (NCDC), Delhi and a few selected virus research and diagnostic laboratories of the Indian Council of Medical Research (ICMR). Reviews are being held at higher level.

DGHS had also issued an advisory earlier this year on 26th April and Director, NCVBDC have issued two advisories in February and April, 2024 to forewarn states on Zika, Dengue and Chikungunya transmitted by same vector mosquito.

IPC issues drug safety alert on Amlodipine and Acetazolamide

New Delhi, India: The Indian Pharmacopoeia Commission has issued a drug safety alert on amlodipine and acetazolamide. amlodipine has shown Adverse Drug Reactions on Lichenoid Keratosis. amlodipine is to reduce fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke and to reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery diseases, stated IPC.

IPC added that Acetazolamide has shown Adverse Drug Reactions on Choroidal effusion or Choroidal detachment. Acetazolamide is used in treatment of chronic open-angle glaucoma; secondary glaucoma; as part of pre-operative treatment of acute-angle closure glaucoma. Glaucoma is a group of eye diseases that lead to damage of the optic nerve, which transmits visual information from the eye to the brain. Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs, stated IPC.

Indian pharma market registers over 8% growth in June 2024: Pharmarack

New Delhi, India: The Indian pharmaceutical market (IPM) exhibited a growth of 8.8 per cent in June and there was a rise seen in sales of drugs related to Respiratory, Anti-Infective, Anti-Malaria and Gastrointestinal SG, according to market research firm Pharmarack. The research firm said that there was a significant rise seen in the sales of Anti-Tuberculosis drugs possibly due to stocking up at patient level fearing the supply chain issues of previous months to prevail further.

Corporates like Sun, Mankind, Cipla, Torrent, Intas, Alkem, Macleods, Aristo, GSK, USV, Glenmark & Micro outperformed the market with a robust double-digit growth in Jun 2, stated Pharmarack. Fourrts continued with highest growth among 21 to 40 rank corporates in the IPM for the month of June as well. Other corporates like FDC, La Renon, Himalaya, Indoco, Corona, Hetero,

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Bharat Serums, Blue Cross and Wallace registered a double-digit growth.

Indian CRO/CDMO businesses to benefit from Passage of US Biosecure Act: India Ratings

Mumbai, India: India Ratings and Research opines Indian pharma companies operating in the contract development and manufacturing organization (CDMO) and contract research organisation (CRO) segments are likely to reap benefits from increased orders, stemming from the passage of the US Biosecure Act, from US pharma companies over the next 12-18 months. Indian companies, in anticipation, have incurred significant capex over the past two years, resulting in elevated leverage ratios. The agency expects the ratio to moderate with the benefits of operating leverage feeding into margins and cash flows.

"CDMO players, which were impacted due to weaker capacity utilization during FY22/FY23 owing to higher capex in the past, witnessed operating leverage benefits play out during FY24, despite debt levels remaining unchanged, leading to an improvement in their credit metrics. Given the expectation that the trend is likely to sustain, Ind-Ra upgraded three entities over the past 12 months. While capex requirements will remain high, leverage levels will remain consistent with the revised ratings," says Vivek Jain, Director, Corporate Ratings, Ind-Ra.

India Ratings expects the act, if passed, will lead to re-orientation of supply chains, given the restriction on US federal agencies procuring equipment and services from certain "biotechnology companies of concern," primarily large Chinese pharma companies. Consequently, Ind-Ra expects the supply of numerous drugs used in clinical trials and critical raw materials to be impacted, given the trade that most pharma companies have with these agencies. This would provide opportunities for Indian companies to act as alternatives. The green shoots are already visible, as over 60% of listed pharma have witnessed an increase in the number of enquires for new businesses, and 33% of them believe that the act, if implemented, can be a business driver.

A recent report published by L.E.K. Consulting on the Impact of US BIOSECURE Act on Biopharmas, Contract Services and Investors highlights the sharp deterioration in the confidence of US-based bio pharma entities to partner with Chinese companies once the act becomes a law. The agency believes that pharmaceutical and biotech firms are taking proactive measures to counter the impact of the impending Act. They are analysing supply chains to identify reliance on blacklisted Chinese companies and working on alternative sourcing strategies.

Indian domestic formulations market expected to more than double: Avendus Capital

Mumbai, India: Avendus Capital, India's leading investment bank, released a comprehensive report that navigates the shifting tides in the Indian Domestic Formulations (DomForm) market, estimating that it will cross ₹~5.5 trillion by 2034 at a CAGR of 10%. The report foresees some fundamental model shifts, such as a gradual transition from a primarily doctor branded prescription model to an alternative marketing and channel mix, aided by more stringent quality compliance, which would lead to a rationalisation of supply chains. This will be driven as much by government policies and regulatory measures as by underlying business and economic factors.

Based on extensive research and interviews with several industry experts, pharma promoters, professionals, consultants and investors, the report attempts a deep dive into understanding the evolution of the DomForm sector and its emergence as a largely Branded Generics (BGx) market. The report also unveils Avendus' proprietary model on the 10-year outlook for the Indian DomForm sector.

Commenting on the launch of the report, Anshul Gupta, Managing Director and Head, Healthcare Investment Banking, Avendus Capital said, "Despite India earning its rightful title as the pharmacy to the world, there remains significant under penetration in the domestic market, especially in Tier 2/3+ towns and rural areas. As India progresses on the path of transitioning to a developed economy, the resultant economic prosperity will bode well for continued growth of this sector. We are also encouraged by the Government of India's Pharma Vision 2047, which is aimed at making medicines more equitable, accessible and affordable while ensuring high quality and more sustainable manufacturing practices." Prasshanth Hari, Director, Healthcare Investment Banking, Avendus Capital added, "DomForm has attracted large strategic and private equity investments in deals worth USD 14+ billion over the last 6 years. We estimate that the market would continue growing at 9-10% CAGR over the next 10 years. With the expansion

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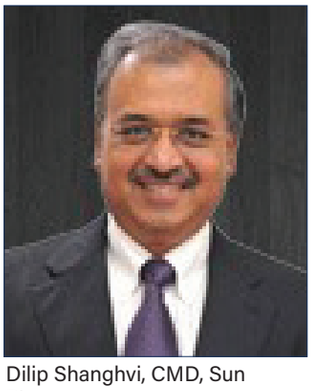
of Trade Generics (TGx) and Jan Aushadhi, we expect ~30% volume contribution from these channels over the next decade. Despite this shift, BGx is still expected to be 65-70% of the market by value with a CAGR of 8%+ over this period. This channel shift could result in a moderate EBITDA margin contraction, potentially offset by cost optimization measures such as MR rationalization, reduction in free samples and reduction of doctor-related expenses, each of which could potentially result in 100 bps of cost savings."

Sun Pharmaceutical completes merger of Taro Pharmaceutical Industries


Dilip Shanghvi, CMD, Sun Pharma

Mumbai, India: Sun Pharmaceutical Industries Limited announced the successful completion of the merger of Taro Pharmaceutical Industries Ltd with its subsidiary. As part of this merger, Sun Pharma acquired all outstanding ordinary shares of Taro other than the shares already held by Sun Pharma or its affiliates. As a result of the merger, Taro is now a private company and wholly-owned by Sun Pharma. Sun Pharma has been the majority shareholder of Taro since 2010.

Dilip Shanghvi, Chairman and Managing Director of Sun Pharma, said, "We are pleased with the successful completion of Taro merger process. This milestone marks a significant step forward for both organizations, allowing us to effectively leverage each other's strengths and capabilities. Together, we are excited about starting this new chapter and creating a more robust, successful future for the combined entity."

The company announced that it has entered into a non-exclusive patent licensing agreement with Takeda Pharmaceutical Company Limited (Takeda) to commercialise Vonoprazan tablets 10 mg, 20 mg in India under the brand name "Voltapraz". Vonoprazan is a novel, orally active potassium competitive acid blocker (PCAB), used to treat reflux esophagitis and other acid peptic disorders.

Nidlegy is given intralesionally for 4 weeks and acts by boosting the immune system against neoplastic lesions. Under the terms of this agreement, Takeda has granted Sun Pharma non-exclusive patent licensing rights for the commercialization of Vonoprazan in India.

Commenting on the development, Kirti Ganorkar, CEO - India Business, Sun Pharma said, "Sun Pharma is a leader in Gastroenterology and we are excited to introduce Vonoprazan in India under non-exclusive patent license from Takeda. This partnership demonstrates our commitment to Gastrointestinal health by providing patients and healthcare practitioners with a novel treatment option to manage reflux esophagitis and other acid peptic disorders."

Dr. Reddy's to acquire Nicotinell and related portfolio

Hyderabad, India: Dr. Reddy's Laboratories Ltd, a global pharmaceutical company, announced that its subsidiary Dr. Reddy's Laboratories SA has signed a definitive agreement with Haleon plc, a leading consumer healthcare company, for purchase of shares of Northstar Switzerland SARL, a Haleon group company, to acquire Haleon's global portfolio of consumer healthcare brands in the Nicotine Replacement Therapy ("NRT") category outside of the United States.

The portfolio to be acquired consists of Nicotinell, a global leader in the NRT category with an extensive footprint in over 30 countries spanning Europe, Asia including Japan, and Latin America, and local market-leading brand names of the product – Nicabate in Australia, Thrive in Canada, and Habitrol in New Zealand and Canada. The proposed acquisition will be inclusive of all formats such as lozenge, patch, gum as well as pipeline products, in all applicable global markets outside of the United States. Nicotinell is the second biggest brand globally (excluding the United States) in the NRT category. It holds the first or second position in 14 of the top 17 global markets, with the lozenge/mini lozenge format holding top position globally . Nicotinell ranks among the top 15 biggest brands among all OTC brands in Europe (excluding Russia, Italy), and ranks 32 among all OTC global brands (excluding the US). In CY'23, the portfolio generated approximately GBP 217 million in revenue.

Dr. Reddy's will acquire the share capital of Northstar Switzerland SARL for a total consideration of GBP 500 million with an upfront cash payment of GBP 458 million and performance-based contingent payments of up to GBP 42 million, payable in 2025 and 2026. The closing of the transaction is subject to satisfactory completion of customary conditions to closing, including regulatory

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approvals. The transaction is expected to close in early Q4 of calendar year 2024.

Upon closing of the transaction, Dr. Reddy's will acquire the NRT business in all countries outside of the United States. However, operations will transition to Dr. Reddy's in a phased approach to ensure successful integration of the business.

Wockhardt to launch Clinical Zaynich by FY25

Mumbai, India: Wockhardt Ltd stated that its candidate Zaynich (Zidebactam/Cefepime- WCK 5222) is undergoing a multinational Phase 3 study, which is expected to be completed by FY 2025, facilitating its global registration and marketing authorization.

In the June 24, 2024 plenary session of Clinical and Laboratory Standards Institute (CLSI), Zaynich (Zidebactam/Cefepime- WCK 5222) has been granted a susceptibility breakpoint of 64 mg/L for around 10 Gram negative pathogens showing high resistance rates. Susceptibility breakpoints guides the doctors about selection of most efficacious antibiotic for treating various infections caused by different pathogens.

A high breakpoint of 64 mg/L suggests Zaynich's (Zidebactam/Cefepime- WCK 5222) strong potential to cover all the clinically important, extreme drug resistant Gram negative pathogens in seriously ill patients.

Since the introduction of penicillin in 1928, more than 250 antibiotics have been approved and used clinically, however, this is 1st time ever that an antibiotic has been granted a susceptible breakpoint of as high as 64 mg/L for all the three families of Gram negative pathogens; Enterobacterales, Pseudomonas and Acinetobacter. Pending Zaynich's (Zidebactam/Cefepime- WCK 5222) formal approval, CLSI has designated these breakpoints as Investigational Breakpoints to facilitate clinical trials and compassionate use of this life saving antibiotic.

In granting of the breakpoints, >8 years of research data on Zaynich (Zidebactam/Cefepime- WCK 5222) was reviewed by three sub-committees of CLSI sequentially, followed by independent rounds of voting by the members at each stage. The final plenary session unanimously approved the investigational breakpoints for Zaynich (Zidebactam/Cefepime- WCK 5222).

During >1 year, Zaynich (Zidebactam/Cefepime- WCK 5222), has been successfully used to treat 30 patients under compassionate use who were inflicted with infections caused by extreme-drug resistant Gram-negative pathogens, including Pseudomonas, Klebsiella, E. coli, Acinetobacter, and Serratia not amenable to any of the available antibiotics. The high breakpoints assigned to Zaynich are supportive of consistent clinical cure and microbiological eradication demonstrated in these compassionate use patients.

Glenmark receives ANDA approval for Esomeprazole Magnesium DR Capsules

Mumbai, India: Glenmark Specialty SA (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC), determined by the FDA to be bioequivalent to Nexium 24 HR Delayed-Release Capsules, 20 mg (OTC), of Haleon U.S. Holdings LLC. Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC), will be distributed in the U.S. by Glenmark Therapeutics Inc., USA.

According to Nielsen syndicated data for the latest 52 weeks period ending May 18, 2024, the Nexium 24 HR Delayed-Release Capsules, 20 mg (OTC) market achieved annual sales of approximately $259.2 million*.

Glenmark's current portfolio consists of 197 products authorized for distribution in the U.S. marketplace and 50 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.

Tata Capital Healthcare Fund II invests upto USD 20 million in Orbicular Pharmaceutical

Mumbai, India: Tata Capital Healthcare Fund II (TCHF II), the healthcare focused private equity fund of Tata Capital Ltd., announced that it has invested an amount of $ c.20 million in Orbicular Pharmaceutical Technologies Private Limited for an undisclosed equity stake. Orbicular, a Hyderabad-based specialty pharmaceutical company, excelling in developing complex generics for global pharmaceutical markets will utilize the capital for accelerating the development of product pipeline.

The specialty generics industry (market size USD 60+ bn) is rapidly expanding, driven by increasing demand for cost-effective alternatives to complex and high-cost branded medications. Orbicular has developed a robust

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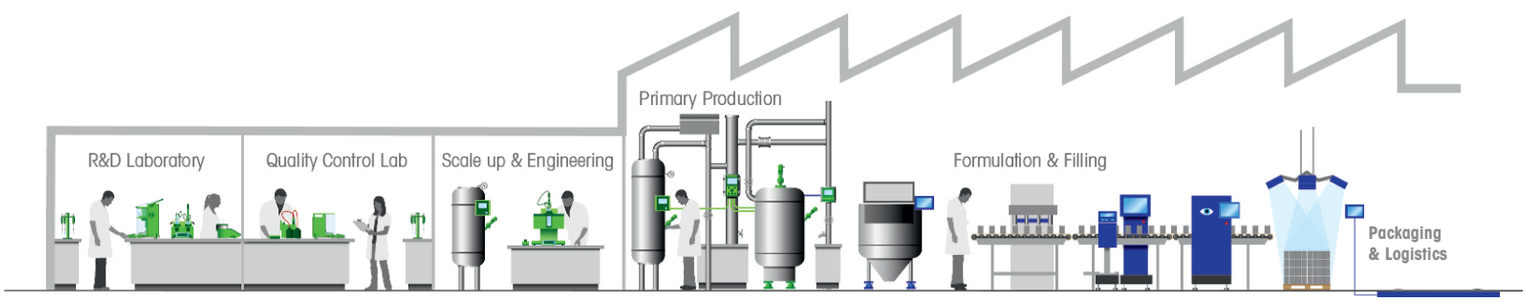

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pipeline of niche products in the specialty generics space positioning them as an ideal partner for global generic players targeting regulated markets.

Speaking on the partnership, Visalakshi Chandramouli, Managing Partner, Tata Capital Healthcare Fund said, "We are thrilled to partner with Orbicular which is at the forefront of R&D leadership in the field of complex generics. Under the able leadership of Dr. M.S. Mohan, Orbicular has developed a strong product pipeline for the regulated markets. We are proud to support the dynamic team at Orbicular and be a part of their growth story. This investment reinforces our fund's core philosophy of identifying the big shifts in the industry and being a "capital plus" partner to our companies.

Speaking on the capital raise, Dr. M.S. Mohan, Managing Director, Orbicular said, "Today is a transformative milestone in our journey of starting as a bootstrapped company to successfully being backed by Tata Capital Healthcare Fund. Having positioned Orbicular as a differentiated specialty pharmaceutical company in the complex generics space, the investment will further strengthen our global partnerships. I am immensely proud of our team, its achievements, and together, we will continue to drive differentiation, pursue advance healthcare solutions, and make a positive impact on the lives of millions across the globe."

Orchid Pharma partners with Cipla to launch antibiotic Cefepime-Enmetazobactam in India

Umang Vohra, MD & Global CEO, Cipla

New Delhi, India : Orchid Pharma Limited, based in Chennai, India, the only Indian pharmaceutical company to have ever invented a New Chemical Entity (NCE), announced the launch of its new drug - Cefepime-Enmetazobactam, which has been approved for the treatment of complicated Urinary Tract infections (cUTI), Hospital-Acquired Pneumonia (HAP) and Ventilator-Associated Pneumonia (VAP) indications. In a landmark collaboration, Orchid Pharma has partnered with Cipla Limited ('Cipla') to ensure widespread and rapid distribution of this breakthrough antibiotic combination across India.

The launch of Cefepime-Enmetazobactam marks a significant milestone for India's pharmaceutical industry in the fight against AMR, a growing global health issue, reinforcing India's leadership in medical innovation. Orchid Pharma and Cipla are confident that this collaboration will set a new benchmark for addressing critical healthcare challenges through strategic partnerships and advanced research.

Both companies are committed to responsible antibiotic stewardship and will work closely with healthcare professionals to ensure appropriate use of this new antibiotic combination. Orchid Pharma Ltd. (Orchid) is a vertically integrated Company spanning the entire pharmaceutical value chain with established credentials in research, manufacturing, and marketing.

Speaking on the launch, Manish Dhanuka, Managing Director Orchid Pharma said, "With increasing resistance to the current drugs most commonly used for treatment of these indications – e.g. Piperacillin-Tazobactam for cUTI – doctors were forced to start using Carbapenems – a reserve drug meant to be used when most other drugs don't work. Now, Orchid's Cefepime-Enmetazobactam will allow doctors to spare Carbapenems, prolonging their effective life by restricting their use."

Umang Vohra, Managing Director & Global Chief Executive Officer, Cipla, said, "AMR is an urgent and serious healthcare challenge that needs global attention With the rising incidence of potentially-life threatening infections, there is a strong need for novel anti-infectives in the effective treatment of MDR infections. This partnership enhances Cipla's commitment to AMR stewardship and strengthens our efforts to combat infectious diseases and deliver advanced, innovative therapies to patient."

Marksans Pharma subsidiary Relonchem receives marketing authorisation from UKMHRA for products

Mumbai, India: Marksans Pharma Ltd announced that its wholly owned subsidiary Relonchem Ltd. has received marketing authorisation from UKMHRA for products such as Rasagiline Relonchem 1 mg Tablets, Olmesartan 10 mg Film-coated Tablets, Olmesartan 20 mg Film-coated Tablets, Olmesartan 40 mg Film-coated Tablets. Marksans Pharma Limited headquartered at Mumbai, India is engaged in Research, Manufacturing

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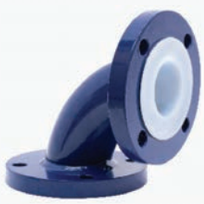

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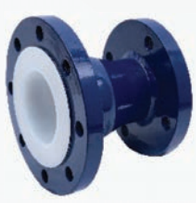
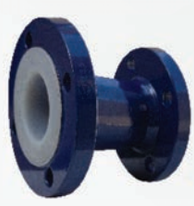


CONCENTRIC REDUCER



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& Marketing of generic pharmaceutical formulation in the global markets. The company's manufacturing facilities located in India, USA and UK are approved by several leading regulatory agencies including USFDA, UKMHRA and Australian TGA.

USFDA concludes inspection at Shilpa Medicare facility

Hyderabad, Telangana: Shilpa Medicare Limited announced that company's Bio Analytical Laboratory, Unit 7, Nacharam, Hyderabad, India was inspected by USFDA from 26th February to 1st March 2024. The inspection was concluded with zero 483 observations and no discussion items.

The Agency has concluded that this inspection has now been closed with the issuance of the Establishment Inspection Report (EIR). The facility is classified as "No Action Indicated" (NAI).

This unit of Shilpa Medicare is engaged in testing biological samples of clinical studies and BA/BE studies in human subjects as per global regulatory requirements. This is a newly set up Centre for bio-analytical testing and this is the first regulatory inspection and approval for this Site from USFDA.

Alembic Pharma announces USFDA approval for Doxycycline Capsules, 40 mg

Vadodara, India: Alembic Pharmaceuticals Ltd announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Doxycycline Capsules, 40 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Oracea Capsules, 40 mg, of Galderma Laboratories, L.P. (Galderma). Doxycycline capsules are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. Refer label for a detailed indication.

Doxycycline Capsules, 40 mg have an estimated market size of USD123 million for twelve months ending March 2024 according to IQVIA. Alembic has a cumulative total of 205 ANDA approvals (179 final approvals and 26 tentative approvals) from USFDA.

Aurobindo Pharma's subsidiary acquires Ace Laboratories, UK

Hyderabad, India: Aurobindo Pharma Ltd. announced that its subsidiary, Agile Pharma BV, The Netherlands, a wholly owned step-down subsidiary of the Company, has acquired entire share capital of Ace Laboratories Limited in UK.

The acquisition is largely for the captive purposes of the Company's business requirements in the European region. Based on capacity utilization, additional external revenue will also add to company's revenue stream. Ace Lab has total revenue of ₹ 8.95 crores for the 12 months period ended 30th June 2023.

Aurobindo Pharma Limited (www.aurobindo.com), is an integrated global pharmaceutical company headquartered in Hyderabad, India. The Company develops, manufactures, and commercializes a wide range of generic pharmaceuticals, branded specialty pharmaceuticals and active pharmaceutical ingredients globally in over 150 countries.

The company has 25 manufacturing and packaging facilities that are approved by leading regulatory agencies including USFDA, UK MHRA, EDQM, Japan PMDA, WHO, Health Canada, South Africa MCC, Brazil ANVISA. The company's robust product portfolio is spread over 7 major therapeutic/product areas encompassing CNS, Anti-Retroviral, CVS, Antibiotics, Gastroenterological, Anti-Diabetics and Anti-Allergic, supported by a strong R&D set-up.

Lupin receives tentative approval from U.S. FDA for Empagliflozin, Linagliptin and Metformin Hydrochloride ER Tablets

Mumbai, India: Global pharma major Lupin Limited announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA)for its Abbreviated New Drug Application for Empagliflozin, Linagliptin and Metformin Hydrochloride Extended-Release (ER) Tablets, 5 mg/2.5 mg/1,000 mg, 10 mg/5 mg/1,000 mg, 12.5 mg/2.5 mg/1,000 mg, and 25 mg/5 mg/1,000 mg, to market a generic equivalent of Trijardy® XR Extended-Release Tablets, 5 mg/2.5 mg/1,000 mg, 10 mg/5 mg/1,000 mg, 12.5 mg/2.5 mg/1,000 mg, and 25 mg/5 mg/1,000 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. This product will be manufactured at Lupin's Pithampur facility in India. Empagliflozin, Linagliptin and Metformin Hydrochloride

Extended-Release (ER) Tablets (RLD Trijardy XR) had an estimated annual sale of USD111million in the U.S. (IQVIA MAT April 2024).

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.

Kemwell Biopharma partners with RevOpsis Therapeutics

Anurag Bagaria, CEO, Kemwell Biopharma

Bangalore, India: RevOpsis Therapeutics, a next-generation biopharmaceutical company spearheading innovation of multispecific ophthalmic therapies, and Kemwell Biopharma, a leading biologics contract development and manufacturing organization (CDMO), announced a broad strategic manufacturing partnership. This collaboration aims to accelerate the development of RevOpsis' lead candidate, RO-104, a first-in-class tri-specific biologic for the treatment of neovascular age-related macular degeneration (nAMD).

Under this partnership, Kemwell will manufacture RO-104, a novel tri-specific biologic designed to target the three dominant angiogenic pathways (VEGF-A, VEGF-C, Ang-2) for treating nAMD, a leading cause of blindness worldwide. The unique ability of RO-104 to bind these three validated targets simultaneously positions it as a first-in-class fully human monotherapy biologic, poised to redefine the treatment landscape for retinal vascular diseases.

As India's first commercial current Good Manufacturing Practices (cGMP) manufacturing facility, Kemwell is a trusted and respected partner with extensive experience in complex protein manufacturing. This collaboration leverages Kemwell's well-established manufacturing excellence and RevOpsis' innovative Rev-Mod platform to expedite the development of novel multispecific biologics

"Partnering with Kemwell is a pivotal step in accelerating the development of our lead candidate, RO-104, and advancing our pipeline of innovative multispecific biologics," said Ram Bhandari, MD, Co-founder and Interim CEO of RevOpsis. "Kemwell's exemplary track record in high-quality biologics manufacturing and their efficiency in reducing timelines, combined with our proprietary Rev-Mod platform, ensures we can deliver transformative therapies to patients efficiently. This collaboration aligns with our mission to develop groundbreaking treatments expeditiously, and bring our innovation to patients worldwide."

Anurag Bagaria, CEO of Kemwell Biopharma, added, "We are excited to collaborate with RevOpsis to manufacture and commercialize RO-104. Our expertise in complex protein manufacturing, coupled with RevOpsis' innovative therapeutic approaches, holds great promise for advancing the treatment of retinal vascular diseases. This strategic partnership underscores our commitment to delivering high-quality biologics for patients in need."

Indegene announces strategic collaboration with Microsoft

Tarun Mathur, CTO, Indegene

Bengaluru, India: Indegene announced a strategic collaboration with Microsoft to empower global life sciences companies to scale up the adoption of purpose-built, enterprise-grade Generative AI (GenAI) services, thereby driving faster innovation at scale. Indegene and Microsoft have committed to developing resources in highly specialized and skilled medical and technology tools to co-innovate generative AI services and workflows across commercial, medical, regulatory, and clinical functions.

"GenAI presents a once-in-a-decade opportunity for life sciences companies to modernize business processes and reimagine the effectiveness and efficiency of their operations throughout the value chain. Using GenAI, we're closely working with many of our clients to solve specific business problems, with nearly 50 real-world

use cases already in an advanced pilot stage", said Tarun Mathur, CTO, Indegene. "As we double down on efforts to strengthen our innovation prowess, we will keep exploring opportunities for greater collaboration with key technology providers. We remain focused on helping our clients harness the potential of GenAI with targeted solutions to address some of their most pressing operational challenges and make their business future-ready."

Alok Lall, Chief Operating Officer, Microsoft India & South Asia, said, "Generative AI is profoundly shaping every industry, including life sciences, by offering unprecedented avenues for healthcare technology advancements. According to a Microsoft-commissioned study conducted by IDC, a staggering 79% of healthcare organizations have now embraced AI. This demonstrates that the tangible business value of this transformation is indisputable. By seamlessly integrating Indegene's domain knowledge with Microsoft Azure OpenAI Service and Microsoft Copilot, we stand at the forefront of advancing generative AI within the life sciences sector. This collaborative effort empowers life sciences companies to fully harness AI's capabilities, fostering innovation and scalability within the industry."

To develop a future-ready workforce, Indegene has also instituted the 'GenAI @ Work' initiative, where all its 5,000+ employees will be trained on various facets of GenAI to enhance automation and productivity, allowing its employees to focus on higher-value tasks. As part of this initiative, Indegene has deployed Microsoft Copilot in several of its core business processes and has already started seeing significant productivity improvements.

Akums Introduces GERD Relief Antacid Chewable tablet

Sanjeev Jain, MD,Akums Drugs & Pharmaceuticals

New Delhi, India: Akums Drugs & Pharmaceuticals Ltd., Largest India-focused CDMO serving the Indian domestic pharmaceutical industry, has launched Advanced Anti-Reflux Antacid - Sodium Alginate + Potassium Bicarbonate Chewable Tablet, approved by the Drugs Controller General of India (DCGI).

This chewable tablet falls under the category of 'reflux suppressants,' which form a protective layer on top of stomach contents to prevent acid from escaping into the oesophagus, thereby alleviating pain and discomfort. Each tablet contains Sodium Alginate IP 500mg and Potassium Bicarbonate IP 100mg.

It is designed to treat symptoms such as acid regurgitation, heartburn, and indigestion, which can occur after gastric surgery, due to hiatus hernia, during pregnancy, and in conjunction with reflux oesophagitis. It is also aimed to treat laryngopharyngeal reflux symptoms like hoarseness, sore throats, and cough.

Sanjeev Jain, Managing Director of Akums Drugs & Pharmaceuticals Ltd stated, "The increasing prevalence of GERD and its complications necessitates advanced treatment options, and our new product is aimed to offer a unique solution with its dual-action approach of forming a protective barrier and neutralising stomach acid."

Sandeep Jain, Managing Director of Akums Drugs & Pharmaceuticals Ltd., added, "Driven by our commitment to enhancing patient well-being, we engage in continuous research and development. GERD disrupts daily life, causing heartburn and regurgitation, affecting activities and comfort. Akums' Advanced Anti-Reflux Antacid chewable tablets aims to provide relief, restore comfort and enable patients to enjoy meals and daily tasks without discomfort. This formulation not only addresses GERD symptoms but also aims to offer a convenient, effective, and safe treatment option for diverse patients."

The tablet is intended for oral administration. Adults and children over 12 years should take one to two tablets after meals and at bedtime when symptoms occur. Children under 12 years should use the product only under medical advice. It is suitable for pregnant women and offers an extra-strength formula.

Sai Life Sciences files DRHP with SEBI

Mumbai, India: Sai Life Sciences Limited, has filed its Draft Red Herring Prospectus ("DRHP") with market regulator Securities and Exchange Board of India ("SEBI"). Sai Life Sciences provides end-to-end services across the drug discovery, development, and manufacturing value chain, for small molecule new chemical entities ("NCE"), to global pharmaceutical innovator companies and biotechnology firms. The company plans to raise funds through offer of equity

shares (face value ₹ 1 each) through initial public offerings. The offer comprises of fresh issue of Equity Shares aggregating up to ₹ 800 crores and offer for sale up to 61,573,120 equity share by Selling Shareholders.

Sai Life Sciences proposes to utilize net proceeds from fresh issue towards-Repayment/ prepayment, in full or part, of all or certain outstanding borrowings availed by Company to ₹ 600 crores and for General corporate purposes.

Sanofi announces expansion of its Global Capacity Centre in Hyderabad

Hyderabad, India: Sanofi Healthcare India Pvt. Ltd. announces the expansion of its Global Capacity Centre (GCC) in Hyderabad, with plans to invest €400 million over the next six years, with €100 million by 2025. Over the next two years, this GCC (hub) will expand to host up to ~2600 employees, making it the largest of Sanofi's four global hubs. Sanofi's 4 Global Capacity Centres are strategic Hubs across the Globe that give the company a competitive edge in delivering best-in-class enterprise solutions. These hubs are key 'nerve-centers' that enable centralization and modernization and allow for scaling-up opportunities across Sanofi's value chain, offering a wide array of services ranging from commercial, manufacturing & supply to R&D and digital.

Established in 2019, the Hyderabad hub has grown exponentially from being a Medical Hub to now providing several best-in-class services to Sanofi's global functions and affiliates across the world. This future-forward global hub for talent in Hyderabad, is a state-of-the-art workplace designed to be environmentally sustainable and foster diversity and inclusivity.

Sri Duddilla Sridhar BabuHonorable Minister – Information Technology, Electronics & Communications, Industries & Commerce and Legislative Affairs, Telangana said, ""The expansion of Sanofi's Global Capability Center in Hyderabad marks a remarkable step forward for Telangana's ever-growing prominence in the global pharmaceutical landscape. This substantial additional investment of over 400 million euros and the creation of over 2,600 jobs in the next two years underscore Telangana's commitment to fostering a thriving environment for innovation and growth. We are proud to support Sanofi's vision of advancing healthcare and are confident that this expansion will significantly contribute to our local economy and the global well-being."

Madeleine Roach Executive Vice President, Business Operations, Sanofi "I thank Hon'ble Minister Sri Duddilla Sridhar Babu for welcoming Sanofi's largest GCC and inaugurating our new workplace. Hyderabad is emerging as a preferred shared services destination with a large pool of talent. We're excited to invest and build this hub here to become a great global community striving for excellence, with digitalization at the heart of our transformation. This hub will be a catalyst enabling Sanofi to accelerate efficiency and reinvent how we work, as we chase the miracles of science to improve people's lives."

Emmanuel Frenehard, Executive Vice President, Chief Digital Officer, Sanofi said, ""Our ambition is to be the first biopharma company powered by Artificial Intelligence (AI) at scale. From discovery to treatment, we are using AI ethically and safely to get to market faster with our drugs as there's plenty of unmet needs. We intend to onboard talent at the Hyderabad hub to embrace the power of AI across our value chain to harness the pace of scientific discovery, improve our productivity and place better decision intelligence in the hands of our people."

Entod Pharmaceuticals introduces innovative eye drop preservative system

Mumbai, India: Mumbai-based pharmaceutical company ENTOD Pharmaceuticals has developed an innovative eye drop preservative system called EyeBS that eliminates the need for harmful detergent-based preservatives such as Benzalkonium Chloride (BAK) and Polyquaternium-1 that are traditionally used in eye drop formulations, ensuring safety and efficacy while minimizing adverse reactions.

The EyeBS proprietary preservative system is based on an ionic buffer containing a unique blend of borate, sorbitol, propylene glycol and zinc, and doesn't cause any cytotoxic side effects as seen with conventional detergent-based ophthalmic preservatives.

This unique preservative system functions as an oxidizing preservative with both antibacterial and

antifungal properties. It effectively and safely maintains the sterility of ophthalmic solutions throughout its shelf life without harming ocular tissues, making it a safe option for long-term use. Apart from strong antimicrobial protection it also offers excellent biocompatibility with ocular tissues.

The use of EyeBS™ in eye drops also significantly reduces the risk of irritation, dryness, and other ocular surface disorders commonly associated with prolonged use of conventional detergent-based ophthalmic preservatives.

The efficacy, comfort and biocompatibility of the EyeBS preservative system has been shown in various formulations and clinical studies worldwide, and approved by drug regulators in several countries.

Mrs Bharati S Jadhav, Senior Scientific Manager at Entod Pharmaceuticals, expressed her excitement, saying, "Such a transformative approach in maintaining the sterility of eye drops whilst prioritising patient safety and comfort without compromising efficacy marks a new era in the technology for eye drops. The expertise, dedication and perseverance of our formulation research team has allowed us to successfully develop this preservative system for eye drops that meets all global standards."

ENTOD Pharmaceutical's CEO Mr Nikkhil K Masurkar said, "This is indeed an exciting development in the field of eye drop technology. ENTOD Pharmaceuticals have been pioneers of eye drop preservative systems whether it's the development of the safer and disappearing biodegradable ocular preservative Stabilized Oxychloro complex (SOC) way back in 2010 or the more recent EyeBS preservative system in 2024. EyeBS preserved eye drops will be exclusively marketed and sold by ENTOD Pharmaceuticals, and the commercialisation of such eye drops is already under way."

Rusan Pharma's API Plant in Ankleshwar Receives (India) USFDA GMP approval

Ankleshwar, India: Rusan Pharma Private Ltd, a pharmaceutical company based in India specializing in the area of addiction treatment and pain management, announced that the United States Food and Drug Administration (US FDA) has granted Good Manufacturing Practice (GMP) approval for its Active Pharmaceutical Ingredient (API) facility in Ankleshwar (Gujarat, India). The approval, received on May 29, 2024, followed a comprehensive five-day on-site inspection conducted from April 29 to May 3, 2024. This milestone marks a significant achievement for the company as it paves the way for it to enter the US API market. With an active US Drug Master File (DMF) for niche APIs like Eflornithine Hydrochloride Monohydrate and Nalmefene Hydrochloride, Rusan Pharma plans to expand its portfolio with additional APIs, including Apomorphine, Buprenorphine, Naloxone, Naltrexone, Nalbuphine, Sodium Oxybate, Clonazepam, Diazepam, Nitrazepam, Oxazepam, and Temazepam.

Speaking on the achievement, Dr. Kunal Saxena, Managing Director of Rusan Pharma, highlights, "This GMP approval by the US FDA underscores our unwavering commitment to maintaining the highest standards of quality and manufacturing excellence, expanding our global presence and credibility. This achievement instils confidence in our partners and clients, reassuring them of our dedication to excellence in producing high-quality APIs that meet the most stringent global standards."

The US FDA approval of the Ankleshwar facility is a critical development in Rusan Pharma's strategy to become a key player in the global pharmaceutical industry. Currently, the company supplies APIs to various US-based companies focused on orphan drugs, addiction treatment, and obesity medications. The approval will further enhance Rusan's capabilities, expand its API product portfolio, and increase its footprint in the growing US pharmaceutical sector.

Following on-site audits, Rusan's API facility in Ankleshwar is GMP approved by other stringent international agencies such as Health Canada, the European Union (EU), and ANVISA (Brazil). Rusan implemented 21-CFR-compliant software solutions like SAP, Laboratory Information Management System (LIMS), document & quality management systems (DMS & QMS) and electronic logbooks, ensuring a move towards paperless manufacturing. This transition, along with comprehensive staff training and monitoring, posed significant challenges that the company successfully overcame.

Before receiving this approval, Rusan Pharma established a robust presence in key markets such as Australia, Brazil, Canada, EU, Mexico, New Zealand, and the United Kingdom. The US FDA's endorsement enables the company to market its APIs to US clients with existing marketing authorizations and those developing new formulations. This approval further bolsters our customers' and regulatory agencies' trust and confidence in us globally. ■

EMA approves Biocon Biologics' New mAbs Facility in India

Bengaluru, Karnataka, India: Biocon Biologics Ltd (BBL), a global, fully integrated biosimilars company and a subsidiary of Biocon Ltd, has received approval from the European Medicines Agency (EMA) to manufacture biosimilar Bevacizumab at its new, world-class, multi-product monoclonal antibodies (mAbs) drug substance facility at Bengaluru. This approval will provide significant additional capacity to address patients' needs across markets in Europe. The facility has previously been approved to manufacture biosimilar Trastuzumab in September 2022. The company also announced that EMA has renewed its Good Manufacturing Practice (GMP) Certificates of Compliance for its biosimilars manufacturing facility at Bengaluru and its insulin facility in Malaysia following routine GMP inspections. These certificates were issued by the Health Products Regulatory Authority (HPRA), Ireland, on behalf of EMA.

Cipla EU to invest an additional EUR 3 million in Ethris

Mumbai, India: Cipla Limited announced that its wholly-owned subsidiary in United Kingdom, Cipla (EU) Limited (hereinafter together referred as "Cipla") will invest an additional EUR 3 million in Ethris GmbH ("Ethris"), a global leader in delivering mRNAs directly to the respiratory system. This additional investment through a convertible loan will accelerate Cipla's participation in the mRNA space.

Cipla had earlier invested EUR 15 million in Ethris in 2022. This additional investment reaffirms Cipla's confidence in Ethris's proprietary mRNA platform and its potential for patients in emerging markets. Together, Cipla and Ethris are working towards a long-term strategic partnership to fast-track innovative mRNA-based treatments. During the COVID19 pandemic, mRNA vaccines gained importance due to the first regulatory approvals for SARS-CoV-2. mRNA-based medicines have a huge potential in several indications as infectious disease vaccines, therapeutic cancer vaccines, and protein replacement therapies.

Umang Vohra, Managing Director & Global Chief Executive Officer of Cipla, said, "At Cipla, we strive to dial-up our focus and investment towards innovative modalities and bring new age therapies to emerging countries, including India. The follow-on investment in Ethris will help get cutting-edge healthcare solutions like mRNA-based therapies to the Global South. As we lead Cipla ahead, we will continue to work towards building an innovative future and build brands that re-enforce our ethos of 'caring for life."

Dr. Carsten Rudolph, CEO of Ethris, added, "The additional investment by Cipla further validates the broad potential of our platform and Ethris' innovative approaches to developing respiratory RNA-based medicines. We deeply value this ongoing relationship to bring effective solutions to developing countries. The capital will enable us to continue advancing our pipeline and we look forward to providing an update on our lead program in the near term."

AstraZeneca plans to invest ₹ 250 crore to grow Global Innovation & Technology Centre in India

Mumbai, India: AstraZeneca India Private Limited (AZIPL), the Global Capability Centre (GCC) of AstraZeneca, announced an investment of ₹ 250 crore (USD30 million) to expand its Global Innovation and Technology Centre (GITC) in Chennai, Tamil Nadu, which includes close to 1,300 roles focused on driving innovation, enhancing efficiency, and streamlining operations across the company globally.

The expanded facility was inaugurated today in a ceremony officiated by the Minister of Industries Tamil Nadu, Dr. T.R.B. Rajaa, British Deputy High Commissioner to India, Christina Scott CMG, AstraZeneca Vice President for Asia Area Sylvia Varela, as well as AstraZeneca's leadership team in the country.

The investment marks a significant milestone in AstraZeneca's growth story in India as it celebrates its 45th year in the country this month. With the highly skilled roles to be brought in by 2025, the expanded GITC will propel company's vision to leverage technologies such as enterprise platforms, artificial intelligence, machine learning, data science, and supply chain analytics to shape healthcare outcomes.

Siva Padmanabhan, Managing Director, AstraZeneca India Private Limited (AZIPL) said, "At AstraZeneca, we are evolving our technologies constantly so that we can stay ahead of the curve in healthcare and pharmaceutical industries to better serve our patients in countries where we operate. We are deeply invested in infusing the best of technology and innovation practices into the healthcare ecosystem." Dr. Sanjeev Panchal, Managing Director & Country President AstraZeneca Pharma

India Limited (AZPIL), said, "Our expansion in Chennai signifies AstraZeneca's unwavering commitment to pioneering science and innovation. India's rich talent pool and dynamic ecosystem for digital advancements make it a pivotal hub for our global operations. This strategic investment underscores our dedication to improving patient outcomes through cutting-edge technology and reinforces our aspiration to transform the future of the healthcare industry. I am immensely proud of our team's achievements and excited for the future as we continue to harness science to bring life-changing medicines to patients worldwide."

AGI Greenpac invests ₹230 Crore to modernize production facilities

Hyderabad, India: With the global glass packaging market poised for significant growth, from USD 67.28 billion in 2024 to USD 93.69 billion by 2032. AGI Greenpac, a focused Packaging Products company in India, is implementing a two-pronged strategy to capitalize on this growth. AGI Greenpac is making a strategic investment of ₹230 crore to modernize its existing furnaces, implement cutting-edge technologies, and optimize production. This initiative will enable the company to better serve the growing demand for high-quality glass packaging solutions.

AGI Greenpac is also strategically expanding its reach beyond India's borders to establish itself as a key force in the international glass packaging landscape. Fueled by the growing global demand for high-quality glass packaging, the company is actively exploring export opportunities in the Middle East and Europe, following the establishment of a strategic export channel in the USA. This move reflects AGI Greenpac's commitment to effectively serving global markets and fostering stronger relationships with customers worldwide. On the sidelines of a plant visit, Rajesh Khosla, CEO, AGI Greenpac, said, "Our investment in our production capabilities will ensure we are well-positioned to meet the demand for our innovative, high-quality glass packaging solutions. This commitment to best-in-class practices not only strengthens our domestic offerings but also allows us to venture into new markets." ■

UNION BUDGET 2024

2024 Union Budget: Industry Leader's Reaction

2024 Union Budget has been announced by Finance Minister Nirmala Sitharaman. Here are the few eminent industry leader's reaction.

Saransh Chaudhary
President, Global Critical Care, Venus Remedies Ltd and CEO, Venus Medicine Research Centre

"The Central government's decision to exempt three more cancer medicines from customs duty is a commendable step towards making cancer drugs more affordable. It will also make oncology exports more competitive and incentivise manufacturers by reducing their costs. We also welcome the Finance Minister's announcement to include manufacturing & services and innovation, research & development among the nine priority areas identified by the government to ensure fast-paced growth in line with its vision of "Viksit Bharat". Pharma manufacturing being India's strength, we expect the government to build on it with its incentive-based approach. A renewed focus on innovation and R&D, on the other hand, will transform India into a value-driven economy, unleashing its immense potential wealth creation potential."

Shamsher Dewan
Senior Vice President & Group Head Corporate Ratings, ICRA Limited

"Budgetary allocation towards healthcare increased by 13.0% for BE FY2025 BE from RE FY2024. Given the backdrop of under-penetrated healthcare infrastructure in the country, increased budgetary allocation towards the healthcare sector is a welcome move. Exemption on customs duty for three more cancer drugs will make the associated treatments more affordable, thus benefitting the patients and the healthcare ecosystem. Reduction/ exemption in customs duty on raw materials used in medical devices and implants is expected to reduce costs for medical device manufacturers. ~7.4% increase in allocation towards the Ayushman Bharat scheme reaffirms the government's focus on national health protection and is expected to increase patient footfalls for healthcare companies."

UNION BUDGET 2024

Srivardhan Khemka

Director, Sanjivani Paranteral

"The Finance Minister has shown a strong commitment to facilitating higher participation of women in the workforce in the Budget 2024. As a company with 60% women in our workforce these measures will undoubtedly create a more supportive and inclusive environment for women, enabling them to contribute more effectively to the economy. Additionally measures such as organizing women-specific skilling programs and promoting market access for women, SHG enterprises is a step in the right direction. By focusing on skilling and market access, the government is empowering women to not only enter but thrive in the workforce. We look forward to supporting and participating in these initiatives, which will enhance the capabilities of our female employees and, in turn, drive the overall growth and success of our industry."

Anand K

Managing Director & CEO of Agilus Diagnostics

"The Economic Survey has highlighted the growing concern of obesity. Recent studies show that the burden of Non-Communicable Diseases (NCDs) has tripled since 1995. Addressing these issues demand robust budgetary and policy measures, yet the overall health budget allocation remains low. As the industry grapples with post-pandemic challenges, strong initiatives are needed to build a resilient health system.We welcome the Union Budget's measures in the healthcare sector. The custom duty changes on x-ray tubes and flat panel detectors is a positive development. Moreover, the exemption of three critical cancer medicines from custom duty is a crucial step in making life-saving treatments more accessible to patients across the country.

Shuchi Ray

Partner, Deloitte India

"The Government has allocated ₹89,287 crores towards healthcare sector, which is marginally higher than the original budget allocation estimate of Rs. 89,155 crores last year. A few very specific announcements pertaining to the sector are welcome, viz., exemption of three cancer medicines from customs duties keeping in perspective affordability and rationalizing the customs duty in case of X-ray tubes and Flat panel detectors and for some input materials used in manufacturing of orthopedic implants and artificial parts of the body, is clearly a recognition towards boosting domestic manufacturing of such medical equipment / devices. While healthcare has not found its place in the budget priorities, however, it has clearly been integrated with most of the priorities announced. In pursuance of priority relating to manufacturing and services, development of Digital Public Infrastructure Applications is proposed in various areas including healthcare, and under Priority relating to Next Generation Reforms, it has been recognized to step up adoption of technology towards digitalization of the economy aiming at improving access to everyone including health.

UNION BUDGET 2024

Anil Matai
Director General, Organisation of Pharmaceutical Producers of India (OPPI)

"We deeply appreciate the government's decision to exempt three critical cancer medicines - Trastuzumab Deruxtecan, Osimertinib, and Durvalumab - from customs duties. This move will provide much-needed relief to cancer patients by reducing the financial burden of these life-saving drugs. The current customs duty of 10% was a significant cost barrier, and this exemption is a welcome step towards making advanced cancer treatments more accessible.We appreciate that the Government of India has reiterated the importance and necessity of Patient Assistance Programmes (PAP) offered by the pharmaceutical industry to improve access of life-saving drugs by extending the customs duty waiver on drugs and medicines imported to India for the supply under PAP through to March 31, 2029. The clarion call of Jai Jawan, Jai Kisan, Jai Vigyan, Jai Anusandhan" by Prime Minister Narendra Modi has once again been reiterated with Innovation and Research & Development being announced as one of the nine priority areas envisaged by the Government in this budget.

Overall, the Union Budget 2024 reflects a forward-looking and inclusive approach, and the pharmaceutical sector looks forward to actively participating in and contributing to the realization of these transformative initiatives."

Swarup Bose
Founder & CEO, Celcius Logistics

"Food wastage has been a grave concern for the country. The government's focus to strengthen vegetable production and supply chain through the development of large-scale clusters near major consumption centres is a crucial step in curbing the wastage issue and be self-sufficient. By promoting farmer producer organizations, cooperatives, and startups, the government is nurturing an ecosystem that encourages innovation and collaboration. These steps are crucial for reducing food wastage and improving market access for farmers and new age Agri-startups. Additionally, the commitment to digital public infrastructure for agriculture is a transformative move that will enable better tracking, transparency, and efficiency across the supply chain. These initiatives will optimize cold supply chain logistics, ensuring fresher produce reaches consumers faster and more efficiently. The allocation of Rs 1.52 lakh crore for agriculture and allied sectors will significantly enhance the efficiency and reach for logistics services provider.

The improved connectivity will help last mile delivery of temperature sensitive pharma products. More and more temperature sensitive products will be delivered to remotest of the area due to robust infrastructure. This budget reflects a strong commitment to sustainable agricultural growth and efficient logistics management, and we look forward to contributing to these goals."

INTERVIEW

"Gujarat FDCA is likely undertaking new projects to align with changing regulations"

Dr Hemant Koshia
Commissioner,
Food & Drugs Control Administration Gujarat

Gujarat is India's leading state in pharmaceutical industry, with a 33% share in drug manufacturing and 28% share in drug exports. Gujarat FDCA makes optimum use of information technology for achieving excellence in performance. This is the first State to initiate online software for sales and manufacturing licenses and is responsible for issuing licenses and monitoring the quality of food and drugs.

Hemant Koshia emphasizes about the initiatives undertaken by the Gujarat government and also addressed the challenges in regards to regulatory compliance.

What are the key challenges that your team face in the state when it comes to regulatory compliance?

Food & Drugs Control Administration (FDCA) in Gujarat, responsible for issuing licenses and monitoring the quality of food and drugs. Regulatory compliance in the pharmaceutical sector typically involves stringent requirements related to manufacturing practices, quality control, documentation, and adherence to safety standards. Some challenges team might face could include keeping up with evolving regulatory frameworks, ensuring consistency in compliance across different scales of operations (from small to large companies), and effectively managing inspections and audits.

Please tell us about the key initiative undertaken by the Gujarat government?

The Gujarat government has been proactive in promoting the pharmaceutical sector through various initiatives such as infrastructure development, incentives for pharmaceutical companies, skill development programs, and knowledge upgradation. E-initiatives by Gujarat FDCA could include digitalization of regulatory processes, online submission of applications, electronic document management systems, and real-time monitoring of drug applications like xln.gujarat, dmla, idmla, cosmla, ayumla etc.

What are the new projects that the Gujarat FDCA is currently undertaking to keep up with the change in regulation?

Gujarat FDCA is likely undertaking new projects to align with changing regulations. These could include implementing electronic systems for licensing and approvals, enhancing surveillance mechanisms for drug safety, and conducting awareness programs for stakeholders.

What is the size of the Gujarat pharma industry? What are the factors that attract the pharma sector to Gujarat?

The Gujarat pharmaceutical industry is substantial, contributing significantly to India's overall pharmaceutical production and exports. Specific current statistics can vary, but Gujarat is known as a major hub for pharmaceutical manufacturing in India. As of year 2022-232, the Gujarat pharma industry's annual turnover was around ₹ 1.75 lakh crore.

Gujarat is attractive to the pharmaceutical sector due to its robust infrastructure, favourable industrial policies, skilled workforce, presence of educational and research institutions, and a conducive business environment.

How does Gujarat FDCA ensure business friendly model in the state while maintaining a stringent regulatory framework?

Gujarat FDCA likely ensures a business-friendly environment by streamlining processes, providing transparent guidelines, offering online services for ease of compliance, and conducting regular stakeholder consultations while maintaining strict adherence to regulatory standards.

Brief us about MoU with NIPER Ahmedabad? How do you plan to build capacities? What are the training programmes are you coming up with?

The Gujarat FDCA has signed an MoU with National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad, which signifies collaboration in research, training, and capacity building. Training programs could cover areas such as pharmaceutical analysis, regulatory affairs, quality assurance, and good manufacturing practices (GMP).

Having Bulk Drug Park on stream, how do you plan to monitor in terms of regulations in place?

With Bulk Drug Parks, Gujarat FDCA would monitor compliance through regular inspections, audits, and stringent adherence to environmental, safety, and quality standards. Collaboration with park authorities and industry stakeholders would ensure effective regulation and oversight. ■

GUEST COLUMN

Deciphering the World of Biologics and Vaccines

Dr Sandeep Arora
Head of Medical Affairs and Patient Services –
Takeda Biopharmaceuticals India

Biological products, or therapeutics, also called biologics, comprise a broad range of products that include vaccines, monoclonal antibodies, immune modulators, and growth factors, including those derived from plasma and human blood. As a class of medicines, biologics are grown and purified from large-scale cell cultures of yeast, bacteria, or animal or plant cells. **Dr. Sandeep Arora** emphasizes about the rise of biologics and the varied challenges in vaccine development.

Understanding Biologics

Biologics are distinguished from other medicines as they are typically proteins purified from blood or living culture systems. Conversely, other medicines are deemed to be small molecules, either purified from plants or made synthetically.

After being isolated from various natural sources (microorganisms, humans, or animals), biologics can be produced by biotechnology means and allied cutting-edge technologies. For instance, gene-based and cellular biologics are often at the forefront of biomedical research and may be used to treat various medical conditions where no treatments are currently available.

Unlike most drugs that are synthesized chemically and have known structures, most biologics, being complex mixtures, cannot be easily characterized or identified. Moreover, unlike most conventional drugs, biological products, including those manufactured through biotechnology, are usually heat-sensitive and vulnerable to microbial contamination. As a result, it's imperative to maintain aseptic norms, as is done in the initial manufacturing stages.

Given the differences in nature and the manner of production, biologics are tested, regulated, and controlled differently compared to other drugs. To safeguard quality, safety, and efficacy, each batch of a biological product needs to be tested extensively at every production stage to ascertain its consistency with the previous batches. Using WHO international reference standards further ensures consistency of products across multiple batches while allowing biologics from different manufacturers and/or nations to be compared.

Comprehending the Pros and Cons

Much like the various kinds of products, the beneficial impact of biologics can be equally varied. Vaccines remain one of the most powerful and cost-effective means to lower the global disease burden. It is estimated that vaccines save around two to three million lives each year. Besides other diseases, smallpox and two types of polio have been eradicated due to worldwide efforts to vaccinate people and control their spread.

Nonetheless, since several infectious diseases keep claiming millions of victims annually, new vaccines and allied biological products are constantly in the R&D pipeline. Apart from the development of novel vaccines, other universal public health challenges include finding new methods for improving the quality, potency, efficacy, and safety of vaccines and other biologics. For example, life-saving products such as blood are widely used during surgery, especially in patients with trauma or bleeding disorders, including people undergoing chemotherapy to treat cancer. Since most donated blood is segregated into distinct components, a single unit can save numerous patients needing a transfusion.

Likewise, there are various other biologic therapeutics, such as insulin used in treating diabetes, interferons for cancer therapy, and viral infections, as well as monoclonal antibodies that treat some forms of cancer or autoimmune disorders. This class of agents includes some gene therapies and stem cells. Such products are excellent examples of how biologics stand out in managing challenging health conditions.

The rise of biologics has transformed the treatment of several autoimmune and inflammatory conditions. Nonetheless, while biologics have emerged as a crucial component in treating various inflammatory ailments, they could disrupt a patient's natural immune response to pathogens. Thereby, this can increase the risk of infection.

Since some infections could be prevented or become a lesser risk via appropriate vaccinations, a patient's vaccine history should be considered carefully before preparing for biologics. Thereafter, it must be updated annually to optimize benefits while curbing adverse effects.

Broad Benefits of Vaccines

As biological products enhance a body's defenses against infectious ailments, the development of vaccines represents one of the biggest medical milestones. Constant scientific innovations have been a substantial influence on the periodic progress in vaccine development.

In the Indian context, be it the first smallpox vaccine or the latest COVID-19 nasal vaccine, domestic vaccine development has advanced significantly. Across geographies, a range of vaccines has helped in lowering the global morbidity and mortality burden from innumerable diseases, which include endemic and emerging threats. This is possible because many live attenuated viruses, parasites, or inactive bacteria are used in creating vaccines to combat diverse diseases.

Vaccines are also a big boon in boosting child survival rates by lowering morbidity levels against many childhood diseases, either by eliminating them or reducing their threat. The WHO states that vaccines reportedly save five lives per minute.

One can well imagine the millions of lives saved since the first smallpox vaccine was developed by Dr. Edward Jenner in May 1796. In the realm of public health, the eradication of smallpox in 1980 is one of modern medicine's greatest achievements. For at least 3,000 years, smallpox plagued humanity, killing 300 million people in the 20th century alone.

Frequent breakthroughs and enhancements in the techniques of cell culture, genome sequencing, etc. have immensely influenced the development of novel vaccines. These include the nucleic acid vaccine, the viral vector vaccine, the RNA vaccine, and more.

Varied Challenges in Vaccine Development

However, due to the high expenditure on making these biological products, vaccine manufacturers are

relatively few compared to drug makers globally. Apart from steep investments, the development of vaccines needs specialized infrastructure, such as laboratories and equipment, as well as skilled human resources. During the pandemic, India made major investments to build infrastructure that could accelerate the development of coronavirus vaccines.

The time-consuming development process is an additional impediment to accelerating vaccine development in the country. Whether it is R&D or clinical trials, every stage requires time and money. Fortunately, during the pandemic, requisite funding from the government and non-profit entities facilitated the faster adoption of effective vaccines. This made it possible to hasten the construction and expansion of production units while also establishing contract manufacturing facilities and distribution networks.

Yet, the challenges don't end there. Another critical aspect is the stability of vaccines. Various vaccines have differing stability needs along with varying temperatures. Accordingly, it calls for much care and consideration while storing vaccines safely to safeguard their efficacy. Generally, vaccines are stored in coolers or refrigerators at a predetermined temperature range. To avoid instabilities, intranasal vaccines are now preferred, wherever the option exists.

Three Main Routes of Administration

The other key aspect concerns the route of vaccine administration. This determines the mechanism via which the vaccine will be absorbed by the body while also influencing its safety and effectiveness. The right route of delivery is necessary to maximize benefits while minimizing any adverse effects or potential risks. Injection, oral, and intranasal are the most common routes of administering vaccines. Each route of administration has its pros and cons, which vary as per the kind of vaccine used and the target cohort.

Injections are the most common vaccine administration route, allowing swift absorption and a speedy immune response. Since some people have an inherent fear of needles, this route is less desirable in such cases. Injections could be administered intramuscularly, intradermally, or subcutaneously.

Intramuscular injections administer medications into a muscle. Specific medications are absorbed rapidly through the intramuscular route. The choice of a specific muscle depends on the volume of medication and the age and size of the patient. Poor technique or inaccurate land-marking of the injection site could cause suboptimal absorption of medication, site reactions, and adverse events.

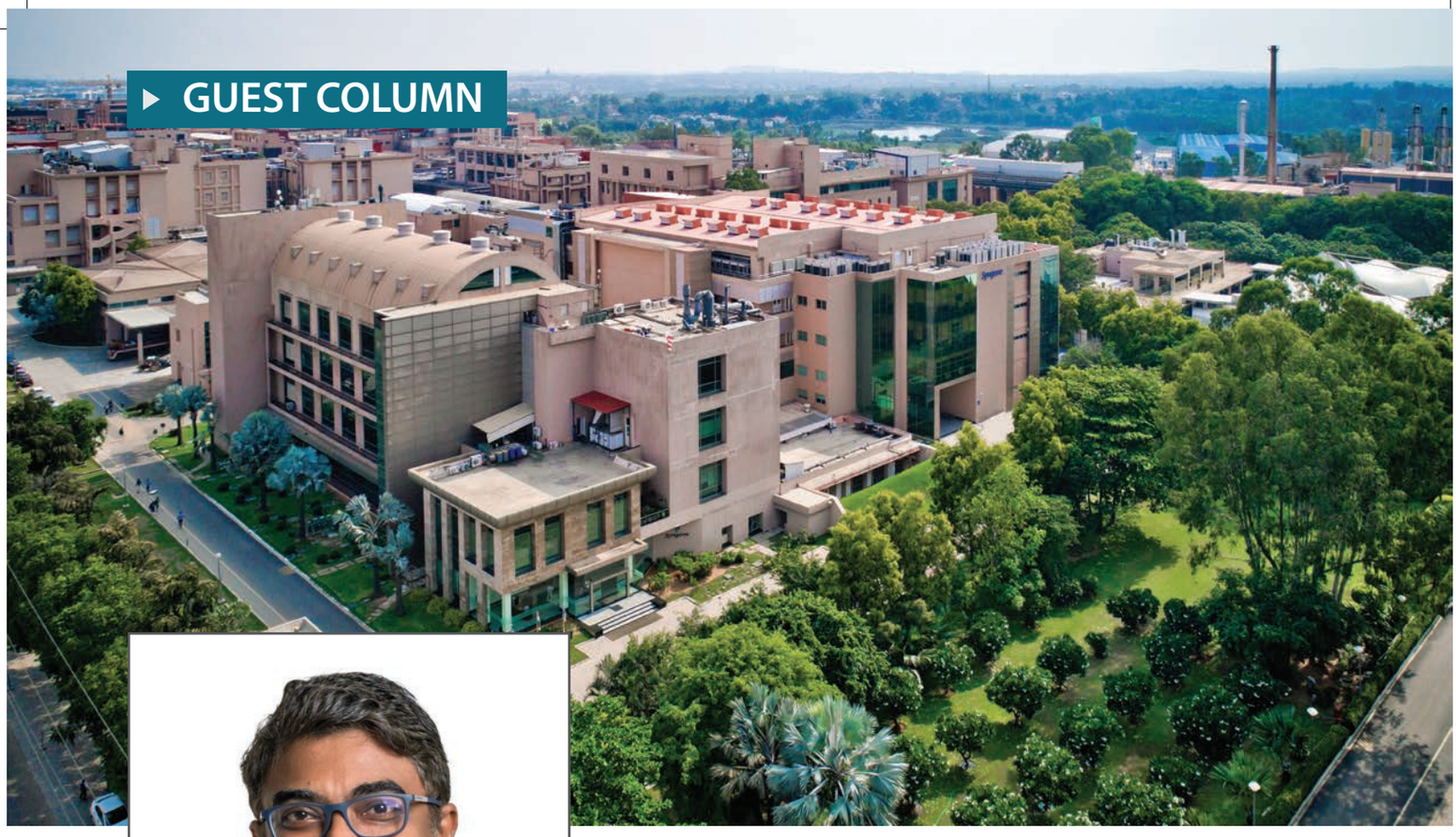
When it comes to intradermal injections, they are administered into the dermis, which is the layer of skin that is just below the epidermis. Though this administration route is not frequently used for vaccines, it may be used for specific types of vaccines, e.g., the hepatitis B vaccine, the tuberculosis vaccine, and the rabies vaccine (for prophylaxis).

As for subcutaneous injections, these are normally given under the skin, usually the upper arms and abdomen. As this administration route is generally shallower compared to intramuscular injections, it delivers the dose into the fatty tissue lying just below the skin. Rabies vaccine, yellow fever vaccine, and pneumococcal vaccine are administered through this method to cure these diseases.

In the case of oral vaccines, since they are more convenient to administer, they do not need a trained healthcare professional. However, multiple doses could be required to ensure adequate immunity. As more than 60% of novel molecular drug products on the market use the oral administration route, it is the most popular and patient-accepted approach.

Then there are nasal vaccines, more accurately termed intranasal vaccines. Thanks to their ease of administration, they remain the preferred parental way of administering. Self-administration is the other main advantage of this route. It is also extremely effective against pathogenic microbes (e.g., influenza and COVID-19) that enter through the nasal passage. Offering both mucosal and systemic protection, nasal vaccines are easy to store and transport, making them preferable to intramuscular vaccines.

Going by these advantages, it is not surprising that vaccines have gained global popularity as the most practical and cost-effective means of combating infectious diseases while safeguarding public health. ■



Navigating the Shift from China: The Future of Global Pharma Supply Chains

Sibaji Biswas
ED & CFO, Syngene International

Sibaji Biswas, ED & CFO, Syngene International shares insights about future of global Pharma supply chain. He also emphasizes about the India's significant opportunity to emerge as a viable alternative to China, leveraging its robust pharmaceutical ecosystem and skilled workforce to attract global pharmaceutical companies.

The disruptive impact of the COVID-19 pandemic and the recent BioSecure Act have created a pivotal moment for the global pharmaceutical industry. These events have compelled organizations to re-evaluate their strategic dependencies and accelerate the drive towards diversifying supply chains away from overreliance on China.

This shift presents both opportunities and challenges for Indian Contract Research, Development and Manufacturing organisations (CRDMOs), particularly in identifying alternative manufacturing hubs that ensure continuity and flexibility. For India, this represents a significant opportunity to emerge as a viable alternative to China, leveraging its robust pharmaceutical ecosystem and skilled workforce to attract global pharmaceutical companies.

While global pharma and biotech companies are exploring raw material supply points beyond India,

including Eastern Europe and other East Asian countries, India remains an attractive destination due to its established pharmaceutical infrastructure, competitive pricing advantages, and skilled workforce.

Building a Comprehensive Ecosystem

While India's deep-rooted expertise in chemistry, entrepreneurial spirit, and innovative drive enhances its global competitiveness, the nation requires developing a comprehensive ecosystem that supports the entire supply chain, from raw materials to finished products, including robust quality systems adhering to international standards, advanced technologies, strong collaboration, backward integration for raw materials, a skilled workforce, government support, and a focus on research and development to ensure a sustainable and globally competitive supply chain.

Companies like Syngene are already at the forefront of this transformation, attracting global partnerships and collaborations. By fostering a holistic ecosystem that ensures compliance with global quality standards, India can create a supply chain that is not only robust but also globally competitive.

The key to this ecosystem is the establishment of robust quality systems. Indian companies must adhere to stringent international standards to compete on the global stage. The adoption of Good Manufacturing Practices (GMP) and International Organization for Standardization (ISO) certifications will be essential in ensuring that Indian pharmaceutical products meet global quality benchmarks. Moreover, investing in advanced technologies such as automation, artificial intelligence (AI), and blockchain can enhance traceability, efficiency, and transparency within the supply chain.

Harnessing the Power of Collaboration

A critical aspect of building a sustainable and scalable ecosystem in the country requires earnest collaboration among pharmaceutical companies and Indian Contract Research Development Manufacturing Organizations (CRDMOs). Historically, many companies preferred sourcing from China due to lower costs and established relationships. By pooling resources, sharing knowledge, and building cohesive strategies, Indian companies can overcome these hurdles and capitalize on the opportunities presented by the current geopolitical landscape.

India has the power to build a collaborative ecosystem—one that combines the entrepreneurial spirit of generic manufacturers with the scientific prowess of CRDMOs like Syngene. This combination can create a dynamic and innovative environment, fostering growth and competitiveness.

A collaborative effort can also lead to the development of specialized pharmaceutical clusters, similar to the IT hubs in Bengaluru and Hyderabad. These clusters can provide a conducive environment for innovation, research and development (R&D), and commercialization of new drugs. By creating a network of interconnected companies, research institutions, and regulatory bodies, India can foster a vibrant ecosystem that drives growth and innovation in the pharmaceutical sector.

Leading in Inventory Management and Technological Innovation

In addition to harnessing the power of collaboration, it is imperative for the ecosystem and companies to embrace technology that will help them integrate and leverage supply chains effectively. Indian companies are now leveraging advanced technologies such as AI and machine learning to enhance forecasting and demand planning. The pandemic highlighted the critical importance of efficient inventory management and supply chain resilience. Indian companies are now leveraging advanced technologies such as AI and machine learning to enhance forecasting and demand planning, ensuring more responsive and adaptive supply chains.

Efficient inventory management and advanced technologies like AI, machine learning, Internet of Things (IoT), and blockchain enable Indian pharmaceutical companies to optimize production, reduce lead times, enhance supply chain visibility, and ensure product quality. These innovations not only strengthen supply chain resilience but also highlight India's potential to lead in pharmaceutical technology and infrastructure, solidifying its role as a global powerhouse in the industry.

Government Support: A Catalyst for Growth

The Indian government also has a crucial role to play in this transformative journey. Supportive policies and incentives can accelerate the development of a resilient pharmaceutical ecosystem. Production-linked incentive (PLI) schemes are already boosting domestic

manufacturing, but further measures are needed to sustain momentum. Furthermore, government initiatives like the "Make in India" campaign and the Atmanirbhar Bharat (self-reliant India) mission emphasize the importance of developing domestic capabilities and reducing reliance on imports.

Policies encouraging investment in infrastructure, research and development, and quality control can significantly enhance India's global standing. Streamlined regulatory frameworks will attract global investments and position India as a preferred destination for pharmaceutical manufacturing.

A Vision for the Future

India's emergence as a global pharmaceutical leader is not just a possibility but a strategic imperative. By leveraging its inherent strengths, fostering collaboration, and securing robust government support, India can lead the global pharma industry through this transformative period.

The future of the global pharmaceutical supply chain hinges on proactive strategies and visionary leadership. India's commitment to innovation, quality, and collaboration will pave the way for a more secure, sustainable, and resilient global supply chain. By taking decisive action today, India can ensure a prosperous future, reducing global dependency on any single country and building a balanced and resilient global supply chain that benefits all.

The BioSecure Act has provided a unique opportunity for India to step up and become a central figure in the global pharmaceutical supply chain. By harnessing its strategic advantages, fostering collaboration, and leveraging government support, India can build a comprehensive ecosystem that supports the entire supply chain, from raw materials to finished products. This moment offers India the chance to lead the way towards a more secure, sustainable, and resilient global pharmaceutical industry. With the right strategies and a commitment to excellence, India can seize this opportunity to enhance its global standing and drive significant advancements in the pharmaceutical sector. ■

Molecular Diagnostics: Revolutionizing Drug Development & Pharmacogenomics.

In the intricate realm of genetic code composition, precision medicine aims to customize healthcare interventions according to individual patient requirements. The advent of molecular diagnostics and whole gene sequencing marks a transformative shift in healthcare, enabling the identification of new challenges and offering significant potential in guiding treatment strategies. **Dr. Chaitali Nikam, Director at HaystackAnalytics, Infexn division,** explores the science behind these advancing technologies that are set to revolutionize drug development and pharmacogenomics.

In the orbit of modern medicine, where individuality reigns supreme, the promise of precision medicine has long captivated the imagination of healthcare professionals and patients alike. Imagine a world where treatments are tailored not just to diseases but also to the unique genetic makeup of each patient. Each individual is a unique composition of genetic code, environmental influences, and lifestyle factors. Amidst this complexity, the pursuit of precision medicine seeks to tailor healthcare interventions to the specific needs of each patient, ushering in an era where treatments are not just effective but truly personalized.

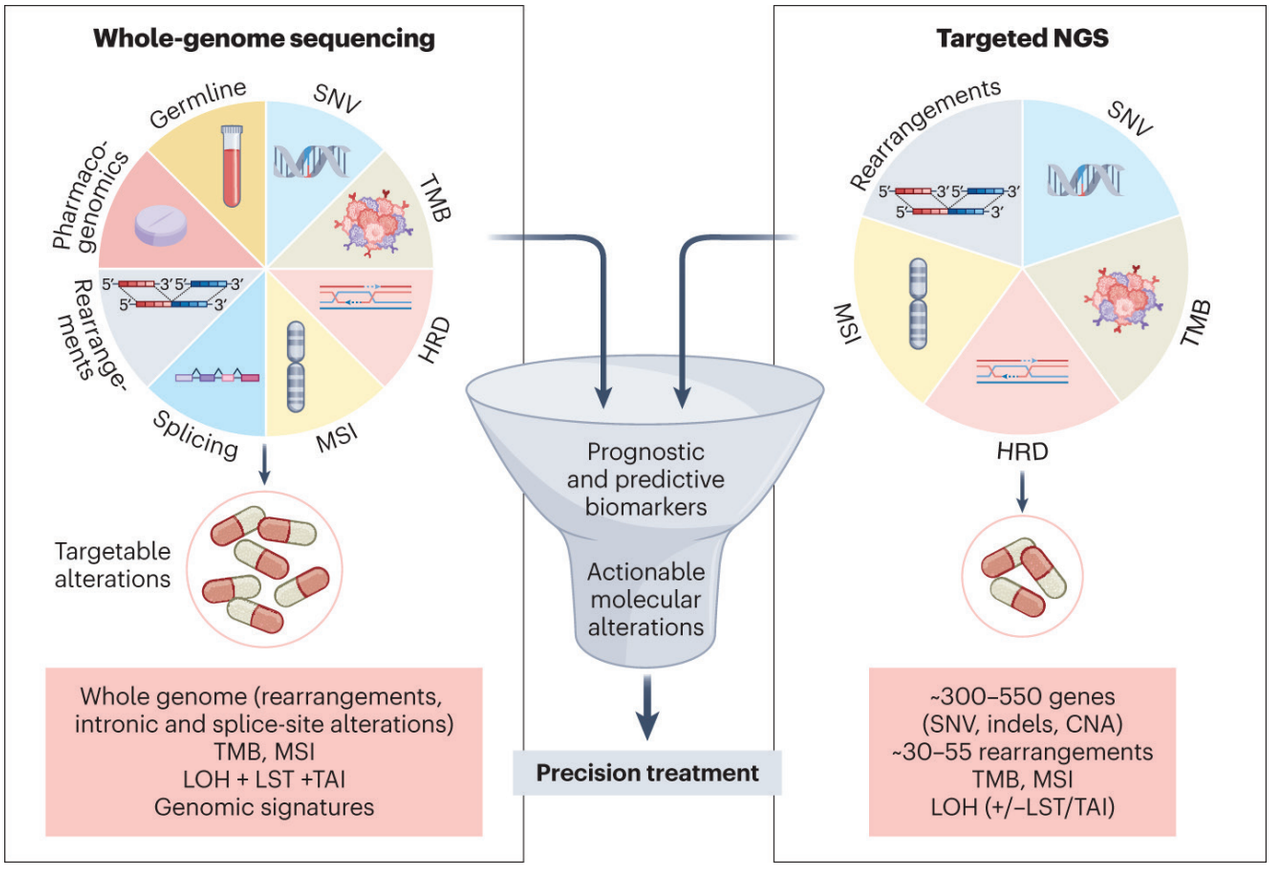
Decoding the DNA

At the forefront of this revolution stands Whole Genome Sequencing (WGS), a transformative technology poised to unravel the mysteries encoded within our DNA and redefine the practice of medicine as we know it. Whole Genome Sequencing, as the name suggests, involves the comprehensive analysis of an individual's entire genetic blueprint, spanning the entirety of their DNA. This exhaustive approach stands in contrast to traditional genetic testing methods that focus on specific genes or regions of interest. By decoding all 3.2 billion base pairs of DNA, WGS provides a holistic view of an individual's genetic makeup, offering insights into both rare and common genetic variations that underlie health and disease.

One of the most profound applications of WGS lies in the realm of disease diagnosis and risk assessment. By analyzing an individual's entire genome, clinicians can identify genetic variants associated with inherited disorders, enabling earlier detection and intervention. For patients with undiagnosed or rare diseases, WGS offers a lifeline, uncovering elusive genetic mutations that may have eluded traditional diagnostic approaches. Moreover, WGS can elucidate an individual's predisposition to common diseases such as cancer, cardiovascular disorders, and neurodegenerative conditions, empowering proactive measures for prevention and early intervention. For patients with undiagnosed or rare diseases, WGS offers a beacon of hope, uncovering elusive genetic mutations that may have evaded traditional diagnostic approaches.

A personalized approach

In addition to diagnosis, WGS holds immense promise



for guiding treatment decisions in oncology, where the landscape of cancer therapy is rapidly evolving towards personalized approaches. By scrutinizing the genetic alterations driving tumor growth, clinicians can pinpoint targeted therapies tailored to the molecular profile of each patient's cancer. This paradigm shift from a one-size-fits-all approach to precision oncology has already yielded remarkable outcomes, with improved response rates and survival benefits observed across a spectrum of malignancies. Furthermore, WGS enables the identification of novel drug targets based on genetic insights into disease mechanisms, paving the way for the development of more efficacious and targeted therapies.

Developing tailored pharmacotherapies

Beyond diagnosis and treatment, WGS is poised to revolutionize drug development and pharmacogenomics, the study of how genetic variations influence an individual's response to medications. By elucidating the genetic factors underlying drug efficacy and toxicity, WGS enables the development of tailored pharmacotherapies, minimizing adverse reactions and maximizing therapeutic outcomes. Moreover, WGS facilitates the identification of novel drug targets based on genetic insights into disease mechanisms, fostering the development of more efficacious and targeted therapies across a breadth of medical conditions.

Also, in the ongoing battle against infectious diseases and antimicrobial resistance, the need for innovative solutions has never been more pressing. With pathogens evolving and spreading at an alarming rate, traditional diagnostic and treatment approaches are often outpaced by the relentless march of microbial adversaries. However, amidst this challenge, a powerful tool has emerged on the horizon: WGS. By deciphering the genetic code of pathogens with unprecedented precision, WGS holds the potential to revolutionize the field of infectious disease management, ushering in an era of precision medicine tailored to combat microbial threats as well.

Accuracy in pathogen identification

In the context of infectious diseases, WGS involves the comprehensive analysis of an organism's entire genetic blueprint, offering insights into its evolutionary history, virulence factors, and drug resistance mechanisms.

WGS enables rapid and accurate identification of pathogens, facilitating targeted interventions and containment strategies. Unlike traditional culture-based methods that can be time-consuming and limited in their scope, WGS provides a comprehensive view of microbial genomes, allowing for the detection of emerging threats and the tracking of disease outbreaks in real-time.

Moreover, WGS holds immense promises for guiding treatment decisions and combating antimicrobial resistance, one of the most pressing public health threats of our time. By analyzing the genetic makeup of pathogens, clinicians can identify mutations associated with drug resistance, enabling personalized treatment regimens tailored to the specific resistance profiles of individual strains. This precision medicine approach not only improves patient outcomes but also helps preserve the efficacy of existing antimicrobial agents by minimizing inappropriate antibiotic use and the emergence of resistance in infections like TB, HIV, and many others.

One of the most significant applications of WGS in infectious disease management lies in the space of outbreak investigation and epidemiological surveillance. By sequencing the genomes of pathogens isolated from infected individuals, public health authorities can trace the spread of infectious diseases with unprecedented precision, elucidating transmission dynamics and identifying sources of infection. This genomic epidemiology approach has been instrumental in controlling outbreaks of diseases such as Ebola, Zika, and COVID-19, enabling rapid response and containment measures to limit the spread of infection.

Identifying potential drug targets & mechanisms

Furthermore, WGS facilitates the development of novel antimicrobial therapies by uncovering potential drug targets and mechanisms of action based on genomic insights into microbial physiology and pathogenesis. By elucidating the genetic underpinnings of drug resistance, WGS enables the design of more effective antimicrobial agents that can bypass or overcome resistance mechanisms, offering new hope in the fight against resistant infections. Additionally, WGS can inform public health policies and antimicrobial stewardship programs by providing actionable data on the prevalence and distribution of drug-resistant pathogens, guiding efforts to mitigate the spread of resistance on a global scale.

Cost , Complexities & Ethics

However, realizing the full potential of WGS in precision medicine requires overcoming a myriad of challenges. Foremost among these are the cost and complexity of genomic sequencing, which have historically limited widespread adoption and access to this transformative technology. While the cost of sequencing has dropped dramatically in recent years, it remains a barrier for many patients and healthcare systems. Moreover, the interpretation of genomic data presents a significant challenge, requiring sophisticated algorithms and expertise to translate raw genetic information into actionable insights for clinical decision-making. The cost and complexity of WGS remain significant hurdles, limiting widespread adoption and access to this transformative technology. Moreover, standardization of sequencing protocols and data sharing practices is essential to ensuring the interoperability and comparability of genomic data across different laboratories and healthcare settings.

Ethical considerations also pose a large threat in the era of genomic medicine, genomic epidemiology, and precision medicine. Questions surrounding data privacy, informed consent, and the potential for genetic discrimination must be addressed with care and foresight. Robust regulatory frameworks and ethical guidelines are essential to safeguarding patient autonomy and confidentiality in the era of WGS. Moreover, disparities in access to genomic testing and personalized treatments must be addressed to ensure equitable healthcare delivery for all patients, regardless of socioeconomic status or geographic location.

Informed decision making

Despite these challenges, the promise of WGS in precision medicine is too great to ignore. As technology continues to advance and costs continue to decline, WGS is poised to become an integral component of routine clinical practice. The integration of genomic data into electronic health records promises to empower clinicians with actionable insights at the point of care, facilitating informed decision-making and personalized treatment strategies. Moreover, collaborative efforts to aggregate and analyze large-scale genomic datasets hold the key to unlocking the full potential of WGS

in precision medicine, enabling the development of more precise risk prediction models and therapeutic interventions.

Furthermore, collaborative efforts to aggregate and analyze large-scale genomic datasets hold the key to unraveling the complex interplay between genetics, environment, and disease, paving the way for the development of more precise risk prediction models and therapeutic interventions. Initiatives such as the All of Us Research Program and the UK Biobank exemplify the transformative potential of large-scale genomic initiatives in advancing our understanding of human health and disease.

Conclusion

Whole Genome Sequencing represents a paradigm shift in the practice of medicine and in the fight against infectious diseases and antimicrobial resistance, offering unprecedented insights into the genetic underpinnings of health and disease. From diagnosis and treatment to drug development and beyond, WGS has the potential to revolutionize precision medicine and improve patient outcomes on a global scale. As we continue to navigate the complexities and opportunities afforded by genomic medicine and infectious disease management in the 21st century, let us embrace the transformative power of WGS in shaping the future of healthcare and ushering in a new era of personalized medicine tailored to the individual needs of each patient. ■

Author

Dr Chaitali Nikam
Director (infexn), HaystackAnalytics

Navigating the Shifting Landscape of the Pharmaceutical Industry

The pharmaceutical packaging industry plays a crucial role in ensuring the safety, efficacy, and traceability of medication. **Rishad Dadachanji, Managing Director, Dadachanji Group** addresses about the upcoming trends in the pharma packaging industry and highlights the importance of packaging in safeguarding patient health.

The pharmaceutical industry is constantly changing. To meet the requirements of pharma firms, the packaging sector must evolve and adapt constantly. Accessibility for patients, environmentally and sustainably friendly packaging, simplicity of manufacturing, child-resistant packaging, user-friendly packaging, tamper-evident packaging, and more are some of the newest trends in pharmaceutical packaging.

The pharma packaging industry is becoming important in guaranteeing the safety of patients since it contains important product information, ensures tamper-evidence, and enables product traceability.

There are a few key trends in the pharma industry which include the below-mentioned things:

Smart Packaging: One of the top trends in pharmaceutical packaging for 2024 is smart packaging. The pharma packaging sector has been impacted by technologies such as NFC (near-field communication) and RFID (radio frequency identification). The introduction of QR codes has decreased the demand for paper pamphlets. The new and emerging technologies help inform the consumer of information such as side effects, ingredients, the best intake methods, storage, and preservation methods.

Child-resistant Packaging: Pharmaceutical packaging mostly uses child-resistant packaging which is made in a way to prevent children from consuming harmful chemicals. Manufacturers do not make various medicines for children, and a child might end up with drug poisoning by accidentally ingesting a dose. Some of the new things in child-resistant packaging include specialized caps, re-closable packs, and non-toxic packaging materials.

Sustainable Pharmaceutical Packaging: The pharma industry can opt for sustainable biodegradable material and compostable packaging materials, as they are easily broken down through natural processes. Biodegradable materials are mainly made with seaweed, fungi, algae, and more.

Sustainable Material: Sustainability helps to secure resources for future generations. There are various packaging materials like LDPE, HDPE, and EVOH that are sustainable and easily degradable. Brands can also go for recyclable plastic or compostable packaging.

Leakproof Packaging: Leak-proof packaging has been among the most preferred pharmaceutical packaging trends over the years. Good brands make sure their packaging is not only appealing but is equally leak-resistant as this prevents the product's spilling.

Tamper-resistant Packaging: Leading pharma brands emphasize sending their products to the end users without any tampering. These various things like tear strips, cap seals, gummed paper tape, and more are used by the brands.

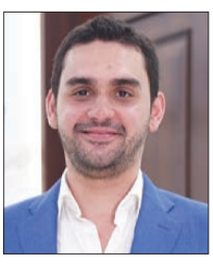
India's pharmaceutical manufacturing costs are among the lowest in the world, less than those of the United States and nearly half of Europe. It is the world's largest supplier of generic drugs. It has fueled the research and development of efficient packing solutions for the pharma industry, ensuring drug safety, and reducing the risk of contamination.

Environment-friendly approach: The industry's focus should be on responsible manufacturing and efforts should be made to protect the environment. There are ways through which pollution can be controlled and managed by cutting down water consumption. Hazardous waste reduction should also be one of the priorities.

About Dadachanji Group:

The Dadachanji Group has been manufacturing pharmaceutical products and solutions for over 30 years and comprises several successful companies with varied interests ranging from pharmaceutical and Biotechnology, Primary and Secondary Packaging, Medical Devices, Machine Building, Automation, Robotics, Sterile Processing, and Aviation. The consolidation of these companies is expected to bring together a wealth of expertise, knowledge, and resources to create a more focused and cohesive organization. ■

Author



Rishad Dadachanji
Managing Director,
Dadachanji Group

Clinical Development

Clinical development is a crucial aspect of the pharmaceutical and biotechnology industries. It involves a series of steps and processes designed to assess the safety and efficacy of new drugs, medical devices, and treatments before they are approved for use in the general population. This development phase encompasses everything from early-stage research to large-scale clinical trials involving human participants.

Dr. Subhash Thuluva, Senior VP & Head-Clinical Development, Biological E. Limited shares insights about the importance and challenges of clinical trials. He also throws light on the regulation and guidelines on clinical trials.

The ultimate goal of clinical development is to ensure that new medical interventions are both safe and effective for their intended use.

The History of Clinical Trials

The history of clinical trials dates back several centuries. One of the earliest documented examples is the scurvy trial conducted by James Lind in 1747. Lind, a Scottish naval surgeon, tested the effects of citrus fruits on sailors suffering from scurvy. His experiment is often considered the first clinical trial, as it employed a controlled methodology to test the effectiveness of different treatments. The modern era of clinical trials began in the early 20th century, with the introduction of more rigorous scientific methods and ethical standards. The Nuremberg Code, established after World War II, laid the foundation for ethical conduct in medical research. It emphasized the necessity of voluntary consent and the importance of weighing the risks and benefits of participation in clinical studies.

Importance of Clinical trials:

Clinical trials are crucial for several reasons

- **Evaluation of Efficacy and Safety:** Clinical trials assess whether new treatments, drugs, or medical devices are effective and safe for human use. This is essential ensuring that new medical interventions provide benefits that outweigh any risks.
- **Advancement of Medical Knowledge:** They contribute to the broader understanding of diseases and their treatments. Insights gained from clinical trials can lead to improvements in standard care and the development of new treatment guidelines.
- **Regulatory Approval:** Regulatory bodies like the FDA (Food and Drug Administration) in the US require clinical trials to approve new drugs and treatments. This rigorous process helps ensure that only safe and effective therapies reach the market.
- **Patient Access to New Treatments:** Participants in clinical trials can access cutting-edge treatments before they are widely available. This can be especially important for patients with conditions that have no effective standard treatments.
- **Public Health:** The results of clinical trials can lead to public health advancements by informing vaccination strategies, disease prevention programs, and emergency responses to health crises like pandemics.

Phases of Clinical Trials

Clinical trials are typically conducted in four distinct phases, each serving a specific purpose in the overall development process.

Phase I: Phase I trials are the first step in testing a new drug or treatment in humans. These studies involve a small number of healthy volunteers and are primarily concerned with assessing safety and determining the appropriate dosage range. Researchers closely monitor participants for any adverse effects and gather data on how the drug is metabolized.

Phase II: Phase II trials involve a larger group of participants, often numbering in the hundreds, who have the condition the new treatment is intended to address. The primary goal of this phase is to evaluate the drug's efficacy and to gather more information about its side effects. This phase helps determine whether the treatment shows enough promise to warrant further investigation. Dose ranging studies are also conducted during Phase II of clinical trials. These studies are a critical part of drug development, designed to determine the appropriate dose levels that are both safe and effective for patients

Phase III: Phase III trials are large-scale studies involving thousands of participants. These trials are designed to confirm the drug's efficacy, monitor side effects, and compare it to existing treatments. Phase III trials provide the comprehensive data needed for regulatory approval.

Phase IV: Once a drug has been approved and is on the market, Phase IV trials (Post-Marketing Surveillance) continue to monitor its safety and effectiveness in the general population. These post-marketing studies can identify rare or long-term side effects that may not have been apparent in earlier phases.

Regulations and Guidelines on Clinical Trials

Clinical trials are subject to strict regulations and guidelines to ensure the safety and well-being of participants and the integrity of the data collected. In the United States, the Food and Drug Administration (FDA) oversees the approval and regulation of new drugs and treatments. The FDA's guidelines are designed to ensure that clinical trials are conducted ethically and that the data obtained is reliable and accurate. Internationally, the World Health Organization (WHO) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) provide guidelines for the conduct of clinical trials. The ICH's Good Clinical Practice (GCP) guidelines are widely adopted and set standards for trial design, conduct, monitoring, and reporting.

Ethics committees, also known as Institutional Review Boards (IRBs) or Research Ethics Committees (RECs), play a crucial role in overseeing clinical trials to ensure the protection of participants and the ethical conduct of research. These committees are typically composed of members with diverse backgrounds, including medical professionals, scientists, ethicists, legal experts, and laypersons. This diversity ensures a comprehensive evaluation of the ethical aspects of clinical trials. Their responsibilities and functions include in reviewing clinical trial protocols to ensure they are ethically sound and scientifically valid. Ethics committees are essential in maintaining the ethical integrity of clinical trials, safeguarding participants, and ensuring that research is conducted responsibly and transparently.

Clinical Trials in India

India has become an increasingly important location for clinical trials due to its large and diverse population, skilled workforce, and cost advantages. The country offers a unique opportunity to conduct trials across various therapeutic areas and disease conditions. The Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare governs the Indian regulatory framework for clinical trials. Key regulations include the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019. These regulations outline the requirements for conducting clinical trials, including the need for ethics committee approval, informed consent, and adherence to GCP guidelines. The New Drugs and Clinical Trials Rules, 2019, introduced several significant changes aimed at streamlining the approval process and enhancing participant protection. These changes include faster approval timelines, improved compensation mechanisms for trial-related injuries, and stricter penalties for non-compliance.

Challenges in Clinical Trials

Conducting clinical trials presents several challenges, including:

Recruitment and Retention: Enrolling and retaining participants can be difficult, particularly for rare diseases or specific population groups.

Regulatory Hurdles: Navigating the complex regulatory landscape requires significant time and resources.

Ethical Concerns: Ensuring informed consent and protecting participant rights and well-being are paramount.

Cost: Clinical trials are expensive, with costs often running into millions of dollars.

Future of Clinical Trials

The future of clinical trials is poised for significant transformation, driven by advances in technology, increased focus on patient-centric approaches, and evolving regulatory landscapes.

Digital and Decentralized Trials

Digital technologies, including electronic health records (EHRs), wearable devices, and mobile health applications, are revolutionizing the way clinical trials are conducted. These technologies enable remote monitoring, reduce the need for frequent site visits, and enhance data collection accuracy. Decentralized trials, which utilize virtual and remote methods, have gained traction, particularly during the COVID-19 pandemic, and are expected to continue growing.

Precision Medicine

The shift towards precision medicine, which tailors treatments to individual patient characteristics, is influencing clinical trial design. Trials are increasingly focusing on specific genetic, biomarker, or phenotypic subgroups to enhance efficacy and reduce adverse effects.

Adaptive Trial Designs

Adaptive trial designs allow for modifications to the trial protocol based on interim results. This flexibility can lead to more efficient and informative trials, reducing the time and cost required to bring new treatments to market.

AI in Clinical Trials

Artificial intelligence (AI) is emerging as a powerful tool in clinical trials, offering the potential to enhance efficiency, reduce costs, and improve outcomes. Key applications of AI in clinical trials include:

Patient Recruitment: AI algorithms can analyse large datasets to identify potential trial participants more quickly and accurately, improving recruitment rates and diversity.

Data Analysis: AI can process and analyse vast amounts of data, identifying patterns and insights that may not be apparent through traditional methods.

Predictive Modelling: AI models can predict trial outcomes, helping researchers design trials that are more effective and make data-driven decisions.

Monitoring and Compliance: AI-powered monitoring systems can detect anomalies in real-time, ensuring compliance with protocols and improving patient safety.

Clinical development is a complex and dynamic field that plays a critical role in bringing new medical treatments to market. The history of clinical trials reflects the evolution of scientific and ethical standards, while modern regulations and guidelines ensure the safety and efficacy of new interventions. As technology continues to advance, the future of clinical trials looks promising, with innovations like AI, precision medicine, and decentralized trials poised to transform the landscape. Despite the challenges, the ongoing commitment to rigorous clinical development processes will continue to drive progress in medical science and improve patient outcomes worldwide. In summary, clinical trials are foundational to the progress of medical science, ensuring that new treatments are both effective and safe, while also advancing overall healthcare quality and patient outcomes. ■

Author

Dr. Subhash Thuluva
Senior VP & Head- Clinical Development,
Biological E. Limited

The Impact and Future of EU GMP Annex 1 on Primary Pharmaceutical Packaging

It is almost a year since the European Union's Good Manufacturing Practice (GMP) revised guidelines came into force. This revision of the EU GMP Annex 1, developed with the ultimate goal of enhancing levels of public health protection, has undoubtedly caused a seismic shift in drug manufacturing. **Kok Li Kwang, Director, Scientific Affairs & Technical Services, Asia Pacific, West Pharmaceutical Services** emphasizes that Biopharma firms need to adopt a more holistic approach to primary packaging in regards to revised EU GMP Annex 1.

While it applies officially to the manufacturing of sterile medicinal products in the EU, it has essentially shifted the benchmark for quality medicinal standards globally as the heightened requirements and standards will likely trickle down into pharmaceutical production around the world. The revision of EU GMP Annex 1 was driven jointly by Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the European Medicines Agency GMP/GDP Inspectors' Working Group (GMDP IWG) in close co-operation with the European Commission (EC) and the World Health Organization (WHO). Participating members of PIC/S include regulatory authorities outside of the EU, such as United States Food and Drug Administration (US FDA), Australia's Therapeutic Goods Administration (TGA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and South Korea's Ministry of Food and Drug Safety (MFDS).

As such, even though the guidelines are targeted at drug manufacturers in the EU, it is expected that agencies outside of the EU will also consider the adoption of all or part of the EU GMP Annex 1's requirements to raise the quality and safety standards of medicinal products around the world. In Asia Pacific, pharmaceutical firms have demonstrated an increased awareness and attention to the EU GMP Annex 1 updates, which is evident from the numerous conversations held at industry events, some even preceding the official launch.

The regulations have more than tripled in length, including new requirements for Container Closure

Integrity (CCI). More significantly, a comprehensive fit-for-purpose Contamination Control Strategy (CCS) is one of the new and main focuses in the revised Annex 1, requiring pharmaceutical manufacturers to document their approach to assuring the sterile drug products' quality and patient safety.

A deep dive into the revised Annex 1 will find that it contains over 30 references to primary packaging material alone. Section 8.2 in Annex 1 defines "Primary packaging containers and components should be cleaned using validated processes to ensure that particulate, pyrogen and bioburden contamination is appropriately controlled."

In response to this, many pharmaceutical manufacturers have begun to expand their policies and measures to include more approaches beyond microbial, particulates and pyrogen contamination control. Pharmaceutical and biotech firms may face initial challenges in navigating the new regulations effectively. Overcoming these hurdles and being successful in implementing the new measures, will lead to an overall positive impact on the industry that will benefit us all and good progress has already been observed.

The impact of EU GMP Annex 1: Biopharma firms need to adopt a more holistic approach to primary packaging

With this regulatory change, on top of the rapid growth of biologics, primary packaging will emerge as an area in which a more considered approach must be applied. Considering biologics are more complex large molecules that can be a challenge to fully characterize, with greater sensitivity to contamination and reactions, the strong focus on primary packaging in the revised EU GMP Annex 1 will spur more firms to ensure that their drugs and packaging are manufactured in highly controlled environments where sterility is controlled and assured.

At an operational, equipment and process level, manufacturers must ensure that systems are geared towards continual improvement of contamination-limiting measures. This will mean days of intense audit performed internally or by third parties, to ensure full compliance across the entire manufacturing supply chain, especially where primary packaging is involved.

Simultaneously, firms will also find themselves having to consider primary packaging contamination risks from a behavioral perspective, since the sterility of cleanroom environments has the potential to be compromised by human activity. Equipping staff with a 'contamination-control mindset' through continual education and communication will be fundamental for quality measures to be upheld and enhanced over time.

In the past, these areas may have been overlooked to some degree by drug manufacturers but are now well and truly back in the spotlight due to the revised Annex 1 regulations. It is only when the manufacturing process is tightened up, the facilities are assessed and well-run by trained staff with sanitary equipment, all in line with the Annex 1 requirements, can we begin to witness a true rise in standards for biologics medicines and packaging. For biopharma firms, devoting resources and time toward a strict adherence to compliance regulations will also support their continual improvement into the future.

For the future: Points of consideration for EU GMP Annex 1 Regulations

Nearly a year into the launch of the revised EU GMP Annex 1, some biopharma firms may still be trying to find their bearings in developing an effective strategy to align their workflows, especially those who are looking to serve the EU markets but are based outside the EU. This pool of biopharma firms was not directly impacted by the regulations in August 2023, but are now facing greater pressure to meet the primary packaging standards from their international stakeholders, especially when they target to go abroad.

When developing a strategy to align with the revised EU GMP Annex 1 standards, there are a few areas of considerations, namely:

- Product: Analyzing the current quality level of packaging components, understanding the current and required specifications for particulate, bioburden, and endotoxins, and if a tighter specification is required.
- Process (manufacturing design): Where is the product processed and sterilized- is it in-house or with the component supplier? How will components be introduced on the fill/finish line? Will sealing occur in an aseptic environment?
- Protection (CCI): Is there a robust understanding of the factors that will impact the CCI? Is there a monitoring and testing plan in place over the shelf life of the drug product?
- Partners: Does your supplier have a CCS and are they focused on continual improvement? What documentation is available to support your CCS?

An assessment of these points will guide firms to develop a much more effective strategy for contamination control, in line with the regulatory standards set by EU GMP Annex 1. For firms who do not develop their own packaging, these pointers will also serve as a metric to help assess partners who provide or work closely with primary packaging.

Even beyond traditional biologics, these pointers also apply most to biopharma firms involved in the development of advanced therapies where sterility and product stability is of utmost importance. The adoption of a holistic approach in packaging systems hence is most pivotal to meet the increasingly unique requirements of complex drugs and treatments in the pharmaceutical industry.

What we are observing now is a rising pressure globally to deliver high-quality and safer drugs. Beginning from stricter compliance requirements in key markets, the end goal for all of us in the industry remain the same: to enhance patient care everywhere. With this goal in mind, biopharma firms must rise to the challenge by developing holistic approaches and forging strong partnerships. This will ensure their contribution to the safe and effective delivery of medication. ■

Author

Kok Li Kwang
Director, Scientific Affairs & Technical Services, Asia Pacific,
West Pharmaceutical Services

CAR-T Therapies-Engineering Immune System to Fight Cancer

The cancer burden in India is on the rise, impacting not only patients but also their caregivers and families. Developing effective treatments with minimal side effects is crucial for improving patient outcomes and easing the burden on caregivers.

Dr Prudwidhar S - Country Medical Affairs Director, Miltenyi Biotec emphasized about CAR-T Therapy plays an important role in cancer treatment that uses the immune system to kill cancer cells.

Immunotherapy has emerged as a revolutionary approach in cancer treatment, leveraging the patient's own immune system for targeted and effective results.

Understanding CAR-T Therapy

CAR-T therapy involves modifying a patient's T-cells, a type of blood cell integral to the immune system, to express receptors specific to cancer cells. These chimeric antigen receptors (CARs) are designed to recognize and bind to proteins on the surface of cancer cells. Once bound, the CAR-T cells are activated to attack and kill these cancer cells.

How CAR-T Cells Are Made

The process begins with extracting T-cells from the patient through a procedure called apheresis. These T-cells are then sent to a specialized facility, where they are genetically engineered using a virus to express the CAR that targets specific cancer antigens. After this genetic modification, the CAR-T cells are proliferated to meet product specifications and then shipped back to the hospital for infusion into the patient. Before infusion, patients typically undergo a conditioning regimen to enhance the uptake and effectiveness of the CAR-T cells.

Diseases Treated with CAR-T Therapy

CAR-T therapy has shown remarkable success in treating hematologic malignancies, including:

- Acute Lymphoblastic Leukaemia (ALL): Particularly in paediatric and young adult patients with relapsed or refractory disease, targeting CD19.
- Lymphomas: Including diffuse large B-cell lymphoma (DLBCL) and other subtypes, also targeting CD19.
- Multiple Myeloma: Targeting BCMA (B-cell maturation antigen).

In addition, various CAR-T therapies are being explored for the management of solid tumours as well.

Manufacturing and Logistics of CAR-T cells

The logistics of CAR-T therapy are complex and distinct from those of traditional chemotherapy. The process involves multiple steps, including T-cell extraction, genetic modification, cell proliferation, quality controls, and transportation back to the patient for infusion. This complexity adds to the cost and duration of treatment.

Performing these processes in an open system, where different personnel handle various steps on different machines, makes it challenging to maintain process control and product quality across multiple manufacturing sites. To address this, some manufacturers consider centralizing the production in a single facility. However, this centralization requires transporting the patient's apheresis sample to the facility and then shipping the finished CAR-T product back to the treatment site, creating a significant logistical

burden, further increasing costs and treatment duration. Physicians must manage patients with conditioning regimens until the product is ready for infusion.

An alternative approach is decentralized or place-of-care manufacturing at academic or tertiary care centres using fully automated, closed, GMP-compliant devices. This approach has demonstrated reliable and reproducible manufacturing of CAR-T products in advanced countries, reducing quality concerns and ensuring consistency and replicability. Decentralized manufacturing produces comparable and consistent products across different sites, with closed systems and end-to-end processes reducing the risk of contamination and product failure. The use of standardized quality control equipment and reagents meeting stringent testing requirements, further ensure patient safety.

Process automation results in robust manufacturing and standardized product quality, whereas manual operations and open steps contribute to greater variability and a higher risk of contamination and errors. Closed and automated manufacturing systems enhance efficiency and quality, requiring fewer cleanroom requirements. These integrated systems reduce manufacturing complexity when used in decentralized setups and facilitate easy technology transfer between sites, ensuring comparability.

Decentralized manufacturing means production closer to the patient, reducing vein-to-vein time and sparing patients from the necessity of bridging therapy, correlating with improved outcomes. By eliminating the need for large-scale manufacturing facilities and extensive shipping logistics, decentralized manufacturing could reduce the cost of manufacturing CAR-T as well.

Common Toxicities and Management

While CAR-T therapy shows promise, it is not without adverse effects:

- Cytokine Release Syndrome (CRS): A systemic inflammatory response caused by the rapid activation and proliferation of CAR-T cells. Symptoms range from mild flu-like symptoms to severe, life-threatening conditions. Management often includes IL-6 blockers such as tocilizumab.
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS): Neurological toxicity presenting as confusion, seizures, and other neurocognitive symptoms.
- Cytopenias: Including reductions in white blood cells, red blood cells, and platelets.
- On-target Off-tumour Effects: Damage to normal tissues expressing the target antigen.

Future Directions

Researchers worldwide are developing innovative strategies to enhance the effectiveness and safety of CAR-T therapy. These include:

- Combination Therapies: Integrating CAR-T cells with other anticancer treatments to improve outcomes.
- Advanced CAR Engineering: Creating CARs with better anti-tumour activity and reduced toxicity.
- Targeting Multiple Receptors: To prevent antigen escape and improve efficacy.
- Enhanced Tumour Infiltration: Modifying CAR-T cells to better penetrate and persist in the tumour microenvironment.

Conclusion

CAR-T therapy offers hope by leveraging the immune system to fight cancer. The advancements in closed and automated manufacturing platforms help in setting up decentralized or place of care CAR-T manufacturing these reducing costs and improving access. We are currently witnessing scientific innovation to engineer immune system to make newer and efficient CAR-Ts to manage treatment of cancers more effectively and widely. ■

Author

Dr Prudwidhar S
Country Medical Affairs Director
Miltenyi Biotec

The Role of Diagnostic Labs in Monitoring and Managing Chronic Diseases

Chronic diseases are a leading cause of death and disability worldwide, affecting millions of individuals and placing a significant burden on healthcare systems. According to the World Health Organization, chronic diseases account for nearly 70% of all deaths globally.

Dr Anurag Bansal, Technical Director, Agilus Diagnostics emphasized about the role of diagnostic labs in managing chronic diseases.

These ongoing and persistent health conditions, such as heart disease, cancer, diabetes, and respiratory illnesses, require continuous monitoring and management to prevent complications and improve quality of life.

Chronic diseases are characterized by their long-lasting nature and often result from a combination of genetic, physiological, environmental, and lifestyle factors. Effective management of these conditions is crucial to mitigate their impact on individuals and society. Regular monitoring and timely interventions play a vital role in controlling symptoms, slowing disease progression, and preventing further complications.

Diagnostic labs play a pivotal role in monitoring and managing chronic diseases by providing accurate and timely diagnostic testing. These specialized facilities utilize advanced technologies and skilled professionals to analyze various biomarkers, imaging studies, and other diagnostic tests, enabling healthcare providers to make informed decisions about treatment plans and disease management strategies.

Understanding Chronic Diseases

Chronic diseases are long-term health conditions that persist for an extended period, often requiring ongoing medical attention and lifestyle modifications. These diseases can have a significant impact on an individual's quality of life and can lead to complications if not managed effectively. Cardiovascular disease (CVD), diabetes, hypertension, cancer, and chronic respiratory diseases together formed around 60% of all the factors responsible for deaths in India in 2014. The incidence in the last decade has further gone up.

Some of the most common chronic diseases include:

Diabetes: A metabolic disorder characterized by high blood sugar levels due to the body's inability to produce or effectively use insulin. According to IDF (International Diabetes Federation), one out of every seven diabetic adults worldwide resides in India, and one in every third household has diabetic patients. The importance of screening for diabetes cannot be overstated given the increasing precedence in the last few decades.

Heart disease: A broad term encompassing conditions that affect the heart and blood vessels, such as coronary artery disease, heart failure, and arrhythmias. India has one of the highest burdens of cardiovascular disease (CVD) worldwide. Coronary heart disease prevalence rates in India have been estimated over the past several decades and have ranged from 1.6% to 7.4% in rural populations and from 1% to 13.2% in urban populations.

Cancer: Characterized by the uncontrolled growth and spread of abnormal cells in the body. In 2022,

the projected number of new cancer cases in India was 1,461,427, with a crude incidence rate of 100.4 per 100,000 individuals. Approximately one in nine people in India is expected to face a cancer diagnosis during their lifetime.

Arthritis: A group of conditions causing inflammation and pain in the joints, leading to stiffness and decreased mobility. In India, Osteoarthritis is the second most common rheumatologic problem and it is the most frequent joint disease in the country with a prevalence of 22 per cent to 39 per cent.

Asthma: A chronic respiratory condition characterized by airway inflammation and breathing difficulties. A recent Global Burden of Disease (GBD, 1990–2019) estimated the total burden of asthma in India as 34.3 million, accounting for 13.09% of the global burden. It also attributed that there were 13.2 per thousand deaths due to asthma in India.

Managing chronic diseases can be challenging, as it often requires lifestyle changes, strict adherence to medication regimens, and regular monitoring to track disease progression and treatment efficacy. Early detection and regular monitoring are crucial for better disease management, as they can help identify potential issues before they become more severe and allow for timely interventions.

The Role of Diagnostic Labs

Diagnostic tests are essential tools in the assessment, diagnosis, and management of chronic diseases. They provide valuable insights into an individual's health status, disease progression, and response to treatment. Different types of diagnostic tests are used for chronic disease monitoring, including:

Blood tests: These tests analyze various biomarkers in the blood, such as glucose levels for diabetes, cholesterol levels for heart disease, and tumor markers for cancer.

Imaging tests: Techniques like X-rays, CT scans, MRI, and ultrasound are used to visualize internal structures and identify abnormalities or changes related to chronic diseases.

Biopsies: Tissue samples are collected and analyzed for the presence of cancerous cells or other abnormalities.

Genetic tests: These tests analyze an individual's genetic makeup to identify potential risk factors or predispositions for certain chronic diseases.

Accurate and timely diagnostic testing is crucial for chronic disease management. Diagnostic lab results provide healthcare professionals with valuable information to:

- Monitor disease progression and treatment efficacy
- Adjust treatment plans and medication dosages as needed
- Identify potential complications or side effects
- Develop personalized disease management strategies

Key Diagnostic Tests for Chronic Diseases

Chronic diseases often require specific diagnostic tests for monitoring and management. Here are some key diagnostic tests used for common chronic diseases:

Diabetes:

Glycated hemoglobin (HbA1c) test: This blood test measures the average blood sugar levels over the past 2-3 months, providing an overview of how well diabetes is being managed.

Fasting blood glucose test: This test measures the level of glucose in the blood after an overnight fast, helping to diagnose diabetes and monitor treatment effectiveness.

Oral glucose tolerance test: This test evaluates how the body processes glucose by measuring blood sugar levels before and after consuming a sugary drink.

Heart Disease:

Lipid panel: This blood test measures levels of cholesterol (LDL, HDL), triglycerides, and other lipids, which are risk factors for heart disease.

Electrocardiogram (ECG/EKG): This non-invasive test records the electrical activity of the heart, helping to detect irregular heart rhythms or signs of heart damage.

Cardiac imaging tests (echocardiogram, CT angiography, nuclear stress test): These tests provide detailed images of the heart's structure and function, helping to identify blockages or abnormalities.

Cancer:

Tumor marker tests: These blood tests measure specific substances produced by cancer cells or released by the body in response to cancer, aiding in diagnosis, monitoring treatment response, and detecting recurrence.

Imaging tests (CT scans, MRI, PET scans): These advanced imaging techniques help detect and locate tumors, assess their size and spread, and monitor treatment response.

Biopsies: Tissue samples are collected and examined under a microscope for the presence of cancerous cells and to determine the type and stage of cancer.

Arthritis:

Blood tests: Rheumatoid factor and anti-cyclic citrullinated peptide (anti-CCP) tests can help diagnose rheumatoid arthritis and monitor disease activity.

Imaging tests (X-rays, MRI, ultrasound): These tests can detect joint damage, inflammation, and other changes associated with different types of arthritis.

Synovial fluid analysis: This test involves analyzing the fluid from the joints to detect inflammation or infection.

When preparing for diagnostic tests, it is crucial to follow any specific instructions provided by the healthcare provider or diagnostic lab. These instructions may include:

Fasting requirements: Some tests, such as blood glucose or lipid panels, may require fasting for a specific period before the test.

Medication adjustments: Certain medications may need to be temporarily discontinued or adjusted before the test to avoid interfering with the results.

Dietary restrictions: For some tests, individuals may need to follow specific dietary guidelines or avoid certain foods before the test.

Taking an active role in chronic disease management by utilizing diagnostic services and understanding test results can empower individuals to make informed decisions about their health.

Conclusion

Chronic diseases are a significant health concern globally, and effective monitoring and management are crucial for mitigating their impact on individuals and healthcare systems. Diagnostic labs play a vital role in this process by providing accurate and timely diagnostic testing, which serves as the foundation for informed decision-making and personalized treatment plans. ■

Author

Dr Anurag Bansal
Technical Director, Agilus Diagnostics

Digital Analytical Sensor Technology in Modern Pharmaceutical Production

In the pharmaceutical industry, there is significant pressure from market conditions to reduce overall production costs, including maintenance expenditure, without altering product quality. Therefore, governments and regulatory bodies are keeping a close eye on pharmaceutical companies to ensure regulatory compliance continues to be adhered to. Meeting quality and compliance objectives, while keeping costs under control, is a challenge many companies face from early R & D to commercial stages.

Obtaining reliable and consistent measurement data at multiple bioreactor sizes is another challenge for some pharmaceutical producers. METTLER TOLEDO has developed a modern technology for analytical measurements called Intelligent Sensor Management (ISM) to address all these industry challenges.

ISM is a digital technology for in-line process analytics that incorporates intelligent algorithms into sensors. ISM provides real-time diagnostics information, improves process control, and maximizes process equipment availability. With ISM, sensor handling and maintenance management become simpler. iSense software is a support and maintenance tool for ISM sensors. It provides a fully controllable method of managing sensors via an intuitive interface, and maximizing their use from first installation until disposal. The numerous features and benefits of ISM translate into increased measurement accuracy, process reliability, and reduced operating costs.

Five reasons why production at pharmaceutical plants can benefit from ISM technology –

- Provides accuracy at multiple bioreactor sizes
- Enables economic maintenance across the plant through preventative maintenance and calibration away from the process
- Responds to unforeseen demand and process conditions through predictive diagnostics
- Simplifies regulatory compliance via regulatory-compliant software
- Reduces analytical risks as all sensors are continuously monitored in-line

About METTLER TOLEDO

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

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

Complete environmental monitoring solution – testo Saveris Pharma

There are several critical applications in the industry like research and development that demand for continuous & reliable monitoring of important environmental parameters. From medical, bio-technical, chemical and pharmaceutical laboratories to cleanrooms, biobanks up to blood and tissue banks, a holistic monitoring system is very necessary which reliably records different measurement parameters in these rooms and at equipment. Wherever there is a need to adhere to necessary standards, ensure traceability and audit compliance, especially Pharma, these solutions become crucial in the facility operation.

The most efficient way to address this requirement is the implementation of fully automated environmental monitoring system testo Saveris Pharma. It monitors and documents temperature, humidity, differential pressure, and other parameters without interruption and compliantly with GxP so that audits and inspections are conducted smoothly. As a complete solution, testo Saveris Pharma combines

- High-precision measurements with secured data communication
- Intuitive and pro validation software
- Comprehensive services.

The system consists of following components

Data logger and communication modules

Data loggers are the components that measure / log the data continuously at different locations in the facility. They communicate with the base unit to transfer the recorded data. Because there are numerous tasks to fulfil in research and development, there are various models of data logger to measure different parameters.

Another important task is data transfer and for that communication modules are used. Each data logger can be flexibly connected to one of the three communication modules.

- WLAN Module
- LAN Module
- Radio via Testo Ultra range communication Module

testo UltraRange ensures that a strong and robust radio signal is available even over long distances or in closed rooms. All data loggers can be exactly calibrated, and depending on the model, can record temperature and relative air humidity. As per the applications, Data Loggers are selected for Environment Monitoring for Warehouse, Analytical/ Microbiology Lab, Animal house or Equipment Monitoring like Refrigerator, Freezer, Chiller, Walk in chamber, etc.

The base station

The base is literally the heart of testo Saveris Pharma system. It can connect with 1000 different Data Loggers at a time. It collects measurement values and analyse it limit value violation or any other critical event occurs. It plays an important role in prompt alarm management. The base unit can be positioned centrally at a given facility location or office. Base station delivers alarms to users via an alarm relay and an LTE stick that enables alarms by SMS as well in addition to visual and audible alarms.

Digital and analog sensors

The instrumentation utilised to measure parameters like temperature and humidity is in the form of variety of digital and analog sensors that are easy to handle and install. The Digital sensors has advantage over analog sensors as it can be quickly exchanged during continuing operation for calibration or defect correction. Calibration of Digital Sensor is independent of its Logger. Thus, it ensures no gap in the measurement values or documentation. The measuring ranges of the temperature probes extends from -200 °C to +1300 °C, covering almost any possible scenario in the field of research & development. The integration of other measurement parameters such as differential pressure, particles etc. also work smoothly with the analog coupler as a standardized interface.

System software

Once the data is recorded by Loggers and analysed by the base station, the testo Saveris Pharma software comes into play where all readings are collated, stored, visualized, and backed up seamlessly. Automatic reports are generated and sent over email to concerned users. Some important features are applied like electronic signature, Electronic Record, Access Control, Audit Trail, Alarm Logs. There are two versions of the testo Saveris software;

- testo Saveris PRO software- It is suitable for the automated and uninterrupted data monitoring with less stringent regulations, normally other than Pharma Industry.
- testo Saveris CFR software – It guarantees unconditional adherence to US 21 CFR Part 11 as well as Annex 11 of the EU guidelines for GMP. In addition to the range of function of the PRO version, it offers Audit Trail and electronic signatures.

In addition, we provide Web access to the data with testo Saveris Pharma Cockpit - a web based and intuitive user interface which allows data access from different end devices. Alarms can be identified and acknowledged via a smartphone, tablet or PC at any time. It also supports features like digital signature post any action as well as a mandatory comment on the event.

Comprehensive Services

The most important aspect of any solution is after sales service. This is one of the strongest values offered by Testo to its customers. Testo extends its support from site survey, Installation commissioning, IQ-OQ documentation to annual maintenance work and recalibration. So, all the end-to-end services are offered under one roof as an OEM by Testo. Thus, user do not have to run pillar to post to get support, Testo ensures rich user's experience throughout life cycle of the system.

Areas of application

- Area Monitoring in Labs, Production, Warehouse, Animal House in Pharma
- Equipment monitoring for QA/QC, Microbiology in Pharma
- Clean room area Monitoring in Pharma
- Refrigeration and deep-freezer applications in Pharma
- Uninterrupted cold chain monitoring & controlled freezing in blood and bio banks
- Applicable for lab equipment from laboratory extractor to water bath
- Data centre Area Monitoring
- Calibration and Testing Lab area monitoring . ■

For more details, login to our website www.testo.com or write back to us on info@testo.in

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Lombardyne Industries: Pioneers in Zero Liquid Discharge Solutions

Established in 1988, Lombardyne Industries has set out to be one of the finest Zero Liquid Discharge Plant manufacturing companies in India. Our deep experience in Thermo-dynamics has helped us become a leader in manufacturing Innovative products to achieve ZLD in the Industry. Our specially designed and patented products such as Heat Pump MVR Vacuum Evaporators and Industrial Heat Pumps have given us a substantiable lead in the market.

Our MVR Vacuum Evaporators are designed on the working principle of Latent Heat Recovery Technology which enables our customers to save a substantial cost on external Thermal energy. Our Evaporators can reduce the running cost upto 70% when compared to a conventional one. Also our inbuilt Heat Pumps in our Evaporators help our customers eliminate the need to supply External Steam.

Similarly in today's age, Customers want the Evaporators to run continuously without any breakdown. Conventional Evaporators are built on the basis of a Calandria. It is common knowledge that Calandria tends to choke frequently thus having frequent breakdowns. Lombardyne Evaporators are built on the working principle of a Reactor system. This enables our customers to take extra advantage of achieving much higher Concentrate levels upto 60% without any choking, thus far less breakdowns.

Lombardyne is catering to all Industries such as Chemical, Pharmaceutical, API, Dyes and Textile, and Automobile which are facing issues with effluent generation and want to achieve Zero Liquid Discharge. Lombardyne has always been and will continue to develop innovative products which help the Industry to achieve far better results with simpler, practical and Eco-friendly solutions. ■

For more details,
Web: www.Lombardyne.in
Email:Lombardyne@gmail.com
Sales@Lombardynevaporator.com
Marketing@Lombardynevaporator.com

Indian Pharma Industry continues to strive to become a global benchmark in quality: Sudarshan Jain

Mumbai, India: Quality remains fundamental to our industry, and the Indian Pharma Industry continues to strive to become a global benchmark in quality, stated Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance, at the 9th edition of the Global Pharmaceutical Quality Summit 2024. The Summit brought together industry leaders, global regulators, quality experts, and stakeholders to foster knowledge exchange and deliberate on areas of importance in shaping the pharmaceutical landscape in India.

"The Summit has indeed grown from strength to strength since its inception in 2016. This year's theme, 'Advances in Manufacturing and Quality with focus on Patient Centricity,' highlighted the unwavering commitment of the industry to enhance the culture of quality in the pharmaceutical sector, always prioritizing patient welfare", stated Jain. The summit witnessed 16 sessions and 45 speakers from around the globe including senior officials from the Government of India, USFDA, MHRA and IGBA. Sudarshan Jain, Secretary General, IPA, began with the welcome address, followed by opening remarks from Nilesh Gupta, Chair, Quality Committee, IPA and MD, Lupin and Patrizia Cavazzoni, Director, CDER, USFDA; special remarks by Rajeev Raghuvanshi, Drug Controller General of India, Government of India. Arunish Chawla, Secretary, Department of Pharmaceuticals, Government of India delivered the keynote address.

The highlight of the day featured insightful panel discussions on charting the next decade of pharma quality and operations and the biopharma opportunity which saw leaders from leading pharma companies. The Summit concluded with closing remarks from Nilesh Gupta, emphasizing continuous improvement and building on the culture of quality for the sector.

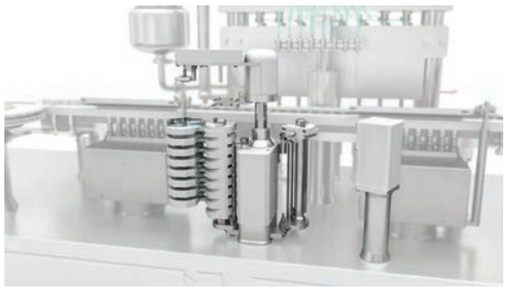
Rajeev Raghuvanshi, Drug Controller General of India, Government of India, said, "Changing the culture is a slow process, but the journey has started well, and we are moving in the right direction. One of the most impactful initiatives is the risk-based inspections, where we inspected about 400 manufacturing units, closing more than 36% for non-compliance. This has significantly improved perceptions and realities on the ground. The first group of industries with more than 250 crores of turnover will soon come under the compliance purview of the revised Schedule M, ensuring higher standards and better quality. Additionally, we are enhancing internal processes, including the transfer of 207 officers to raise a culture of quality and integrity. Our ongoing efforts aim to bring consistency and efficiency to the regulatory framework."

Arunish Chawla - Secretary, Department of Pharmaceuticals, Government of India, said, "Quality is of paramount focus - standing on three essential pillars: market, patient, and neighbour. Market quality commands a premium and builds reputation, which is our best defence against malpractices. Patient quality is driven by robust regulatory systems, and India is progressing rapidly on this front. Our mission going forward is to make quality the center of policy framework. We've upgraded Schedule M of the Drug and Cosmetic Rules, surpassing WHO GMP standards in some areas. With the audits starting in July 2024, we aim to produce world-class products, as emphasized by the Prime Minister's vision of 'Zero defect and Zero effect.' Quality requires investment, and we support medium and small plants through reform initiatives. The integrity of the Indian industry relies on every player's adherence to the highest standards. When one fails, it affects the entire industry. Therefore, we must collectively uphold quality to protect our reputation and ensure excellence in every aspect." ■

Thermo Fisher Scientific introduces automated Plasmid Purification System

Thermo Fisher Scientific Inc., the world leader in serving science, introduced the Thermo Scientific KingFisher PlasmidPro Maxi Processor (PlasmidPro), the only fully automated maxi-scale plasmid DNA (pDNA) purification system. PlasmidPro enables innovation at scale, providing complete automation across mini and maxi scale purification and delivering high-purity plasmid without manual column preparation and intervention. This is the latest addition to the Thermo Scientific KingFisher instrument portfolio which offers a wide range of plasmid DNA extraction products to help drive efficiency and consistency. The PlasmidPro purification system requires no set-up, centrifugation or pipetting and completely automates the purification process from culture to plasmid. The product uses a self-contained cartridge pre-filled with all necessary reagents to perform the purification, eliminating the need for additional instrumentation and plastics while minimizing set-up time and contamination risks. Using 100-150 mL of fresh overnight culture, the system is capable of producing up to 1.5 mg DNA yield. Thermo Fisher Scientific. "By fully automating a critical step in plasmid DNA manufacturing, the PlasmidPro DNA purification system can give time back to our customers to focus on their research and bringing life-saving therapies and vaccines to patients." ■

Syntegon launches patented new development for the pharmaceutical industry



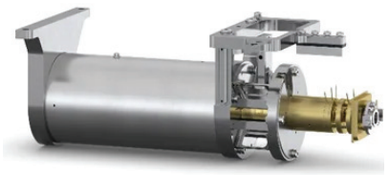
Syntegon presented an important new development that generated a great deal of interest among pharmaceutical manufacturers: the patented Settle Plate Changer (SPC) for automated viable monitoring in the aseptic filling process. With this innovative solution, Syntegon will support customers in complying with the latest for new and existing equipment.

The new patented Settle Plate Changer SPC from Syntegon automates viable monitoring and reduces production interruptions and human intervention in the process zone to a minimum.

"Environmental monitoring is essential in aseptic manufacturing and has become even more important in the context of EU GMP Annex 1," says Steffen Gröber, Global Product Manager Service at Syntegon. Settle plates may be exposed to cleanroom air for a maximum of four hours and must then be replaced to ensure consistent sampling for liquid filling operations. With the new robotic handling unit from Syntegon, this step can now be performed automatically, siginificantly reducing the previously required production interruptions. "Thanks to the SPC, machines only need to be stopped once a day for viable monitoring, which results in noticeably higher machine availability of up to 300 hours per year and therefore more sustainable processes," says Gröber. Process reliability and traceability can also be increased thanks to optional barcode scanning.

The Settle Plate Changer from Syntegon is available both with the purchase of a new machine and as a retrofit for existing equipment. "What's more, it can also be seamlessly integrated into all machines and control systems from third-party suppliers," Steffen Gröber emphasizes. "As a result, we ensure that the service life of existing equipment is increased and pharmaceutical manufacturers can run more sustainable processes thanks to reduced downtimes." ■

Agilent announces Cutting-Edge Advances in GC/MS and LC/Q-TOF Technology

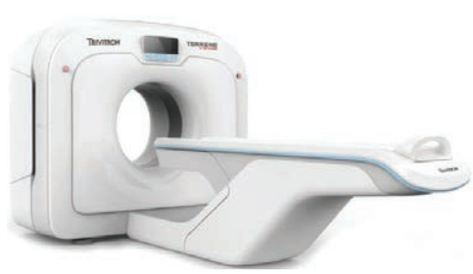


Agilent Technologies Inc., has introduced two new products at the 72nd ASMS Conference on Mass Spectrometry and Allied Topics. The Agilent 7010D Triple Quadrupole GC/MS System which targets the food and environmental markets, offers precision and sensitivity in gas chromatography-mass spectrometry. Additionally, the Agilent ExD Cell for use with the 6545XT AdvanceBio LC/Q-TOF system, serves the biopharma market and life science research. These instruments exemplify Agilent's unwavering commitment to advancing scientific discovery through innovative instrumentation, significantly shaping the landscape of mass spectrometry.

The Agilent 7010D Triple Quadrupole GC/MS System (7010D GC/TQ) features the new HES 2.0 ion source, providing attogram-level sensitivity, unmatched robustness, and industry-leading uptime. Built-in intelligence, including SWARM autotune and Early Maintenance Feedback (EMF), streamlines analytical workflows and reduces unplanned instrument downtime, making it a reliable partner in navigating evolving regulatory requirements.

The 7010D GC/TQ also includes the My Green Lab Accountability, Consistency, and Transparency (ACT) Label, reflecting environmentally conscious manufacturing practices. Additionally, the MassHunter Acquisition 13.0 software enhances user experience with a refreshed interface and compliance tools, enabling users to take control of data integrity and adhere to compliance guidelines such as FDA 21 CFR Part 11, EU Annex 11, and GAMP5. ■

Trivitron Healthcare launches Terrene CT scanner



Trivitron Healthcare, a leading global medical technology company, announced the launch of its state-of-the-art CT scanner, branded as "Terrene." This ground-breaking technology is the first of its kind in India to receive approvals from the Bureau of Indian Standards (BIS), the Atomic Energy Regulatory Board (AERB) and Central Drugs Standard Control Organization (CDSCO), marking a significant milestone in the Indian healthcare industry.

The aim of Terrene CT scanner launch is to ensure accessibility of advanced technology in all the healthcare facilities. The approvals from BIS, AERB & CDSCO accentuate the scanner's exceptional quality, safety, and reliability, having undergone rigorous testing to meet stringent regulatory standards. The Terrene CT Scanner is manufactured at Trivitron's ISO 9001 & ISO 13485 certified manufacturing facility located in Andhra Pradesh MedTech Zone (AMTZ), Visakhapatnam. This achievement reaffirms Trivitron's dedication to excellence in medical technology and its mission to provide advanced and accessible healthcare solutions.

Commenting on this achievement, Dr. GSK Velu, CMD of Trivitron Healthcare, said, "The widespread accessibility of healthcare is essential for a stronger India. Our new Terrene CT technology, proudly made in India, will revolutionize diagnostics across the country. We are dedicated to advancing healthcare in India and are excited to introduce more innovations that will benefit every corner of the nation." ■

Nikon introduces Imaging Technology

Nikon Corporation (Nikon) is expanding its AX series lineup with the introduction of the AX R with NSPARC 2K software. This solution provides maximum resolution performance across four times the field of view. The expanded capabilities of the AX R with NSPARC Super-Resolution Confocal Microscope contributes to accelerated speed and efficiency of experiments across fundamental biology, disease research, and drug development.

The Nikon Spatial Array Confocal (NSPARC) detector combined with the AX R Confocal Microscope system enables more precise observations with extremely low noise and exceptionally sharp image contrast. The newly updated software expands the observation range by about four times*1 at the same magnification compared with previous products. In addition, the image acquisition speed at the same magnification is improved six-fold compared to a traditional galvano scanner.

"With the introduction of this product, Nikon strives to empower the scientific community to more efficiently research and understand complex diseases such as cancer and Alzheimer's disease, as well as to assist research and development efforts in drug discovery," said Tatsuya Yamaguchi, Nikon Executive Officer and General Manager of Healthcare Business Unit.

He added, "Particularly, in diverse biotech subfields such as gene therapy and cell therapy, it will be possible to track the growth processes of cells and tissues within disease models using high throughput and resolution. This new technology will also assist in the understanding of cellular and tissue-level activity which is critical for assessing the efficacy and safety of novel therapies."

To meet the ever-changing needs of the biological and biomedical research community, Nikon continues to develop products that make use of advanced optical technologies to contribute to the understanding of biology, disease, and the development of new therapies." ■

Beckman Coulter introduces new integrated chemistry and immunoassay analyser

BREA, California: Beckman Coulter Diagnostics, a clinical diagnostics leader, today introduces the new DxC 500i Clinical Analyzer*, an integrated clinical chemistry and immunoassay analyzer. As healthcare systems around the world strategically adopt networked laboratory operational models for better efficiency and patient access, Beckman Coulter continues to introduce new innovations to address the needs of the entire network with specific solutions for satellite or independent laboratories, as well as core laboratories. Utilizing Beckman Coulter's common reagents and consumables across its scalable clinical chemistry and immunoassay portfolio, the DxC 500i Analyzer enables commutable patient results, offering hospitals and healthcare networks strategic benefits in patient care and inventory management.

The DxC 500i Clinical Analyzer features FlexMode operations, prioritizing immunoassay and chemistry testing according to each sample's urgency. The new dynamic sample handler manages repeats and re-runs without operator intervention and pulls in a new sample rack as soon as the previous rack is offloaded, optimizing rapid throughput in a compact footprint. Of equal importance, the DxC 500i's intuitive interface supports even the newest users through proactive task indicators, step-by-step instructions and simplified staff onboarding and training. ■

DOMESTIC

Bio Pharma and Lab Analytix World Expo 2026

Dates: 3-6 February, 2026

Venue: Bombay Exhibition Centre, Goregoan East, Mumbai, India

Details: The Bio Pharma and Lab Analytix World Expo 2026 will bring together the stakeholders and leaders for the pharma industry, which will focus on emerging trends and technologies.

Contact: 022-40373636
Email: sales@jasubhai.com
Website: www.chemtech-online.com

PharmaTech Expo & LabTech Expo 2024

Dates: 8-10 August 2024

Venue: Helipad Exhibition Center, Gandhinagar, India

Details: PharmaTech Expo is one of the largest pharma exhibitions in India and is a place for thousands of people from the business to share their experiences related to products, customers, business and sales. This pharmaceutical and lab expo brings together people from across the globe to one destination.

Contact: +91-99090 41613
Email: info@kdclglobal.com
Website: www.hecgujarat.com

InnoPack Pharma Confex 2024

Dates: August 8-9, 2024

Venue: Hyderabad, India

Details: InnoPack Pharma Confex bring together those who matter in pharma packaging under one roof. The industry's most sought-after pharma packaging specialists will be joining as conference speakers to share ground-breaking trend, regulations update and much more on all aspects concerning pharma packaging.

Contact: +91-022-6172 7000
Email: informamarkets@informa.com
Website: www.informamarkets.com

World Congress on Advanced Pharmacy and Clinical Research

Dates: 10 August, 2024

Venue: Pune, India

Details: This conference will create a global platform to researches, scientists, academicians, policymakers, industry experts to share experiences, discuss research findings and acquire and the desired knowledge in the subject from around the world with many networking opportunities.

Contact: +91-96770 07228
Email: info@sfe.net.in
Website: www.sfe.net.in

INTERNATIONAL

Vietnam Medi-Pharm Expo 2024

Dates: 1 - 3 Aug 2024

Venue: Ho Chi Minh, Vietnam

Details: This exhibition is an opportunity for Vietnam's healthcare industry and will showcase a wide range of products and services in the medical, hospital, and pharmaceutical sectors.

Contact: 02439 365 566
Email: xttm@vietfair.vn
Website: www.vietfair.vn

Advanced Clinical Research and Clinical Trials 2024

Dates: August 8-9, 2024

Venue: London, UK

Details: The 30th International Conference on Advanced Clinical Research and Clinical Trials (Clinical Research 2024), will explore the latest advancements, innovations, and breakthroughs in the field of clinical research, this conference promises to be an exceptional opportunity for learning, collaboration, and networking.

Contact: 994507116883
Email: kindcongress@gmail.com
Website: www.kindcongress.com

Annual Immuno-Oncology Summit 2024

Dates: 07 - 09 Aug 2024 Aug 2024

Venue: Philadelphia, USA

Details: The Immuno-Oncology Summit organized by CHI has been the premier event for advancing biotherapeutics for the past 11 years. This exciting three-day program features six tracks, including bi- and multispecific biotherapeutics, CAR T therapies, emerging targeting technologies, personalized immunotherapy, cell-based immunotherapies, and strategies to overcome tumor resistance challenges.

Contact: +1 781.247.1820
Email: cbenners@healthtech.com
Website: www.immuno-oncologysummit.com

The Bioprocessing Summit 2024

Dates: 19 - 22 Aug 2024

Venue: Boston, USA

Details: The summit will feature a comprehensive program, including keynote presentations from renowned industry leaders, interactive panel discussions, and hands-on workshops designed to address the most pressing challenges and opportunities in bioprocessing.

Contact: 781.972.5400
Email: chi@healthtech.com
Website: www.bioprocessingsummit.com

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Bio Pharma World Expo 2026

LAB & ANALYTIX World Expo 2026

International Exhibition & Conferences

3-6 February 2026

Venue: Bombay Exhibition Center, Goregaon (East), Mumbai, India

BIO-PHARMA

Manufacturing
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- Serums
- Biologics & Biosimilars
- Generics
- Bulk Drugs
- Drug Discovery & Development
- Drug Delivery
- Contract Manufacturers

Equipment & Technology
- Pharma & Biopharma Processing
- Mixers & Blenders
- Agitators & Dryers
- Sterlizers & Autoclaves
- Homogenizers & Emulsifiers
- Instrumentation & Automation
- Lab & Analytical technologies
- Bioinformatics
- Packaging Machinery & Equipment
- Filtration & Separation

Pharma Chemicals
- APIs & HPAPIs
- Fine & Specialty Chemicals
- Formulations
- Excipients
- Pharma Ingredients

Research & Development
- Lifesciences
- Contract Research & Clinical Trials
- Contract Development & Manufacturing
- Research Institutes
- Academic Institutes
- Academic Institutions
- Government Institutions
- Testing & Inspection
- Intellectual Property Rights (IPR) & Legal Services

Infrastructure & Logistics
- Biotech Parks
- Warehousing
- Cold chain logistics
- Supply Chain Management
- Logistics services
- Online distributors

LAB ANALYTIX

Laboratory Technology
- Laboratory furniture, equipment, machines
- Chemicals, Consumable, reagents, glassware
- Laboratory data system and documentation
- Laboratory automation
- Laboratory diagnostics
- Instruments for environmental labs
- Forensic lab instruments

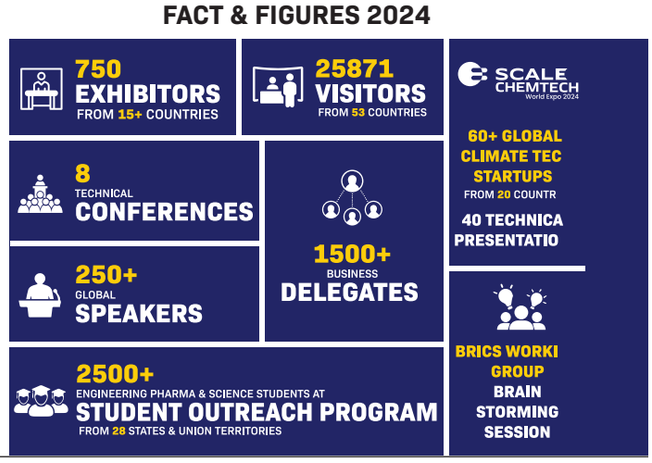
Analysis
- Chromatographes
- Spectroscopes
- Microscopes and imaging
- Analytica instrumentation and systems
- Instruments for physical and chemical analysis

Quality control / Measuring &Testing
- Characterization and properties of materials
- Quality control for pharmaceutical industry
- Material testing

Diagnostics
- Diagnostic Equipment and Reagents
- Diagnostic Technology & Devices
- IVD Medical Devices
- Clinical Diagnostic

Biotechnology
- Biochemicals
- Bioinformatics
- Medicine and diagnostics
- Life Sciences

FACT & FIGURES 2024



Concurrent Events

EPC Expo | Specialty ChemiCAL | Refining & Petro Chemicals 2026 | WaterEX World Expo 2026 | Industry Automation & Control 2026 | PVF Pumps, Valves & Pumps World Expo 2026 | Chlor-Alkali World Expo & Conferences 2026 | Surface Engineering Coating & Corrosion World Expo 2026 | Student Outreach Program 2026 Develop Future Leaders

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Taj Building, 3rd Floor, 210, Dr. D N Road, Fort, Mumbai – 400 001, INDIA.
Tel: +91-22-4037 3636, **Email:** sales@jasubhai.com
Ahmedabad - 09833104834 | Bangalore - 09892644177 | Chennai - 09176963737
Delhi - 09891469629 | Hyderabad / Pune - 09822209183 | Vadodara - 09820544904

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