VOL 23 | ISSUE 3 | OCTOBER 2024 | MUMBAI | TOTAL PAGES 50 | PRICE ₹ 150

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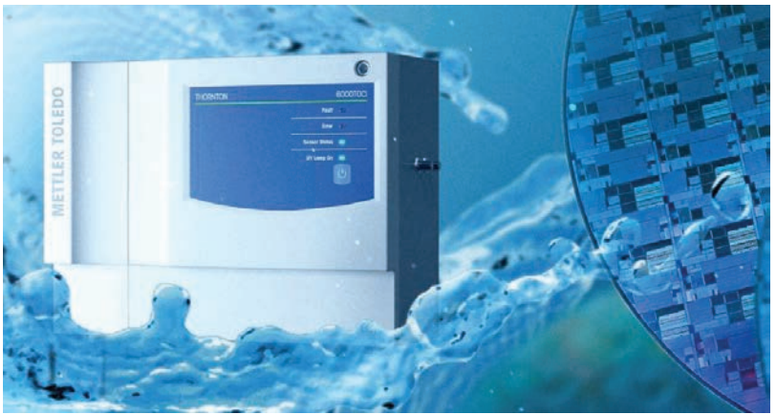

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PHARMA BIO WORLD
R.N.I. No.: MAHENG/2002/08502

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Annual Subscription: ₹ 1620/-, Foreign: USD 180

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PLACE OF PUBLICATION
JASUBHAI MEDIA PVT. LTD.
210, Taj Building, 3rd Floor, Dr. D. N. Road, Fort, Mumbai 400 001, Tel: +91-22-4037 3636

Printed and published by Mr Hemant K. Shetty
Address: 406-D, The Karachi Citizens Co-Op Hosg Soc Ltd., Juhu Varsova Link Road, Andheri West, Mumbai - 400053.

Printed at The Great Art Printers
25, Unique House, S A Brelvi Road, Fort, Mumbai 400 001.

Editor: Ms. Mittravinda Ranjan, 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

Published from Jasubhai Media Pvt .Ltd. 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

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India to add 50 new Greenfield Pharma Plants in 2 Years under PLI scheme

Dr. Arunish Chawla, Secretary, Department of Pharmaceuticals

New Delhi, India: The upcoming 50 new pharma plants in the PLI scheme will be completed in the next two years. More than 50 new Greenfield manufacturing plants for pharmaceuticals and medical devices have already been completed. The PLI plants have catalyzed 10 billion dollars of exports from India to countries with the highest regulatory standards, said Dr. Arunish Chawla Secretary Department of Pharmaceuticals Government of India at Annual Pharma Summit 2024 organised by ASSOCHAM at New Delhi.

While addressing the event, Dr. Arunish Chawla, Secretary Department of Pharmaceuticals said, many reforms have been done in both the regulatory framework and in the schemes. We are working very hard to upgrade the quality framework for all pharma and drug units. We want to make India not just a pharmacy of the world, but a reliable pharmacy of the world. The all-big pharma companies, global and multinational companies are now expanding their footprint and their business in India and also locating their value chains here.

Dr. Arunish Chawla further highlighted that we are the third largest producer of drugs and pharmaceuticals by volume. Drugs and Pharma and Meditech is the fourth largest merchandise export from India. Nine out of top 25 generic firms are located in India. And going forward, our contribution to humankind will increase. We are improving our innovation framework. We have already taken a large number of reforms. Some of these reforms have been notified. A Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) has been launched and going forward, this ecosystem will energize further, said Dr. Chawla.

Health ministry issues notification to register CROs under NDCTR, 2019

New Delhi, India: The Union health ministry has issued notification to register clinical research organisations (CROs) and mandating registration for the organisations to operate under the New Drugs and Clinical Trials Rules (NDCTR), 2019. The amended rules will come into force from April 1, 2025.

"Clinical Research Organisation" means the sponsor or a body, commercial or academic or of other category, owned by an individual or an organisation having status of legal entity by whatsoever name called, to which the sponsor may, delegate or transfer in writing, some or all of the tasks, duties or obligations regarding clinical trial or bioavailability or bioequivalence study, stated Health ministry.

The Ministry added that registration granted under rule 38C shall remain valid for a period of five years from the date of its grant, unless suspended or cancelled by the Central Licencing Authority.

"Any Clinical Research Organisation aggrieved by the order of the Central Licencing Authority under sub-rule (1), may within a period of sixty days from the date of the receipt of the order, make an appeal to the Central Government and the Central Government may, after such enquiry, as deemed necessary and after affording an opportunity of being heard, pass such orders in relation thereto as may be considered appropriate in the facts and circumstances of the case."

For registration, the CROs shall apply with the CLA for registration for conduction such studies, accompanied by a fee of ₹ 5 lakh, along with documents and other required information.

IRGMA welcomes CDSCO's New Guidelines, urges effective implementation

Mumbai, India: The Indian Rubber Gloves Manufacturers Association (IRGMA) has welcomed the fresh guidelines detailing the functions and responsibilities of the Zonal, Sub-zonal, and Port offices of the Central Drugs Standard Control Organization (CDSCO). The association urged the government to take stringent measures to implement the order effectively to stop the import of substandard gloves in the country.

CDSCO issued the new Guidance Document for Functions and Responsibilities of Zonal, Sub-zonal, and

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Port offices on September 12. The guidelines were last released in 2011, and the recent changes—including the introduction of new rules and regulations and the online system through the SUGAM portal—necessitated the revised order in line with the procedures followed in CDSCO offices.

Speaking on the new CDSCO guidelines, the IRGMA General Secretary Man Mohan Singh Gulati said, "The new guidelines issued by CDSCO are a welcome step. However, the implementing authorities, including ADCs posted at ports, must be made aware of the document to effectively control the import of substandard bulk-packed gloves."

The association has long been demanding the Quality Control Order (QCO) for gloves to keep substandard imports at bay and urged the government to expedite its process. This will not only help Indian manufacturers but also contribute to the union government's Make in India initiative to achieve self-sufficiency and reduce dependence on other countries.

The IRGMA general secretary added that the new CDSCO guidance document will bring uniformity, transparency, predictability, and accountability to all offices, incorporating risk-based inspections as part of the organization's technical functions.

Weakness in API Prices to Persist: India Ratings

Mumbai, India: India Ratings and Research expects active pharmaceutical ingredient API prices and volume growth to remain weak for India in FY25, driven by imports and competition in exports, both from China. However, low raw material prices have mitigated the impact of the price decline. This along with costs and forward integration into the formulations business (which has seen higher prices in the regulated markets) has caused EBITDA margins to expand.

This had led to a higher count of positive directional actions on its pharma portfolio over the past 12 months. A wider basket of products across therapies and lower concentration of products exposed to Chinese competition have also led to a healthy financial performance for India Ratings rated pharma companies.

API price decline has ranged from 20% - 50% in key molecules over the past 12 months. While steep price declines have abated since 2QFY25, given prices reaching uneconomical levels even for Chinese players (import prices have declined over 50% yoy in some cases), Ind-Ra opines pricing challenges will persist, primarily led by competition from Chinese players in key large volume molecules.

The agency has also observed significant increase in imports of drug intermediates/bulk drugs used for manufacturing API/formulations from China which have accentuated the downward momentum in realisation. While exports of APIs to regulated markets are long term in nature where the pricing erosion may not be severe, the agency believes Chinese competition may lead to a steep erosion in pricing and profitability in markets excluding regulated ones.

Revenues of Indian pharma companies likely to expand by 9-11% in FY2025: ICRA

Mumbai, India: ICRA expects the revenues of its sample set of companies to expand by a healthy 9-11% in FY2025, albeit a moderation from the YoY increase of 13-14% recorded in FY2024. This will be driven by 9-11% revenue growth from the US market, 7-9% each from the European and domestic markets, and 11-13% from the emerging markets. ICRA's Stable outlook on the industry reflects the steady growth expectations across key markets and the healthy credit profile of pharma players.

Commenting on the near-term expectations of the industry's operating profit margin (OPM), Kinjal Shah, Senior Vice President & Co-Group Head – Corporate Ratings, ICRA, said: "ICRA expects the operating margins of its sample set of companies to remain stable at 23-24% in FY2025, supported by an increase in revenues, higher contribution of complex generics/ specialty molecules and soft prices of raw materials."

ICRA expects the revenue growth from the domestic market for its sample set of companies to improve to 7-9% in FY2025 against 6.4% in FY2024. Growth in the previous fiscal was impacted to an extent by the change in the composition of the National List of Essential Medicines (NLEM), which resulted in a decline in realisations for certain drugs, in addition to an uneven monsoon, which affected acute therapy sales.

In contrast, in Q1 FY2025, ICRA's sample set of companies witnessed a YoY increase of 11.7% in revenues as some of the players gained market share in chronic therapies and enjoyed continued benefits from the introduction of new products.

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Wockhardt files fast-acting Insulin Aspart injection (ASPARAPID) with DCGI


Dr. Habil Khorakiwala, Founder Chairman, Wockhardt

Mumbai, India: Wockhardt, a global pharmaceutical and biotechnology major, announces the filing of its fast-acting insulin analog, Aspart injection (ASPARAPID), with the Drugs Controller General of India (DCGI). This significant milestone reflects Wockhardt's ongoing commitment to address the growing diabetes epidemic both in India and globally.

Wockhardt's Aspart insulin injection (ASPARAPID) is an indigenously developed product, underscoring the company's end-to-end capabilities in research & development, clinical studies, scale up and manufacturing of biosimilars products. By leveraging integrated infrastructure and expertise, Wockhardt has completed all stages of ASPARAPID development - from research to production through in-house development. It offers enhanced quality and accessibility for patients. ASPARAPID will be available in cartridges, vials, and prefilled disposable pens, offering flexibility to the patients for management of diabetes. The market size of Aspart in India is currently estimated over ₹ 260 Crore. with only 2 players and is expected to grow significantly in the coming years.

"We are proud of adding another feather in our diabetes biosimilars portfolio through filing of insulin Aspart injection in a market that has limited competition. This reinforces Wockhardt's ability to develop and manufacture complex biosimilars domestically," said Dr. Habil Khorakiwala, Founder Chairman of Wockhardt. "Our aim is to make world-class diabetes care accessible to patients in India and globally and to contribute meaningfully to the management of diabetes."

Sun Pharma Presents New Clinical efficacy and safety Data in Severe Dermatological conditions

MUMBAI, India & PRINCETON, N.J: Sun Pharmaceutical Industries Limited announced that it will present abstracts across its dermatology portfolio at the 33rd European Academy of Dermatology and Venereology (EADV) Congress being held in Amsterdam, Netherlands from September 25-28, 2024.

Three abstracts, accepted for podium and poster presentation, will highlight clinical efficacy and safety data of LEQSELVI (deuruxolitinib) 8 mg tablets, an oral selective inhibitor of Janus Kinases (JAK) JAK1 and JAK2 approved by the U.S. Food and Drug Administration for the treatment of adults with severe alopecia areata (AA). Notably, data presented in the podium presentation (FC04.04) found a greater proportion (95%) of patients taking deuruxolitinib 8 mg twice a day showed improvement in their hair satisfaction scores, compared to baseline over the 24-week period. Satisfaction with hair regrowth is imperative, as a significant number of patients with AA experience depression and anxiety due to the visible nature of the disease.

The company will also share results in two additional posters for deuruxolitinib, which showed clinically meaningful improvement in anxiety and depression among patients taking deuruxolitinib to treat their severe AA (P2022) as well as dose optimization for deuruxolitinib at 8 mg(P2081).

"Deuruxolitinib targets the immune mechanisms behind alopecia areata, providing patients with an effective treatment option," said Arash Mostaghimi, MD, MPA, MPH, FAAD, Vice Chair, Clinical Trials and Innovation and Director, Inpatient Dermatology, Brigham and Women's Hospital. "As a dermatologist, I find these data particularly encouraging because it addresses the physical effects of hair loss, which can, in turn, address the significant emotional and mental health challenges that patients often face."

Biocon Biologics announces New Dermatology Data at EADV Congress 2024


Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics

Bengaluru, India: Biocon Biologics, an integrated global biosimilars company, announced important new data from two key clinical studies presented at the European Academy of Dermatology and Venereology (EADV) 2024 Congress in Amsterdam. These studies are related to its biosimilar Adalimumab and biosimilar Ustekinumab (Bmab1200) used for the treatment of chronic plaque psoriasis.

Adalimumab Study supports the interchangeability of Biocon Biologics biosimilar Adalimumab-fkjp at low-concentration with high-concentration reference product Adalimumab.

Ustekinumab Biosimilar Study compared Biocon Biologics' biosimilar Ustekinumab, Bmab 1200, to reference product Ustekinumab, a drug used for treating moderate to severe chronic plaque psoriasis (Pso). The results demonstrated that the biosimilar Bmab 1200 is just as safe and effective as the reference product.

These findings support the use of biosimilars, which are more affordable versions of expensive biologic drugs, offering alternate treatment options to patients and reducing overall healthcare costs.

Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics said, "The extensive range of new data being presented at EADV this year underscores Biocon Biologics' commitment to a high-science portfolio of biosimilar medicines that meet the clinical needs of physicians and patients while providing important sustainability benefits to health systems. These clinical studies support the interchangeability of adalimumab-fkjp at low-concentration with high-concentration adalimumab and ustekinumab biosimilarity without variation of clinical outputs in patients with chronic plaque psoriasis."

CCI approves acquisition of Bharat Serums and Vaccines Limited by Mankind Pharma

New Delhi, India: Competition Commission of India has approved the acquisition of Bharat Serums and Vaccines Limited by Mankind Pharma Ltd. The proposed transaction involves the acquisition of 100% shareholding of Bharat Serums and Vaccines Limited (BSV) by Mankind Pharma Ltd.

Mankind is a public listed company and is engaged in developing, manufacturing, and marketing a diverse range of pharmaceutical finished dosage formulations (FDFs) across various acute and chronic therapeutic areas, as well as several consumer healthcare products such as condoms, emergency contraceptives, pregnancy tests, vitamins, minerals, nutrients, antacids and anti-acne preparations segments. Through its subsidiaries, Mankind is also engaged in, inter alia, the manufacture and sale of active pharmaceutical ingredients (APIs), pharmaceutical intermediaries, and packaging products for pharmaceutical products.

BSV, along with its subsidiaries, is engaged in research, development, licensing, manufacturing, importing, exporting, marketing and distribution of FDFs and APIs; biotech and biological formulations and/or API; food and health supplements; medical devices; and ayurvedic medicines; in each case, in the therapeutic areas such as gynaecology, in-vitro fertilisation, critical care and/or emergency medicines for human use. In India, the activities of BSV (including its wholly owned Indian subsidiary, BSV Pharma Private Limited, which is in the process of merging with BSV) are limited to developing, manufacturing, and marketing a range of biological, biotech, and pharmaceutical products in the therapeutic areas of women's health, critical care, IUI-IVF, and emergency medicine.

Dr Reddy's completes acquisition of Haleon's global NRT portfolio

Hyderabad, India: Dr Reddy's Laboratories stated that its Switzerland-based subsidiary has completed the acquisition of UK-based Haleon plc's global portfolio of consumer healthcare brands, outside of the United States (US), in the nicotine replacement therapy (NRT) category.

"We would like to inform you that the acquisition has now been completed, and the company has made a payment of upfront cash consideration of GBP 458 million.Further, as part of this acquisition, Northstar Switzerland along with its wholly owned subsidiaries North Star OpCo Limited (United Kingdom) and North Star Sweden AB (Sweden) are now wholly-owned step-down subsidiaries of the Company with effect from September 30, 2024. " the company said in a regulatory filing.

The company added that its acquired portfolio 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 portfolio is inclusive of all formats such as lozenge, patch, gum as well as pipeline products, in all applicable global markets outside of the United States.

Glenmark Pharma' Aurangabad unit gets clean chit from USFDA

Mumbai, India: Glenmark Pharmaceuticals Ltd stated that U.S. Food and Drug Administration (U.S. FDA) has issued Form 483 with zero observations after an inspection at the Company's formulation manufacturing facility based out of Chhatrapati Sambhaji Nagar (Aurangabad), India between September 09 and September 20, 2024.

Glenmark Pharmaceuticals Ltd. is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 11 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries.

IPA to work with Govt to establish stringent measures against spurious drugs: Sudarshan Jain

Sudarshan Jain, Secretary General, IPA

New Delhi, India: Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance stated that Indian Pharmaceutical Alliance (IPA) is deeply concerned by the gross misrepresentation and deliberate distortion of facts by select media outlets on the drug alert report released by the Central Drugs Standard Control Organisation (CDSCO). The misleading coverage irresponsibly interchanges the terms "Not of Standard Quality" and "Spurious," and wrongfully implicates genuine manufacturers in the production of spurious drugs.

"Manufacturing spurious drugs is a serious criminal offence that threatens public health. The outrageous linking of spurious products with legitimate manufacturers has severe reputational and financial impact. Moreover, this tarnishes India's reputation as a reliable supplier of medicines on a global stage. It is critical that a clear distinction between NSQ and Spurious Drugs is made," added Jain. IPA will continue to work with the Government to strengthen the overall system and establish stringent measures against spurious drugs. This issue is of paramount importance, both for India's global standing and for the protection of public health. India is the global pharmaceutical manufacturing hub and is rightfully recognized as the "Pharmacy of the World". This sector is of strategic importance to the nation. The Industry plays a vital role in supplying affordable quality-assured medicines to over 200 countries.

Lupin enters into Patent Licensing agreement with Takeda to Commercialize Vonoprazan


Rajeev Sibal, President India Region Formulations, Lupin

Mumbai, India: Global pharma major Lupin Limited announced that it has entered into a non-exclusive patent license agreement with Takeda Pharmaceutical Company Limited (Takeda), to commercialize Vonoprazan Tablets in the Indian market. The drug will be marketed under the brand name Lupin's Lupivon and will be available in two strengths - 10 mg and 20 mg.

Under the terms of this agreement, Takeda has granted Lupin non-exclusive patent licensing rights to commercialize Vonoprazan in India. "We are very pleased to commercialize Vonoprazan, a novel treatment option for Acid Peptic Disorders. This is a further step in strengthening our gastroenterology portfolio and is in line with our commitment to introduce innovative medicines to address unmet needs of our patients," said, Rajeev Sibal, President India Region Formulations, Lupin.

Zydus announces licensing agreement for two Gadolinium based MRI injectable in US market

Ahmedabad, India: Zydus Lifesciences Ltd., a global innovation driven healthcare company announced that its wholly owned subsidiary, Zydus Lifesciences Global FZE has entered into an exclusive licensing and supply agreement with Viwit Pharmaceuticals (Viwit), an innovation driven biopharmaceutical and healthcare company, for gadobutrol injection (generic version of GADAVISTTM) and gadoterate meglumine injection (generic version of DOTAREM®) for the US market.

As per the terms of the agreement, Viwit will be responsible for ANDA submission, manufacturing and supplying the generic versions of GADAVIST and DOTAREM®, following the receipt of requisite regulatory approval. Zydus will exclusively market, distribute, and sell these products in the US market.

Both the products are Gadolinium based Magnetic Resonance Imaging (MRI) contrast agents and will be the first set of contrast agent products in Zydus' injectable portfolio for the US market.

AstraZeneca Pharma receives approval for cancer drug Durvalumab

Mumbai, India: AstraZeneca Pharma India Limited has received permission to import for sale and distribution of Durvalumab 120 mg/2.4 mL and 500 mg/10 mL solution for infusion (Imfinzi) from the Central Drugs Standard Control Organisation, Directorate General of Health Services, Government of India for the below mentioned additional indication.

"Durvalumab (IMFINZI) in combination with chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, is indicated for the treatment of patients with resectable (tumours 4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements".

The receipt of this permission paves way for the launch of Durvalumab 120 mg/2.4 mL and 500 mg/10 mL solution for infusion (Imfinzi) in India for the specified additional indication, subject to the receipt of related statutory approvals, if any.

Fermenta Biotech receives EU GMP Certification for the Dahej Manufacturing Facility, Gujarat, India

Mumbai, India: Fermenta Biotech Limited's Active Pharmaceutical Ingredient (API) manufacturing facility situated at Dahej, Gujarat, India has received a certificate of GMP compliance from the Competent Authority of Germany, following a European Union Good Manufacturing Practice (EU GMP) inspection that was conducted in March 2024. This approval reflects Company's unwavering commitment that the Quality Assurance is in compliance with the stringent guidelines of Good Manufacturing Practices.

Prashant Nagre, Managing Director of Fermenta, commented on the occasion, "We are pleased with the positive outcome of the recent EU GMP inspection at our Dahej Manufacturing Facility in Gujarat. The certificate of GMP compliance underscores our commitment to global standards ofquality, compliance and consistency in manufacturing."

Founded in 1951, Fermenta Biotech Limited (FBL) possesses a growing portfolio of nutrition including Customized Premixes, Fortified Rice Kernel (FRK) and other nutritional ingredients. Apart from its nutrition portfolio, FBL is the only manufacturer of Vitamin D3 in India and a leading global player.

Venus Remedies secures marketing authorisations for key oncology drugs from Morocco & Philippines

Saransh Chaudhary, President of Global Critical Care, Venus Remedies

Mumbai, India: Venus Remedies Ltd, a prominent oncology drug manufacturer, has secured marketing authorizations for two key cancer drugs, enhancing its global reach. The approvals include bortezomib in the Philippines and carboplatin in Morocco, boosting the company's oncology portfolio to 508 approvals across 76 countries.

Saransh Chaudhary, President of Global Critical Care at Venus Remedies, expressed, "These approvals are pivotal in our strategy to expand our oncology range and meet the increasing global demand for cancer treatments. We are advancing toward becoming the leading oncology supplier in Southeast Asia."

The Philippine market, the second largest in the ASEAN region, is expected to grow from USD 400 million in 2022 to USD 790 million by 2030. The authorization of bortezomib will enhance the company's ability to deliver advanced cancer solutions in Southeast Asia.

In Morocco, where the oncology drug market is set to reach USD 150.8 million by 2029, the approval of carboplatin will strengthen Venus Remedies' position in the African oncology market.

Aditi K. Chaudhary, President of International Business, emphasized the company's role in supporting global health initiatives, stating, "These authorizations reflect our commitment to providing innovative and accessible healthcare solutions worldwide."

Venus Remedies now holds 15 authorizations in Morocco and 69 in the Philippines. These developments contribute to India's growing pharmaceutical exports, which reached USD 27.9 billion in the 2023-24 fiscal year. The global oncology market is projected to expand significantly, reaching USD 518.25 billion by 2032.

Aurobindo Pharma receives 10 observations from USFDA

Hyderabad, India: Aurobindo Pharma stated that United States Food and Drug Administration (US FDA) inspected Unit-II, an API manufacturing facility, of Apitoria Pharma Private Limited, a wholly owned subsidiary of the Company, situated at Gaddapotharam Village IDA, Jinnaram Mandal, Sanga Reddy District, Telangana from September 23 to 27,2024.

"The inspection closed with 10 observations. The observations are of procedural in nature and will be responded to within the stipulated time," the company added.

Aurobindo Pharma Limited 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 29 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, AntiRetroviral, CVS, Antibiotics, Gastroenterological, Anti-Diabetics and Anti-Allergic, supported by a strong R&D set-up.

Alembic Pharmaceuticals announces USFDA Final Approval for Albendazole Tablets USP, 200 mg

Mumbai, India: Alembic Pharmaceuticals Limited announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Albendazole Tablets USP, 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), LAlbenza Tablets, 200 mg, of Impax Laboratories, Inc. (Impax). Albendazole tablets are indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium.

It is also indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus. Refer label for a detailed indication.

Alembic has a cumulative total of 214 ANDA approvals (186 final approvals and 28 tentative approvals) from USFDA.

Piramal Pharma's GHG Commitment Validated and Approved by SBTi


Nandini Piramal, Chairperson, Piramal Pharma

Mumbai, India: Piramal Pharma Limited, a leading global pharmaceuticals company, has embarked on its sustainability journey as the Science Based Targets initiative (SBTi) validated the company's near-term greenhouse gas (GHG) emission reduction targets. This validation aligns with Piramal Pharma's core purpose of 'Doing Well and Doing Good,' driving its business strategies and strengthening the company's commitment to making consistent, measurable progress toward a more sustainable future.

Piramal Pharma Limited has committed to reduce absolute scope 1 and 2 GHG emissions 42% by FY2030 from a FY2022 base year. Piramal Pharma Limited has also committed to reduce absolute scope 3 GHG emissions from purchased goods and services, fuel and energy related activities, upstream transportation and distribution and use of sold products 25% within the same timeframe.This makes Piramal Pharma the third global pharmaceutical company in India to receive approval from the SBTi.

Speaking on this pivotal step forward, Nandini Piramal, Chairperson, Piramal Pharma Limited, said, "Sustainability is at the heart of our business strategy, and the approval from SBTi reinforces our ongoing commitment to reducing our GHG emissions and aligning with global climate action goals. This is a critical step in our broader sustainability roadmap, and we are committed to doing our part in driving meaningful environmental change across the pharmaceutical industry. To further reinforce our commitment, we are also in the process of developing a comprehensive Carbon Reduction Plan, which will be unveiled soon. While we have come a long way, in many respects, our sustainability journey is just beginning.

Blockchain For Impact (BFI) partners with CSIR- CDRI and BRIC- THSTI to propel India's Biomedical Innovation for Global Healthcare Solutions

Lucknow, India: In a remarkable collaboration aimed at advancing biomedical research, Blockchain For Impact (BFI) has announced partnerships with two of India's leading research institutes: CSIR-Central Drug Research Institute (CDRI) and BRIC-Translational Health Science and Technology Institute (THSTI). These collaborations are a part of BFI's larger BFI-BIOME Virtual Network Program that aims to bring together leading research institutes across the country to promote upstream biomedical research. Under this program, BFI has pledged USD 15 Million to further the advancement of translational biomedical research and innovation to deliver indigenous solutions for healthcare challenges across the Global South.

As per the MoU, under the BFI BIOME Virtual Network program, BFI aims to support innovative research and development initiatives across these two institutes.

Sandeep Nailwal, Founder of BFI, expressed his enthusiasm for the partnerships "Partnering with both CSIR-CDRI and BRIC-THSTI represents a milestone for BFI. These collaborations reaffirm our dedication to advancing home-grown solutions for India's healthcare needs while building an ecosystem that can address the global healthcare challenges of tomorrow."

Dr. Gaurav Singh, CEO of BFI, emphasized the significance of these alliances "The well-established research capabilities of CSIR-CDRI and the translational focus of BRIC-THSTI provide us with a robust platform to further our mission of promoting deep science and sustainable healthcare innovation. Together, we aim to not only address India's healthcare challenges but to create solutions that will have global relevance."

Reflecting on the new partnership, Dr Radha Rangarajan, Director, CSIR-CDRI, said, "We welcome this partnership with BFI-BIOME to advance our drug discovery portfolio. Our shared commitment to addressing India's unmet clinical needs makes this public-private partnership particularly meaningful. The projects receiving funding will build on novel and pioneering research that has been undertaken by our

scientists in the fields of malaria, dengue and metabolic diseases. We look forward to being part of the BFI-BIOME network and jointly creating a new pathway for translational research."

Professor. G Karthikeyan, Director of BRIC-THSTI, underscored the value of the alliance "Our collaboration with BFI underscores the importance of fostering translational research that drives innovation. This partnership complements our ongoing efforts to contribute to India's bio-economy and aligns with the Government of India's BioE3 policy. We look forward to collectively shaping the future of healthcare research."

Strides receives USFDA approval for Fluoxetine Tabs 60 mg

Bangalore, India: Strides Pharma Science Limited announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for Fluoxetine Tabs 60 mg, from the United States Food & Drug Administration (USFDA).The product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Fluoxetine tablets, 60 mg, of TWi Pharmaceuticals, Inc.

With the approval of the Fluoxetine Tabs 60 mg strength, the Company is now positioned to offer a complete portfolio of Fluoxetine across Capsules and Tablets in 10 mg, 20 mg, and 60 mg strengths. Fluoxetine Capsules and Tablets have a combined market size of ~USD 130 Mn as per IMS. The addition of the Fluoxetine Tabs 60 mg will allow for enhanced flexibility in dosing, catering to a broader spectrum of patient needs. The Company plans to launch all three strengths in the near future. The Fluoxetine tablets will be manufactured at the company's facility in Puducherry.

India prepared to become Global Pharmaceutical Innovation Hub: Deloitte Whitepaper

Mumbai, India: At the ASSOCHAM Annual Pharma Summit, Deloitte launched its whitepaper titled 'Positioning India as a Pharmaceutical Innovation Hub' offering a comprehensive analysis of India's emerging role in the global pharmaceutical industry.

The paper highlights India's potential to transform from a leading generic drug producer to a powerhouse of pharmaceutical innovation, driven by advancements in research, regulatory reforms, and strategic global partnerships.

Deloitte's whitepaper showcases how India's adherence to international standards, coupled with its cost-effective manufacturing capabilities, sets the stage for it to emerge as a premier destination for pharmaceutical research and development. With a growing talent pool, rising investments in biotechnology, and an increasing number of clinical trials, India is becoming a credible destination for cutting-edge drug discovery and development. Government initiatives, collaborations between academia and industry, and advancements in digital technologies further bolster India's potential to lead in pharmaceutical innovation.

However, it identifies critical challenges that must be addressed to fully realize India's potential as a global pharmaceutical innovation hub. Key issues include the need for increased investment in R&D, stronger intellectual property protections, and the closing of the talent gap in high-demand areas such as artificial intelligence and data science. The paper also stresses the importance of forging robust partnerships between industry, academia, and government to drive innovation and overcome these hurdles.

On the launch Joydeep Ghosh, Partner and Industry Leader for Life Sciences & Healthcare at Deloitte India said "India is on the cusp of a transformative era in its pharmaceutical sector. With the market projected to reach $130 billion by 2030, growth depends on significant investments in R&D and addressing talent shortages in areas like AI and biotechnology. Government initiatives such as the Production Linked Incentive scheme aim to enhance domestic manufacturing and reduce reliance on imports. By fostering collaboration among academia, industry, and government, India can not only meet its healthcare needs but also position itself as a leader in global pharmaceutical innovation, driving economic growth and improving health outcomes."

Neha Aggarwal, Partner, Deloitte India commented, "To foster a robust innovation ecosystem, it is crucial to develop a cohesive strategy that integrates research, technology investments, commercialization, skilling, and intellectual property. Policies that support substantial research funding for large-scale clinical trials, facilitate the establishment of advanced testing facilities, bolster drug regulation capacity, ensure rigorous quality compliance, align global and Indian standards, and streamline time-based drug approvals will make India a more attractive destination for high-quality clinical research."

Tarun Soneja, Partner, Deloitte India said, "The Indian pharmaceutical sector is on the brink of a transformative era, driven by the convergence of advanced technologies and a robust talent pool. With significant advancements in drug discovery, a growing emphasis on biotechnology, and growing interest from global stakeholders, India is well positioned to elevate its role in the global market."

Dr. R.N. Gupta elected as National President of Indian Pharmaceutical Association

Mu**mbai, India:** Dr. R. N. Gupta has been elected as the National President of the Indian Pharmaceutical Association (IPA), the oldest and largest association of pharmaceutical professionals in the country, for the term 2024 - 2026 (1st October 2024 - 30th September 2026). Dr. Gupta is a senior professional, with almost five decades of experience in the pharmaceutical industry, academia and research.

Currently, an Adjunct Professor with NIPER – Kolkata, Dr. Gupta has earlier worked with Smith Stanistreet Pharmaceuticals Ltd, Kolkata, Bihar State Pharma. & Chemical Development Corporation, Patna, Eastern Chemical Industries, Cuttack and Birla Institute of Technology, Ranchi. With over 100 research publications in peer- reviewed journals and 2 authored books on 'Pharmaceutical Marketing Management' and 'GPP in Hospital Pharmacy' respectively, he has successfully guided 8 Doctorate students.

Dr. Gupta has raised numerous issues concerning various facets of the profession through over 350 'Letters to the Editor' and has succeeded in resolving many of these in favor of the profession, through his sustained advocacy initiatives. He has been expert Committee Member of IPC, PCI, DGHS and various govt Committees and Reviewer of NFI. Dr. Gupta has been awarded with awards including Eminent Pharmacist Award, Best Pharmaceutical Scientist, Schroff Memorial Award, P C Ray Gold Medal, S Laskar Pharma Excellence Award, M L Khorana Best Paper Award, IPA President Oration Award, Best Professional Award, Pharma Achievement Award and Jharkhand Gaurav award.

The other IPA office bearers who have been elected for the term 2024 - 2026 are Dr. Subhash Mandal as National Honorary General Secretary and Dr. Alka Mukne as Honorary Treasurer.

JB Pharma Outlines Key ESG Goals & Targets in its Third Sustainability Report FY24

Mumbai, India: J. B. Chemicals & Pharmaceuticals Ltd (JB Pharma), one of the fastest growing pharma companies in India, has announced its ESG commitments with the launch of its 3rd Sustainability (ESG) Report. This marks a significant step forward in the company's ongoing dedication to sustainability, aimed at driving environmental and social progress.

JB Pharma's third sustainability report highlights the company's achievements in reducing its environmental impact and improving resource efficiency. The company has successfully reduced emissions (Scope 1 & Scope 2) intensity per rupee of turnover by 22.2%, while total Scope 1 & Scope 2 absolute emissions decreased by 13.9%. Renewable energy played a key role for JB Pharma with JB generating 46341 GJ of energy from renewable sources of energy, which is 12.1% of total energy demand. Additionally, it has avoided 9,216.7 tCO2e emissions through renewable sources, reducing its total energy consumption by 5.7% and lowering its energy intensity per rupee of turnover by 14.8%. Water consumption intensity per rupee of turnover also dropped by 4.8%. Waste sent to landfill decreased to 12.2%, down from 17.18% in the previous year. All manufacturing facilities have achieved Zero Liquid Discharge (ZLD), further emphasizing the company's environmental stewardship.

Nikhil Chopra, CEO & Whole Time Director, JB Pharma, at the launch of the report said, "Guided by the theme 'Building a Sustainable Future for Good Health,' happy to announce the release of JB Pharma's 3rd Sustainability Report FY24. We recognize the vital connection between sustainability and public health. This report showcases our ongoing journey towards sustainability, highlighting our innovative strategies and dedication to fostering a healthier and more resilient world.As part of our steadfast commitment to environmental stewardship and social well-being, we are thrilled to have undertaken its inaugural ESG Goals and Targets, reinforcing our commitment to sustainable growth. These targets not only prioritize the most impactful ESG KPIs for our business and stakeholders but also guides our strategies towards long-term value creation". ■

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Piramal Pharma Solutions Announces USD80mn expansion plan for Sterile Injectables Facility in Lexington, Kentucky

Mumbai, India: Piramal Pharma Solutions (PPS), a leading global Contract Development and Manufacturing Organization (CDMO) and part of Piramal Pharma Ltd, has unveiled an USD80M investment plan to expand its Lexington, Kentucky facility. The site specializes in sterile compounding, liquid filling, and lyophilization for sterile injectabledrug products, playing a vital role in Piramal Pharma Solutions integrated antibody-drug conjugate development and manufacturing program, ADCelerate.

The investment, financed by bank loans and internal accruals, aims to enhance the site's existing capacity and capabilities to meet the demands of a rapidly growing market. With this expansion, Piramal Pharma will strengthen its position as an efficient and reliable global partner for biologic manufacturing, leveraging deep scientific expertise and extensive experience managing complex technical projects.

The expansion will equip the Lexington site with an additional 24,000 square feet of manufacturing space, a new laboratory, and state-of-the-art machinery to scale clients' products effectively. Key additions include a new filling line, two commercial-size lyophilizers, a special capping machine, and an external vial washer. Currently, the Lexington site can manufacture 104 product batches per year (utilization at peak levels). Upon completion of the expansion in Q1 of 2027, this capacity will increase to over 240 annual batches.

"This expansion represents a strategic investment in the future of Piramal Pharma Ltd. Filling the commercial manufacturing gap enables the Lexington site to access the rapidly expanding injectables market and establish itself as a key player in the segment," said Nandini Piramal, Chairperson, Piramal Pharma Ltd.

Significant research, development, and scientific innovation have driven rapid growth in the injectables market, with an expected market value exceeding $20B by 2028. This growth underscores the necessity for robust commercial-scale manufacturing capabilities.

"The injectables market has steadily increased in recent years and there is currently insufficient supply. We are committed to adapting to meet this rising demand," said Peter DeYoung, Chief Executive Officer, Global Pharma."This expansion will significantly enhance the capacity and capabilities of our Lexington facility, positioning Piramal Pharma as a comprehensive partner across the entire product life cycle and enabling us to provide treatment solutions to more patients."

Cipla's UK arm inks pact to acquire 6.9124% stake in Cipla Jiangsu Pharmaceuticals

Mumbai, India: Cipla (EU) Limited, wholly owned subsidiary of the Company in UK, has entered into a definitive agreement for purchase of entire 6.9124% equity interest of Jiangsu Xidi Pharmaceuticals Co., Ltd. (formerly known as Jiangsu Acebright Pharmaceuticals Co., Ltd.) held in Cipla (Jiangsu) Pharmaceuticals Co., Ltd., China ('Cipla Jiangsu'), subsidiary. The purchase of additional equity interest will be subject to compliance with applicable laws and approvals from regulatory authorities in China.

The transaction is expected to be completed on or before 15th November 2024 or such other date as maybe mutually agreed between the parties and shall be subject to successful completion/ waiver of conditions as mentioned in such definitive agreementsand receipt of regulatory approvals.

Currently, Cipla EU and Xidi holds 93.0876% and 6.9124% equity interest respectively in Cipla Jiangsu.

PCI Pharma Services Invests USD 365M in EU and US

PHILADELPHIA: PCI Pharma Services are investing more than USD 365 million in infrastructure supporting the clinical and commercial-scale final assembly and packaging of drug-device combination products utilizing advanced drug delivery systems, with an emphasis on injectable formats. Comprising new and expanded facilities in both Europe and North America, the effort is part of PCI's global investment plan, is anchored and funded by recent new business, and is designed to augment and accommodate future growth.

For PCI, the investments build upon 20-plus years of biologics expertise, a leadership position highlighted by the company's world-class Biotech Center of Excellence in Philadelphia. That location employs precision handling equipment for prefilled syringes, syringe assembly and labeling, vial labeling and cartoning, and autoinjector assembly. Recently, PCI heavily invested in complex, automated advanced drug delivery technologies to enhance capabilities and capacities at this facility, ensuring it remains at the forefront of innovation. ■

Algorithms to Treatments: AI's Impact on Modern Drug Discovery

Artificial Intelligence (AI) is revolutionizing drug discovery, shifting it from a lengthy and uncertain process to one marked by rapid precision and innovation in healthcare. By harnessing vast datasets and uncovering complex patterns, AI dramatically speeds up the development of new treatments, making groundbreaking medical advancements more attainable.

Dr. Somesh Sharma, Executive Vice President and Head Discovery Services, Aragen Life Sciences emphasizes how Artificial Intelligence (AI) is transforming drug discovery by enhancing efficiency, reducing costs, and increasing success rates across various stages.

AI-Driven Drug Discovery: Pioneering the Future of Healthcare

Artificial Intelligence (AI) is transforming drug discovery by enhancing efficiency, reducing costs, and increasing success rates across various stages, including target identification, hit discovery, lead optimization, process development and manufacturing. AI technologies, such as knowledge graphs for OMICs data mining, Generative AI (Gen AI) for molecule design, and structure prediction algorithms like AlphaFold, are advancing drug development strategies. These technologies facilitate tasks like protein-ligand docking and virtual screening with unprecedented accuracy, building new chemical space and opening new therapeutic avenues.

From Concept to Cure: Advances in De Novo Drug Design

De novo drug design, which entails the creation of novel drug-like molecules ab initio, has been profoundly transformed by advancements in Generative AI. Contemporary methodologies encompass Simplified Molecular Input Line Entry System (SMILES) based models, which encode molecular structures as linear strings, and molecular graph-based models, which utilize three-dimensional representations to enhance structural fidelity and robustness.

Innovations such as DeepSMILES and SELFIES (Self-Referencing Embedded Strings) have improved the encoding and decoding processes, ensuring higher validity and diversity of generated molecules. Reinforcement Learning (RL) techniques, including Reinforcement Learning-Variational Autoencoder (RL-VAE), further augment these models by optimizing molecular properties through iterative feedback mechanisms.

Moreover, the integration of genetic algorithms with deep learning frameworks, exemplified by Genetic Algorithm with Reinforcement Learning (GARel) and Genetic Evolutionary Reinforcement Algorithm (GENERA), has refined de novo design. These hybrid approaches focus on the generation of unique molecular scaffolds and perform multi-objective optimizations, thereby yielding compounds with enhanced pharmacokinetic and pharmacodynamic properties.

AI-Powered Virtual Screening: Accelerating Therapeutic Discoveries

Traditional virtual screening methods predominantly utilized rigid docking simulations and empirical scoring functions, which constrained the exploration of chemical space. However, the advent of Gen AI, ML, and DL has revolutionized virtual screening in drug discovery, markedly improving the efficiency and accuracy of identifying potential drug candidates.

For instance, Generative Adversarial Networks (GANs), which employ generator-discriminator networks, and Variational Autoencoders (VAEs), which encode

molecular data into latent spaces, have significantly broadened the chemical space explored during virtual screening. ML algorithms such as Random Forests (RFs), Support Vector Machines (SVMs), and k-Nearest Neighbors (KNN) analyze extensive datasets to predict drug-target interactions and classify compounds. Deep Learning techniques, including Convolutional Neural Networks (CNNs) and Recurrent Neural Networks (RNNs), model intricate data patterns to enhance prediction accuracy.

AI Enable Chemistry Platforms for Faster Deliveries

Integration of AI in chemistry laboratories is indeed transformative. AI-powered 'self-driving labs' can autonomously conduct experiments, analyze data, and integrate with biological tools. This significantly accelerates the Design-Make-Test-Analyze (DMTA) cycle, enabling faster decision-making and discovery of novel molecules. AI tools are crucial in optimizing chemical processes. They help in minimizing waste generation and reducing energy consumption, aligning with the principles of 'Green chemistry', making the processes more efficient and environmentally friendly.

Advanced AI tools like SYNTHIA™, Chemical.AI, and ASKCOS assist chemists in identifying the most efficient and cost-effective synthetic routes. These tools can rapidly propose viable routes of synthesis, significantly shortening time required for synthesis. AI tools are also employed for process optimization, predicting impurities, and assessing genotoxicity. These capabilities are essential for ensuring safety and efficacy of chemical processes and products.

Advancements in In Silico ADMET Modelling

AI has significantly impacted all areas of drug discovery research, with its influence being particularly profound in in silico ADME modelling, was primarily driven by high clinical trial failure rates in the late 1990s due to poor pharmacokinetics. Initially, property-based drug-likeness rules and high-throughput assays were adopted for early evaluations of drug efficacy and safety.

Machine Learning (ML) algorithms, including Random Forests (RFs), Support Vector Machines (SVMs), and k-Nearest Neighbors (KNN), along with Deep Learning (DL) techniques such as Convolutional Neural Networks (CNNs) and Recurrent Neural Networks (RNNs), have further advanced ADMET predictions by modeling complex patterns. Graph Neural Networks (GNNs) optimize chemical structures by modeling interactions between molecules and their targets. Tools such as ADMET-AI and ChemMORT exemplify these advancements, offering rapid analysis and enhanced lead optimization.

In the domain of drug toxicity prediction, AI and DL models have significantly advanced the field by analyzing extensive datasets to forecast potential adverse effects. Tools like DeepTox utilize molecular descriptors to predict toxicity, while Deep-PK estimates both toxicity and pharmacokinetics, enabling earlier and more accurate identification of potential drug-related issues.

Gen AI, employing algorithms such as Generative Adversarial Networks (GANs) and Variational Autoencoders (VAEs), advances drug discovery by designing novel molecular structures. VAEs encode and decode molecular data to explore diverse chemical spaces and propose innovative drug candidates.

AI Impact on In vitro Assay Development

AI is playing a pivotal role in the development of in vitro assays, enhancing their efficiency, accuracy, and reproducibility. AI algorithms can design and optimize assays by analysing large datasets to identify the most relevant parameters and conditions for assay robustness. AI tools can process and interpret complex data from in vitro assays, identifying patterns and correlations for a meaningful information, which might lead to more reliable and reproducible assay results.

AI-powered applications can analyse vast amount of data generated through high-throughput screening of compounds in a fraction of the time and enhances the speed and efficiency of screening process.

AI-Driven Drug Optimization

GANs and VAEs models are crucial for optimizing drug candidates by predicting how structural changes impact biological activity and safety. BenevolentAI uses these models to improve amyotrophic lateral sclerosis drug candidates, integrating knowledge graphs for better efficacy and safety. Exscientia's Centaur Chemist™ AI platform, with Sumitomo Dainippon Pharma, identified a novel OCD drug candidate in 12 months, accelerating the process. Insilico Medicine's Pharma.AI platform combines GANs and reinforcement learning to develop molecules for idiopathic pulmonary fibrosis, showing promising trial results. Atomwise's AtomNet®

employs deep learning for structure-based drug design, identifying Ebola virus inhibitors. DeepMind's AlphaFold has revolutionized drug development by predicting protein 3D structures in minutes, with AlphaFold 4.0 enhancing accuracy. Meanwhile, Chai-1 by Chai Discovery sets a new benchmark in molecular structure prediction, surpassing AlphaFold on several benchmarks and offering adaptability for small molecules, proteins, DNA, RNA, and chemical modifications, making it a crucial tool for precise drug development.

AI-Designed Molecules Making Clinical Advances

There are several examples which illustrate the impact of AI in drug discovery with rapid identification and optimisation of novel drug candidates for clinical trials. A few prominent examples include EXS-21546, an A2A receptor antagonist developed by Exscientia and Evotec for treating solid tumors with high adenosine signatures, which is currently in Phase 1/2 clinical trials. DSP-1181, a 5-HT1a agonist for obsessive-compulsive disorder, developed through a collaboration between Exscientia and Sumitomo Dainippon Pharma, has entered Phase 1 clinical trials. Another example is EXS-4318, a selective protein kinase C-theta inhibitor, which is in Phase 1 clinical trials. INS018-055, a TRAF2- and NCK-interacting kinase inhibitor for idiopathic pulmonary fibrosis, developed by Insilico Medicine, has progressed to Phase 2 clinical trials. Additionally, RLY-4008, a highly selective FGFR2 inhibitor for cholangiocarcinoma and other solid tumors, is currently in Phase 1/2 clinical trials. These developments highlight the growing influence of AI in advancing drug discovery.

Challenges and Collaborations in AI-Driven Drug Discovery

AI-driven drug discovery faces multiple challenges, though, it has potential to revolutionise drug discovery. The primary challenge lies in obtaining high-quality data necessary for developing a robust predictive tool. The use of AI raises serious concern on ethical issues, such as data privacy, consent and potential for constructing biased algorithms. The other operational challenge could be in unifying existing workflows and database to integrated AI tools.

To address these challenges and opportunities require continuous refinement, engagement and strong collaborations. A partnership between pharmaceutical companies and tech firms such as Evotec and Exscientia, resulted in the development of EXS-21546, now in clinical trials for solid tumors. A collaborative initiative like the open consortium unite stakeholders to share resources and drive innovation. An evaluation from Critical Assessment of Computational Methods for Protein Structure Prediction (CACHE) and Critical Assessment of Structure Prediction (CASP) are essential initiatives for differentiating between the reality and hype surrounding AI in drug discovery. These assessments are crucial for validating the effectiveness of AI-driven tools and ensuring that they provide practical, reliable results rather than just theoretical or over-hyped claims.

Future Prospects of AI in Drug Discovery

Despite the inherent challenges, AI is poised to play an increasingly pivotal role in drug discovery. An enhanced collaboration and data sharing through open consortia initiatives will further propel innovation in this field. There is a growing emphasis on developing ethical and regulatory frameworks to address data privacy, algorithmic bias, and accountability. The shift from theoretical research to practical applications will broaden AI's accessibility, significantly impacting therapeutic options and improved health outcomes. The future of AI in drug discovery promises substantial advancements, improving research efficiency and leading to more effective, personalized treatments. ■

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Charting a Course for India's API Renaissance: From Volume to Value

The pharmaceutical industry has long been a cornerstone of India's economic landscape, earning the country the moniker "pharmacy of the world". Our nation's prowess in generic drug manufacturing and vaccine production is well-documented, but a critical component of this success story often goes unnoticed: Active Pharmaceutical Ingredients (APIs). **Sethu Madhavan, Senior Vice President and Head-API , Granules India Limited** talks about challenges and opportunity for India's API market. He also emphasizes about the government initiatives for API sector.

For decades, India has been a formidable player in the global pharmaceutical arena. We account for 20% of global generic drug supply by volume and are the largest vaccine manufacturer globally. India's pharmaceutical narrative is one of resilience and reinvention. In the 1970s and 1980s, we were not just self-sufficient in API production; we were global leaders. Our scientists and entrepreneurs had mastered the art of reverse engineering, developing cost-effective processes for manufacturing APIs that the world relied upon. This era saw the rise of Indian pharmaceutical giants that would go on to become household names globally.

Challenges and Opportunities

However, the 1990s brought new challenges. The implementation of the Drug Price Control Order (DPCO) and the onslaught of cheaper imports, particularly from China, began to erode our API manufacturing base. Many Indian companies, facing intense price competition, shifted their focus to formulations and generic finished dosage forms, gradually ceding ground in API production.

Fast forward to the present day, and we find ourselves at a critical juncture. The COVID-19 pandemic laid bare the vulnerabilities in global supply chains, highlighting our

over-dependence on imported APIs. Our dependency on imported APIs, particularly from China, has been a cause for concern.

But every challenge presents an opportunity, and India's pharmaceutical sector is poised for a remarkable transformation. We are witnessing the dawn of an API renaissance in India, driven by a combination of government incentives and initiatives, industry innovation, and a renewed focus on selfreliance.

Government Initiatives Driving Change

The government's Production Linked Incentive (PLI) scheme, launched in 2021, has been a game changer for the API sector. With an outlay of ₹ 6,940 crore, the scheme aims to boost domestic production of 41 critical bulk drugs. As of January 2023, 51 projects have been selected for 34 notified bulk drugs, with 22 projects already commissioned. This initiative has catalysed investments of ₹ 2,019 crore and created 1,900 jobs in a short span, according to data from Invest India.

But the PLI scheme is just one piece of the puzzle. The government's vision extends beyond mere production incentives. The establishment of three bulk drug parks in Gujarat, Himachal Pradesh, and Andhra Pradesh is set to provide a consistent supply of bulk drug active components, ensuring India's drug security. These parks will offer state-of-the-art infrastructure, reducing manufacturing costs and enhancing competitiveness.

Industry Response and Market Growth

The industry's response to these initiatives has been overwhelmingly positive. The API market in India is on an upward trajectory, estimated to grow to $30 billion by 2028, constituting about 35% of the pharma market. This growth is not just about numbers; it represents a fundamental shift in our approach to pharmaceutical manufacturing. We are moving from being mere formulators to becoming end-to-end solution providers, controlling the entire value chain from API to finished dosage forms.

This shift is crucial for several reasons. Firstly, it enhances our control over quality and supply, critical factors in the pharmaceutical industry. Secondly, it positions Indian companies to capture a larger share of the value chain, boosting profitability and global competitiveness. Lastly, and perhaps most importantly, it paves the way for innovation in drug discovery and development.

Developing a focus on Complexity and Sustainability

An exciting development is the increasing focus on niche and complex APIs. While India has traditionally been strong in the production of simple, high-volume APIs, we are now seeing a shift towards more complex molecules. This move up the value chain is crucial for long-term sustainability and profitability in the API sector.

The focus on API manufacturing is also aligning with global trends towards sustainable and environmentally friendly production processes. Many Indian companies are investing in green chemistry initiatives, developing APIs through enzymatic processes, and adopting continuous flow chemistry.

These technologies will not only reduce our environmental footprint but also enhance efficiency and product quality.

The API renaissance is creating ripple effects across the pharmaceutical ecosystem. We're witnessing a surge in demand for skilled professionals in areas like process chemistry, analytical development, and regulatory affairs. This is not only creating employment opportunities but also fostering a culture of innovation and research in the industry.

However, the journey towards API self-reliance is not without its challenges. One of the primary hurdles is the cost competitiveness of Indian manufacturers compared to their Chinese counterparts. Years of government support and economies of scale have given Chinese manufacturers a significant cost advantage. Overcoming this will require sustained investment in technology, process optimisation, and scale.

Another challenge lies in developing the ecosystem for speciality chemicals and intermediates required for API production. While we're making strides in API manufacturing, true self-reliance will only come when we can produce these precursors domestically as well.

Future Outlook

Despite these challenges, the outlook for India's API sector remains overwhelmingly positive. The industry is expected to grow at a CAGR of 9-11% in the coming years, outpacing the overall pharmaceutical market growth. This growth will be driven by increasing domestic demand, export opportunities, and the shift towards more complex APIs.

As we look to the future, it's clear that the API sector will play a pivotal role in shaping India's pharmaceutical landscape. The focus on self-reliance doesn't mean isolation; rather, it's about building resilience and capabilities and network strategies that will allow us to engage more meaningfully in the global pharmaceutical value chain.

The government's vision of an 'Atmanirbhar Bharat' or self-reliant India finds perfect resonance in the API sector. By reducing our dependence on imports and building robust domestic capabilities, we're not just securing our drug supply; we're laying the foundation for India to become a true leader in global pharmaceutical innovation.

As we embark on this journey, collaboration will be key. We need closer cooperation between industry, academia, and government to create an ecosystem that fosters innovation and growth. We need to invest in skilling our workforce, modernising our regulatory framework, and building world-class infrastructure.

India's API renaissance is more than just an industrial trend; it's a transformative movement that has the potential to reshape our pharmaceutical industry and, by extension, global healthcare. As we build our capabilities in API manufacturing, we're not just reducing import dependence; we're creating new possibilities for innovation, sustainability, and growth.

The road ahead may be challenging, but the rewards are immense. With continued focus, investment, and innovation, I believe India can not only achieve self-reliance in API production but also emerge as a global leader in pharmaceutical innovation. The future of India's pharmaceutical industry is being written today, one API at a time, and it's a future filled with promise and potential. ■

Author

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Adverse Drug Reactions and Pharmacovigilance in India: Building on Opportunities

Adverse drug reactions (ADRs) are a significant public health concern worldwide, and India is no exception. With a vast population of over 1.3 billion people and a rapidly growing pharmaceutical industry, India faces unique challenges in ensuring drug safety. Pharmacovigilance, the science of detecting, assessing, and preventing ADRs, plays a crucial role in mitigating these risks. The Indian population's genetic diversity, combined with widespread use of polypharmacy and traditional medicines, increases the risk of ADRs.

Dr. Kausik Maiti, Executive Director,Safety Medical Sciences, Parexel India emphasizes about Adverse Drug Reactions and Pharmacovigilance in India. He also spoke about the Challenges facing Pharmacovigilance in India

Understanding Adverse Drug Reactions

Adverse Drug Reactions (ADRs) are unintended and potentially harmful responses to medications when used as prescribed for therapeutic purposes. These reactions can range from mild discomfort to severe, life-threatening conditions, and they represent a significant challenge in healthcare. The World Health Organization defines an ADR as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."

The incidence and severity of ADRs can vary due to several factors. Patient-related factors such as age, genetics, underlying health conditions, and lifestyle habits play a significant role. Similarly, drug-related factors including type, dosage, frequency of administration, and method of delivery influence the likelihood and severity of ADRs. Understanding ADRs is crucial for healthcare professionals to ensure patient safety, optimize treatment outcomes, and contribute to the ongoing process of pharmacovigilance, which aims to detect, assess, understand, and prevent adverse effects related to medicinal products.

Pharmacovigilance in India: Current Status

India has made significant strides in pharmacovigilance in recent years. The Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the aegis of Ministry of Health & Family Welfare, Government of India initiated a nation-wide pharmacovigilance programme in July 2010. The programme is coordinated by the Indian Pharmacopoeia Commission (IPC) and is supported by the Ministry of Health and Family Welfare. The mission of Pharmacovigilance Programme of India (PvPI) is to safeguard the health of the Indian population by ensuring that the benefit of use of medicine outweighs the risks associated with its use.

The PvPI has achieved several milestones, including:

- Establishment of 250 Adverse Drug Monitoring centres across the country
- Creation of a national database of ADRs, collaboration with WHO
- Development of guidelines for ADR reporting and management
- Conducting training programmes for healthcare professionals

Despite these achievements, challenges persist. ADR reporting rates remain low, and there is a need for increased awareness and training among healthcare professionals. In India, the magnitude of this issue is stark. Between April 2020 and March 2021, over 52,000 ADRs were reported, with more than 28% classified as serious events. However, these numbers likely represent only the tip of the iceberg due to significant underreporting.

Moreover, in the context of India, where traditional medicine systems coexist with modern pharmaceuticals, the scope of pharmacovigilance extends beyond conventional drugs to include herbal and traditional remedies.

Contributory Factors for this trend

In an era where access to health information is more convenient than ever, people turn towards online sources or non-professional recommendations for medications and treatment advice. On the parallel, self-medication with over-the-counter (OTC) medicines is becoming an increasingly popular and perilous practice. Furthermore, the trend extends more than this, the trend of sharing prescriptions and medications among friends and family or using leftover drugs aggravates the risk of adverse effects. Despite the desire to save time and money, self-medication can be far more harmful than anticipated.

Compounding the issue, some pharmacists in India contribute to the problem by prescribing medications without proper medical oversight. It is crucial to address these issues through widespread public awareness and innovation in healthcare to ensure safe and effective treatment practices.

The crucial role of pharmacists

In many countries, pharmacists play a crucial role in medication safety, acting as a final checkpoint before drugs reach patients. However, in India, their role is often diminished, with doctors frequently dispensing medications directly. Elevating the role of pharmacists in the medication use process could significantly enhance drug safety. Their expertise in drug interactions, dosing, and potential adverse effects complements that of physicians and can provide an additional layer of safety for patients.

Challenges in Pharmacovigilance in India

India's unique demographics and healthcare ecosystem present several formidable challenges. One of the most significant challenges facing pharmacovigilance in India is severe underreporting. The country's adverse drug reaction (ADR) reporting rate stands at a mere 1%, significantly lower than the global average of 5%. This stark disparity underscores an urgent need for heightened awareness and active participation from both healthcare providers and patients in reporting adverse events.

Another challenge is the vast genetic diversity of India's population. Genetic variations can profoundly influence how individuals respond to medications, making standardized approaches to drug safety challenging. This genetic diversity introduces a layer of complexity in predicting and managing ADRs.

Furthermore, resource constraints in many healthcare facilities, particularly in rural and semi-urban areas, hamper the implementation of robust pharmacovigilance practices. Inadequate infrastructure and a shortage of trained personnel limit the ability of these facilities to effectively monitor and report ADRs

To address these challenges, it is imperative to enhance ADR reporting rates, and strengthen pharmacovigilance infrastructure across the country. By doing so, India can improve drug safety and protect the health of its population.

Importance of Patient Engagement in Pharmacovigilance

The role of patients in reporting and preventing adverse drug reactions (ADRs) is increasingly recognized as a critical element of pharmacovigilance. Patient engagement and empowerment can greatly enhance medication safety, leading to improved health outcomes and a more robust healthcare system.

Patients play a vital role as independent reporters of ADRs, providing first-hand accounts of their experiences with medications. Their direct reporting can complement the information gathered from healthcare professionals, resulting in a more comprehensive understanding of drug safety. Furthermore, patient involvement in ADR reporting can enhance the detection of adverse reactions, especially for widely prescribed drugs or those used by specific populations. Patient-reported data can provide valuable insights. When patients report adverse events, they are not just sharing their experiences; they are contributing to the safety of future patients. Accurate and timely reporting of adverse events is crucial for identifying potential safety risks and taking appropriate action.

On the other hand, several barriers can impede effective patient reporting of ADRs. A significant challenge is the lack of awareness; many patients may not know they have the right to report ADRs or may be unaware of how to do so.

Additionally, patients may face difficulties in distinguishing between symptoms of their underlying conditions and ADRs, leading to underreporting and missed opportunities for detecting potential signals. Limited access to user-friendly reporting systems can also be a barrier. If existing reporting processes are perceived as cumbersome or time-consuming, patients may be discouraged from participating.

Addressing these barriers through targeted education and improved reporting mechanisms can enhance patient engagement and contribute to a more effective pharmacovigilance system.

Strengthening Pharmacovigilance in India and navigating the challenges

To improve drug safety in India and address existing challenges, several key strategies are essential. Enhancing ADR reporting mechanisms is critical; simplifying and expanding reporting channels and

mediums, through user-friendly mobile apps and helplines, can boost participation from healthcare professionals and patients alike.

Education and training also play a crucial role. Increasing awareness about pharmacovigilance among healthcare providers through targeted training programs is vital, and integrating this knowledge into medical and pharmacy curricula will help instill a culture of vigilance from the beginning of their careers.

Additionally, leveraging technology can significantly advance pharmacovigilance efforts. Implementing advanced tools like artificial intelligence and machine learning can enhance signal detection and data analysis, improving both efficiency and effectiveness. Finally, fostering collaboration among healthcare providers, pharmaceutical companies, research organizations, and regulatory bodies is necessary to create a comprehensive and responsive pharmacovigilance system.

Some examples of technology & scientific advancement that can be implemented in India contributing to improved patient safety, include:

- Artificial intelligence (AI) and machine learning: AI can process and analyse large amounts of data, identify potential safety signals, and automate case processing
- Natural language processing (NLP): NLP can interpret human language and extract data from unstructured sources like medical records and social media
- Big data analytics: Pharmacovigilance teams can use big data analytics to manage large amounts of data from various sources
- Wearable devices and remote monitoring: These devices are being used to monitor select patients regularly to help with pharmacovigilance
- National Digital Health Mission: This initiative aims to create a unified health database, which could significantly enhance ADR tracking and analysis.
- Pharmacogenomics Research: Investigating the genetic basis of ADRs in the Indian population could lead to more personalized and safer medication practices.
- Blockchain Technology: Implementing blockchain for secure and transparent ADR reporting and data management could enhance the integrity and efficiency of the pharmacovigilance system.

India's Path to Enhanced Drug Safety and Global Leadership

As India continues to grow as a global pharmaceutical powerhouse, the importance of robust pharmacovigilance cannot be overstated. By addressing the challenges of underreporting, enhancing regulatory frameworks, and fostering a culture of safety awareness among healthcare providers and patients, India can significantly reduce the burden of adverse drug reactions. This not only protects public health but also strengthens the reputation and reliability of India's pharmaceutical industry on the global stage.

The path to improved drug safety is complex, requiring sustained effort and collaboration across multiple sectors. However, with concerted action and a commitment to continuous improvement, India can build a pharmacovigilance ecosystem that effectively safeguards patient health and sets a standard for other developing nations to follow. ■

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Harnessing Data for a Smarter & Faster Biopharma Industry

In today's era of rapid scientific advancement, the biopharmaceutical industry plays a pivotal role in global health, navigating complex biochemical landscapes to develop life-saving therapies. **Ashok Kumar, Head of Bio4C Commercial – Asia Pacific, Merck Life Sciences - Bio4C** discussed how biopharma industry is likely to witness consistent growth in the years to come and brings new challenges in developing and commercializing innovative therapies.

From drug discovery to production scale-up and ensuring broad accessibility, biopharma companies are essential in building a healthier, safer, and more sustainable world. However, this path is fraught with challenges, including lengthy processes, stringent regulatory compliance, supply chain inconsistencies, and a deluge of data.

To meet evolving market demands—speed, agility, sustainability, value, and quality—the industry is undergoing a transformation. At the core of this shift is patient centricity, ensuring safety, efficacy, and access to quality therapies.

To overcome current and future challenges, biopharma companies are turning to automation and digital technologies like process automation, robotics, data analytics, artificial intelligence (AI), and machine learning (ML). These technologies optimize drug development, streamline manufacturing, and ultimately improve patient outcomes. The concept of Biopharma 4.0 encapsulates this transformation, envisioning an industry where digitalization and automation are fully integrated. However, achieving this vision requires a phased approach, with incremental milestones yielding tangible benefits along the way.

A key focus of this transformation is commercial manufacturing, which is not only the revenue engine but also critical for regulatory compliance. Despite significant investments in digital technologies, there is no standardized approach to implementation due to the complexity and variability of operations. Regardless of these differences, one constant remains: data is at the heart of operations. Manufacturers need to invest in right technology for automation and analytics to fully realize the potential of Biopharma 4.0, and companies must establish ecosystems to integrate disparate systems and processes to enable single source of truth for data. Companies must ensure this data is accurate, relevant, and actionable, transforming it into insights that drive timely, informed decisions. While advances in technology address parts of this issue, the real challenge lies in how effectively companies harness data science and analytics to deliver innovation across the entire value chain.

This raises a critical question: How can biopharma companies effectively manage and analyse the growing volumes of data from both digital and non-digital sources to generate insights and drive innovation?

Bio4C ProcessPad Software

To address the critical need of the industry Merck has released Bio4C ProcessPad Software and still investing in it to add further capabilities that

align with the evolving need of the industry. Bio4C ProcessPad Software as a potential solution to address the data management and analytics need of the biomanufacturers.

Bio4C ProcessPad Software is a data visualization, analytics, and process monitoring platform that enables bioprocess lifecycle management, reporting, investigations, and continued process verification (CPV). The solution intelligently combines process data from multiple sources like batches, Enterprise Resource Planning (ERP), Manufacturing Execution System (MES), Laboratory Information Management System (LIMS), process equipment, and manual sources into a single, validated data source.

Bio4C ProcessPad Software works by breaking down the intricate working of biopharma processes into 3 simple steps: acquire, aggregate, and analyse data. The process starts by collecting and managing information from various paper-based records, spreadsheets, batch records, quality control data, external databases, historians, and streaming machine data in a single software environment. This unrefined information is then automatically assembled into an analysis-ready format while maintaining the relationships that exist between batches, unit operations, and parameters. The output received is then visualized using advanced analytical tools for bioprocess analysis and easy reporting. With this process, Bio4C ProcessPad Software ensures that the data input and reports remain accurate, complete, and contextual throughout the product life cycle.

As a specially curated solution for the BioPharma industry, Bio4C ProcessPad Software provides data integration, analysis and sharing across the manufacturing network and end-to-end data management throughout the process validation lifecycle that successful continued process verification (CPV) requires. At one end biomanufactrerss can reply on out of the box capabilities of the Bio4C ProcessPad Software such as end to end management of CPV, APQR, and other end Bio4C ProcessPad Software also provides advance analytics capabilities such as MVDA based Process Health Monitoring and prediction.

Conclusion

According to a report, the global big data analytics market size was valued at USD 307.51 billion in 2023. The market is projected to grow from USD 348.21 billion in 2024 to USD 924.39 billion by 2032, exhibiting a CAGR of 13.0% during the forecast period. Since the use of data is still in its early phase in the biopharma industry, this growth, if embraced early, can empower pharma companies to stay ahead and function in an informed manner. Leveraging software capabilities like Bio4C will enable better consolidation and collaboration among different internal and external stakeholders by breaking the silos that separate internal functions and achieving better collaboration among teams. ■

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GUEST COLUMN

Transforming Biomanufacturing with AI: A New Era of Innovation

As digital innovation drives the business landscape, Artificial Intelligence (AI) is revolutionizing biomanufacturing, reshaping processes from drug design to regulatory compliance.

Dr. Ratnakar Palakodeti, President - Healthcare & Life Sciences, Innominds Software India Pvt. Ltd explores the profound impact of AI on biomanufacturing, highlighting its applications, industry trends, and the promising future that awaits as we embrace this ever-evolving technology.

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By optimizing resource use, enhancing product quality, and streamlining operations, AI is not only improving efficiency but also paving way for sustainable practices in the life sciences industry.

Artificial Intelligence (AI) is revolutionizing industries by developing advanced systems that analyze large datasets, identify patterns, and leverage insights for faster, more effective decision-making. The widespread adoption of AI today is a testimony to its ability to solving complex business challenges.

Biomanufacturing, the use of biological systems to produce commercially important biomaterials and biomolecules, is undergoing a paradigm shift with the integration of AI. Driven by Quality by Design (QBD), combining AI and real-time process modulation promises to enhance efficiency, improve product quality, and reduce costs, marking a new era for the life sciences sector.

Industry Trends and Insights

Sustainable Biomanufacturing: By optimizing resource use and minimizing waste, it reduces the environmental impact of production processes making biomanufacturing more sustainable. AI Algorithms facilitate efficient use of raw materials thereby lowering costs and increasing economic viability.

I**ntegration with Big Data:** The fusion of AI with big data analytics reveals hidden trends within biological datasets, facilitating innovation and efficiency. By tapping into these insights, biomanufacturers can improve product quality and consistency.

Precision Medicine: AI's ability to analyze complex biological data underpins the development of precision medicine, tailoring treatments to individual genetic profiles. This personalized approach not only enhances treatment efficacy but also informs the production of customized biologics, such as patient-specific cell therapies and personalized vaccines.

Here is a glimpse of how AI is making a significant impact on Biomanufacturing.

Applications of AI in Biomanufacturing

Protein Prediction and Drug Design: AI algorithms can accelerate drug discovery by accurately predicting protein sequences and structures. This capability is vital for designing new therapeutics and understanding disease mechanisms, ultimately speeding up the drug development pipeline.

Process Optimization

AI optimizes complex biological processes essential for creating life-saving therapeutics and vaccines. By analyzing data from sensors and control systems, AI enhances production cycles, reduces waste, and maintains consistent product quality.

Predictive Maintenance and Quality Control

AI plays a key role in predictive maintenance and quality control. By monitoring equipment performance, it helps minimize downtime and ensures product quality. Life Sciences companies can leverage analytics and powerful machine learning algorithms to foresee equipment failure and execute preventive maintenance.

Scalability and Automation: AI streamlines biomanufacturing by automating complex workflows and routine tasks such as sample preparation and data analysis. AI also assists in scaling up production processes to meet increasing demand optimize the design and operation of large-scale biomanufacturing facilities, ensuring efficient and cost-effective production.

Regulatory Compliance: Navigating regulatory landscapes can be complex and time-consuming, especially in the life sciences industry. AI can automate administrative tasks like data extraction, auditing, implementing regulations, and quality management and simplify the process for regulatory approvals.

"AI is the catalyst that will enable biomanufacturers to enhance quality, reduce costs, and drive innovation, setting the stage for a more sustainable and efficient future in life sciences."

Recent advancements in machine learning and deep learning have significantly contributed to the wider scope of AI implementation in biomanufacturing. Enhanced computational power and sophisticated algorithms enable the processing of vast datasets, leading to more accurate predictions and optimizations. Deep learning models analyze complex biological data, uncovering patterns that were previously untraceable. These insights can drive innovations in bioprocessing, from optimizing fermentation conditions to predicting product stability.

With a vision towards sustainable manufacturing, the government of India has released Bio E3 (Biotechnology for Economy, Environment and Employment), a pathbreaking bioeconomy policy for fostering high-performance biomanufacturing. The policy provides a framework for intensifying research and innovation, boosting domestics biomanufacturing capability, accelerating transition to AI-powered biomanufacturing by creating a convergence between biotechnology, engineering, and digitalization for building a more equitable and sustainable future.

The Way Forward

Despite its promise, AI integration in biomanufacturing faces challenges. The vast data generated across processes can be heterogeneous, complicating analysis and raising concerns about data privacy and security. However, the increasing availability of digitized data, advances in deep learning, and cross-industry collaboration can help overcome these barriers.

The global biomanufacturing market is projected to grow significantly, from $263 billion in 2019 to $570 billion by 2032, with next-gen biomanufacturing forecasted to reach USD 34.81 billion by 2031. This growth signals a shift towards increased productivity and cost-effectiveness. Looking ahead, AI has the potential to fully automate biomanufacturing facilities, where systems manage every aspect from input to output. As we stand on the brink of these advancements, the future of AI in biomanufacturing is indeed promising. ■

Advancing Radiology with AI: Transforming Diagnostic Precision

AI is rapidly transforming radiology, revolutionizing diagnostic imaging by improving workflows, increasing accuracy, and enhancing patient outcomes. As the demand for medical imaging services grows, the integration of AI-powered applications is becoming increasingly essential for radiology departments to meet the needs of both patients and healthcare professionals. **Kabir Mahajan, COO, Mahajan Imaging & Labs emphasizes** how AI-based technologies have emerged as vital tools that assist radiologists in streamlining image analysis, reducing the workload, and enabling faster, more precise diagnoses.

Radiology's data-driven nature makes it an ideal field for AI applications. From assisting with image reconstruction to automating routine tasks, AI is set to change how radiologists work, ensuring higher efficiency while maintaining diagnostic quality. This shift not only enhances the work of healthcare professionals but also significantly improves patient care by providing faster, more accurate results.

Optimizing Imaging Workflows with AI

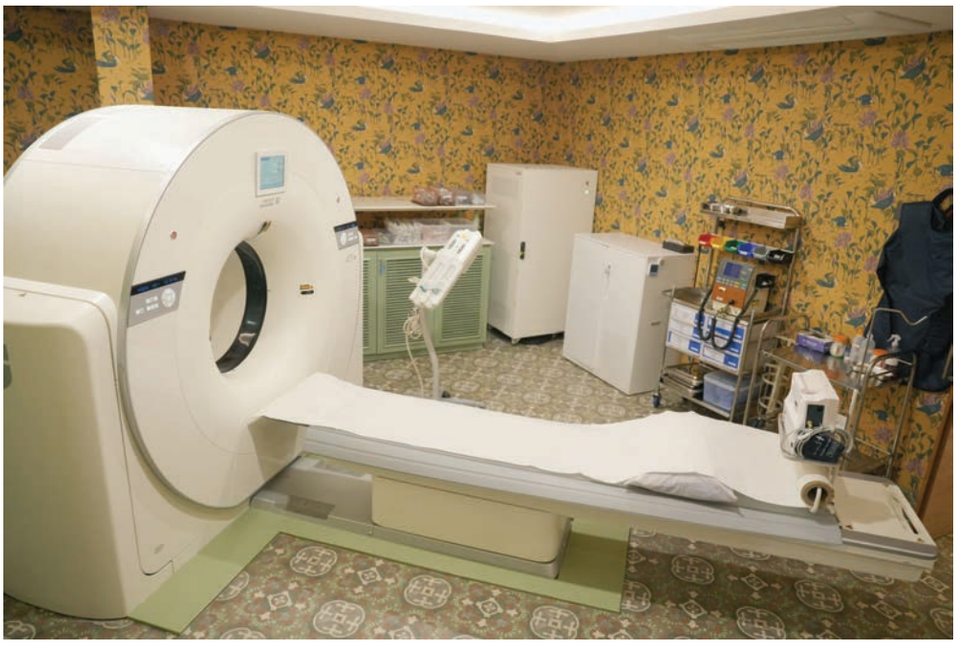
One of AI's most impactful contributions to radiology lies in optimizing imaging workflows. Medical imaging often requires a balance between image quality and time—particularly in modalities like magnetic resonance imaging (MRI) where higher image quality traditionally necessitates longer scan times. With AI-based deep learning techniques, high-quality images can now be reconstructed much faster, reducing scan times without compromising image detail. This innovation not only enhances the workflow but also improves patient comfort and reduces the need for repeat scans, which occur in about 20% of MRI exams. AI automates key aspects of radiology, from exam setup to patient positioning, improving precision and reducing human error. It accelerates diagnostics and enhances efficiency by triaging urgent cases, and flagging abnormalities in real-time for immediate attention.

Enhancing Diagnostic Accuracy with AI-Powered Imaging

AI enhances diagnostic accuracy by analyzing large volumes of imaging data, and detecting subtle abnormalities in complex modalities like CT or MRI that may be missed by radiologists. Trained on vast datasets, AI identifies patterns that improve the reliability of diagnoses, particularly in high-volume or time-sensitive cases. By assisting with routine imaging, AI allows radiologists to focus on complex cases. As AI technology evolves, it will further support clinicians in providing more personalized and precise patient care. By augmenting the radiologist's expertise, AI helps to reduce the rate of misdiagnosis and improves the overall reliability of diagnostic imaging.

Meeting the Growing Demand for Medical Imaging

The demand for medical imaging services has been growing steadily over the years. For instance, MRI procedures increased by 31% between 2007 and 2018, and X-ray imaging remains one of the most commonly used diagnostic tools, accounting for more than 80% of all imaging procedures in 2019. This increasing demand is straining radiology departments, making it essential for them to find ways to operate more efficiently without compromising diagnostic quality. AI-powered tools help radiology departments meet growing demand by automating routine tasks like anatomical positioning



and protocol selection, allowing radiologists to focus on patient care. These tools also standardize imaging protocols, ensuring consistency across machines and operators, and boosting overall efficiency.

Improving Operational Efficiencies in Radiology

AI is transforming healthcare operations by optimizing imaging equipment management and resource allocation. With predictive analytics, administrators can make informed decisions about equipment usage, staff allocation, and scheduling. AI-based digital tools centralize radiology operations, enabling image access across systems and supporting remote collaboration through cloud-based platforms. Additionally, AI helps manage equipment inventory, optimize maintenance, and track asset lifecycles, reducing costs and improving resource efficiency for a better patient experience.

AI as a Catalyst for Sustainable Radiology Practices

AI in radiology not only improves workflows but also drives long-term sustainability in healthcare. As adoption grows, radiology departments gain scalability and efficiency, enabling them to evolve with technological advancements. AI platforms help monitor performance, predict future needs, and create data-driven strategies, ensuring healthcare providers can manage increasing patient volumes and complex diagnostics more effectively

Conclusion

AI-powered tools are transforming radiology by reducing diagnosis time, managing workloads, and enhancing care quality. Their integration boosts efficiency, accuracy, and scalability, benefiting both healthcare professionals and patients. As AI evolves, its role in radiology will expand, making it essential for modern diagnostics. Radiologists and institutions adopting AI are driving medical innovation and improving healthcare outcomes. ■

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Elevate Performance to the Next Level
Harness the success and benefits from a combined QMM & Culture Programme

The disregard for a quality culture throughout a manufacturing facility can have significant impact and negative implications for a business and for patients. **Dr Samantha Atkinson, Executive Vice President, Principal Consultant, NSF Health Sciences** looks at how a positive quality culture can drive business success and ensure consistent supply of products to patients.

Quality Management Maturity (QMM)?

The U.S. Food and Drug Administration's (FDA) Quality Management Maturity (QMM) initiative is part of a broader effort to ensure the quality, reliability, and consistency of pharmaceutical products. The initiative was developed in response to recurring issues within the pharmaceutical supply chain, such as drug shortages and quality-related recalls, which can stem from quality and manufacturing disruptions.

Traditionally, compliance monitoring and regulatory oversight has been more reactive, focusing on adherence to regulatory requirements rather than proactively assessing the effectiveness and robustness of a manufacturer's quality management system. This initiative straddles organisational optimisation and quality culture, the latter being a relatively new area for Regulatory Authorities to venture into.

The concept of QMM is aimed at going beyond basic compliance with Good Manufacturing Practice (GMP). It focuses on assessing a manufacturer's capability to consistently produce high-quality drugs through a mature quality management system. This involves evaluating how well a manufacturer can anticipate and prevent potential quality issues and their ability to continuously improve processes. It also considers the way in which employees behave and interact with the embedded quality system – the organisation's quality culture.

One of the key goals of the QMM initiative is to encourage pharmaceutical organisations to adopt and maintain higher standards of quality management. The FDA aims to create incentives for manufacturers to invest in effective and robust quality systems. Potential benefits for manufacturers could include reduced inspection frequency, expedited review of drug applications, and other regulatory flexibilities.

The FDA continues to refine the QMM initiative. It is seen as a proactive approach to ensuring drug quality and availability, and it represents a shift towards a more holistic, risk-based approach to quality management.

NSF continues to follow in the footsteps of the FDA, providing its QMM Assessment Tool, which can be tailored to the organization. It aligns with the FDA model and includes areas of assessment across strategic, operational, and tactical areas of practice.

What are the links and benefits of Organisational Performance and Quality Culture

The link between culture and organizational performance is well-understood, with numerous studies and real-world examples demonstrating how a strong, positive culture can drive an organization's success.

Culture directly influences how employees feel about their work and their employer. A positive culture fosters a sense of belonging, engagement, and commitment among employees. Higher employee engagement leads to increased productivity, reduced turnover, and better customer service.

Furthermore, engaged employees tend to feel included and fairly treated. This is evident as a positive culture often ensures pushing decisions to the lowest level and empowering employees, it also ensures diverse input to problem solving or innovative initiatives. Innovation is critical for staying competitive. A culture that supports creativity can lead to the development of new products, services, or processes, driving growth and keeping the organization ahead of the curve.

A quality culture that emphasizes efficiency, accountability, and continuous improvement leads to better processes and workflows. When employees understand the importance of quality and performance, they are more likely to work efficiently, and indeed identify inefficiencies. This leads to cost savings, higher output, and better quality of products or services, which directly contributes to financial performance.

A strong quality culture helps organizations to be more quality focused, resilient in the face of challenges, and adaptable to change. Cultures that encourage flexibility, learning, and responsiveness can better navigate disruptions and are more likely to survive and thrive and maintain performance even in difficult times.

A quality culture that emphasizes integrity, ethics, and compliance ensures that employees act in ways that uphold the organization's values and regulatory obligations. This reduces the risk of regulatory issues, enhances the organization's reputation, builds trust with stakeholders, minimises supply disruption - all of which contribute to long-term success.

Why is a combined focus on Operational Optimisation and Quality Culture Maturity essential

The medicines supply chain is global, in which India plays a vital role, and supply challenges can there for be seen and felt around the world.

In the US, the American Society of Health System Pharmacists (ASHP) suggests healthcare professionals are concerned "due to the tremendous resources required to address shortages, estimated at $209 million," stating that shortages occur due to "manufacturing and quality problems, production delays and lack of manufacturing capacity, [and] manufacturer business decisions..."

In 2023, ASHP reported that "there were 309 active, ongoing drug shortages [in the U.S.] — the highest number in nearly a decade and close to the all-time high of 320 shortages."

At an organizational level, the Cost of Poor Quality (COPQ) can result in business and financial difficulties. Much research has been undertaken on the underlying causes and financial impact of quality issues.

Meyer provides a very simple and understandable definition of the COPQ as "any cost that would not be incurred if quality were perfect."

NSF's 2015 study suggested, when referring to COPQ, that in the "pharmaceutical industry, it is not uncommon for such costs to range between 25% and 40% of total sales revenue."

In 2019, the American Society for Quality reported that "many organizations will have true quality-related costs as high as 15%-20% of sales revenue, some going as high as 40% of total operations. A general rule of thumb is that costs of poor quality in a thriving organisation will be about 10%-15% of operations. Effective quality improvement programs can reduce this substantially, making a direct contribution to profits."

Improvements come with investment, organisation and culture optimisation comes as the changes are embedded, and costs reduce as an organization matures. Importantly, when an organization believes it has reached it's peak, it must not stop. Sustained savings and ongoing high performance are achieved though continuous improvement and dedication.

So, how do organizations enhance their maturity level

An organisation needs to take a stepwise approach, much like any good investigation:

- Identification and Recognition
- Analysis and Assessment
- Consideration of Root Cause(s)
- Develop & Implement a Corrective and Preventative Plan
- Monitor and Check Effectiveness

Sounds simple, and a process most will be familiar with, so why is it so hard to do?

It is not just about correcting a process and procedure, although this may also be necessary. It is about changing culture, mindset, the way the organisation works, looks and feels. Time and effort are needed as it is often not a quick fix. It must also be recognised that the organisation is not static – the investigation and maturity activities are ongoing at a time when the organisation is not only working, but continually evolving.

How to build in Quick Wins to a long-term Maturity Roadmap

It is important, following any investigation, to translate the findings into a comprehensive Maturity Roadmap of actions. Thought must be given to how this integrates with current quality processes (e.g. CAPA) and current business transformation initiatives. It is important to maintain both momentum and drive. It should also be recognised that organisations often go through a lot of change, so it is beneficial to spot, implement and celebrate quick wins and small successes, as well as the longer-term plans.

As an example, Data integrity is often identified as a key challenge when deploying QMM. A positive step can be to implement a data integrity maturity assessment as a critical first step to understand the organisation's maturity level of this key quality attribute. Once a baseline is established, the assessment can be repeated periodically to assess progress in data integrity maturity activities. There are often some relatively simple solutions to enhancing this area of data governance and control, along with actions for longer-term cultural adjustments. Quick wins can be rapidly evident with opportunity to celebrate success.

Data integrity remains a hot topic for Regulatory Authorities especially while regulatory non-compliances in this area remain ever-present. Regulatory Authorities are now focusing on data integrity governance system maturity, rather than program setup and implementation. The expectation is that appropriate and compliant governance systems are now embedded and in use.

To ensure success, NSF recommends a high-quality assessment tool for data integrity that closely aligns with the ISPE GAMP DI Maturity Model (RDI Guide Appendix M2) and that has been reviewed by regulatory bodies such as the MHRA and FDA.

Finally, to ensure long-term success, the leadership of the organisation must demonstrate sustained commitment, unwavering dedication to an aligned approach, robust and constructive challenge to minimise distractions, and rapid management of any activities that are out of alignment with the operational and culture transition. ■

Author

Dr Samantha Atkinson
Executive Vice President, Principal Consultant, NSF Health Sciences

Dr. Reddy's signs voluntary licensing agreement with Gilead Sciences

Deepak Sapra, CEO- API and Services, Dr. Reddy's Laboratories Ltd

Hyderabad India: Dr. Reddy's Laboratories Ltd. announced that it has entered into a royalty-free non-exclusive voluntary licensing agreement with Gilead Sciences Ireland UC for the manufacture and commercialisation of the drug, Lenacapavir, in India and 120 other countries.

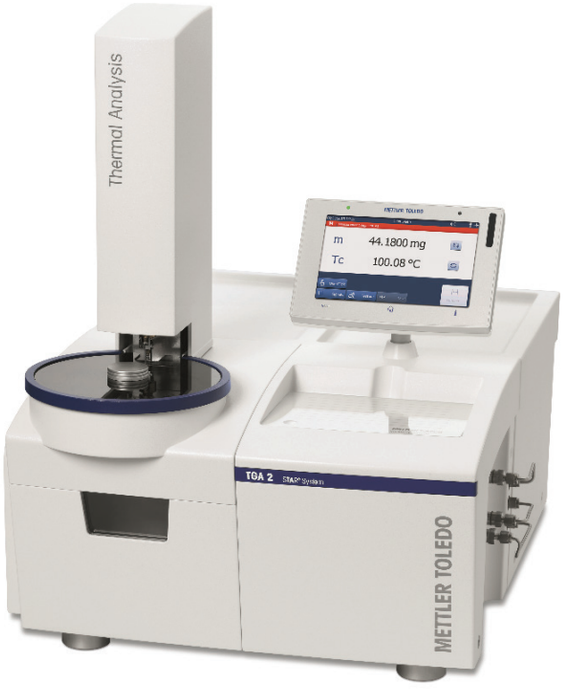
Lenacapavir is a United States Food and Drug Administration (USFDA) approved drug indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. Additionally, Lenacapavir is currently under investigation for the prevention of HIV (PrEP) which is yet to be approved globally.

Gilead Sciences first launched Lenacapavir under the brand name Sunlenca in the United States and Europe markets in the year 2022. It is a first-in-class HIV-1 capsid inhibitor.

Dr. Reddy's has been granted a non-exclusive voluntary licence to manufacture Lenacapavir and market it in 120 countries, for the current approved indication of HIV treatment in heavily treatment-experienced (HTE) adults with multi-drug resistant HIV. Dr. Reddy's will be responsible for technology transfer at its manufacturing site, conducting bioequivalence/clinical studies, product registration and launch in the agreed markets. Additionally, the agreement grants licence to Dr. Reddy's to manufacture and commercialise lenacapavir for the indication of prevention of HIV (PrEP) in 120 countries, if approved.

Deepak Sapra, Chief Executive Officer- API and Services, Dr. Reddy's Laboratories Ltd., said:"Lenacapavir marks an important milestone for Dr. Reddy's in patient access and affordability for pre and post exposure treatment of HIV. The collaboration with Gilead will help us make this latest treatment option available to patients in 120 primarily low- and lower-middle income countries, including in India. Many of these countries have a very high disease burden of HIV. This is an important endeavour in our journey to create impact on 1.5 billion patients by 2030." ■

Thermogravimetry for Routine Analysis: Unlocking Efficiency and Precision



In the realm of material characterization, thermogravimetry (TGA) stands out as a powerful analytical technique. By measuring the change in weight of a sample as it undergoes heating, cooling, or constant temperature holding, TGA provides invaluable insights into material composition. Industries such as plastics, elastomers, ceramics, and pharmaceuticals benefit greatly from TGA's ability to deliver fast, accurate results.

The Role of TGA in Routine Analysis

Thermogravimetry is particularly advantageous for routine analysis, where consistency and speed are essential. With its capacity to assess a wide variety of materials, TGA can streamline quality control processes, ensuring that products meet specified standards. Additionally, it allows for rapid screening of materials, facilitating research and development.

Advantages of METTLER TOLEDO TGA 2

The METTLER TOLEDO TGA 2 is designed to enhance the TGA experience for routine analysis, boasting a range of advanced features that prioritize accuracy and efficiency:

Ultra-Micro Balance Technology: Utilizing the market's leading balance technology ensures precise measurement, even with small samples.

High Resolution: With sub-microgram resolution across the entire weighing range, you can trust that your results are both accurate and reliable.

OneClick Functionality: Streamline your workflow with the OneClick feature, allowing you to initiate experiments at the touch of a button. This ease of use significantly speeds up routine operations.

Automatic Buoyancy Compensation: Eliminate the need for a blank measurement. The TGA 2 automatically corrects for buoyancy effects, allowing for quicker and more accurate results.

Robust Sample Robot: The factory-tested sample robot increases operational efficiency, enabling round-the-clock performance without compromising on reliability. Optimized Analysis with Controlled Atmosphere

The ability to define the furnace atmosphere precisely is crucial for obtaining high-quality results. Built-in mass flow controllers enable users to conduct analyses under various atmospheres, including vacuum, enhancing the versatility of the TGA 2. This controlled environment is essential for producing unambiguous data, leading to improved material characterization.

Hyphenated Techniques for Deeper Insights

For those seeking a more comprehensive understanding of their materials, the METTLER TOLEDO TGA 2 can be coupled with additional analytical techniques. Options include mass spectrometry (MS), FTIR spectrometry, and gas chromatography (GC/MS). These couplings allow for simultaneous analysis, saving time and providing a richer dataset from a single experiment. This integrated approach enhances material identification and compositional analysis, making it invaluable in both industrial and academic settings.

Simple Routine Operation

Efficiency in sample preparation is paramount for routine analysis. Accessories such as the crucible box and toolbox simplify the process, ensuring that everything remains organized. Furthermore, the optional CalPac set with certified weights allows for quick calibration, while the OneClick feature accelerates the initiation of routine measurements.

Conclusion

Thermogravimetry, particularly with the METTLER TOLEDO TGA 2, stands as a cornerstone for routine analysis across diverse industries. Its robust features, precision, and ease of use make it an essential tool for any laboratory focused on efficient material characterization. By investing in advanced TGA technology, organizations can ensure they maintain high-quality standards while streamlining their analytical processes, ultimately leading to better products and enhanced research outcomes.

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. ■

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

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

Respiratory Drug Delivery Asia 2024

Dates: 19-21st November, 2024
Venue: Grand Hyatt, Kochi, Kerala, India

Details: Respiratory Drug Delivery Asia expands US and European meetings into a key emerging market, offering updates on respiratory drug delivery while fostering academic collaboration and commercial development globally.

Contact: +1 804-239-1978
Email: info@rdonline.com
Website: www.rddonline.com

CPHI & PMEC India 2024

Dates: 26 - 28 Nov 2024
Venue: Greater Noida, New Delhi, India

Details: Connect with industry leaders in pharma machinery, technology, and ingredients to gain a competitive edge and drive business growth.

Contact: 9820720785
Email: Kanishka.Ahuja@informa.com
Website: www.cphi.com

International Pharmacology Conference & Annual Conference of Indian Pharmacological Society 2024

Dates: 28-29 Nov, 2024
Venue: New Delhi, India

Details: The conference aims to showcase current trends in pharmacology with the theme of Today's Research-Tomorrow's Medicine. AIIMS, New Delhi, a prestigious medical institution, will host the event, bringing together students, pharmacologists, clinicians, and leaders to discuss drug development and future perspectives.

Contact: 8171544655
Email: ipsaiims2024@gmail.com
Website: IPSCON 2024

International

Global Pharma and Biotech Summit 2024

Dates: 5-7th November 2024
Venue: London, UK

Details: The Global Pharma and Biotech Summit is the essential annual event for you to stay on top of the latest trends and innovations in life sciences. Industry leaders and experts will discuss what's new in areas such as drug discovery, clinical trials, market access and patient engagement.

Contact: +44 (0) 207 775 6653
Email: ftlive@ft.com
Website: www.pharma.live.ft.com

World Congress on Advanced Pharmacy and Clinical Research (WCAPCR-24)

Dates: 27 - 28 November 2024
Venue: Melbourne, Australia

Details: World Congress on Advanced Pharmacy and Clinical Research (WCAPCR-24), which is organized by Institute for Technical and Academic Research (ITAR) will offer researchers, delegates and scholars an incredible chance to interact with each other and share their experience and knowledge of technology application.

Contact: 8870915303
Email: info@itar.in
Website: www.itar.in

International congress on Drug Discovery and Pharmacy Practices (ICDDP-2024)

Dates: 12-13th November, 2024
Venue: Buenos Aires, Argentina

Details: The International congress on Drug Discovery and Pharmacy Practices (ICDDP) is organised by IARF. This event is set to provide a platform for researchers, scientists, and students to share new analytical and simulation methods, and scientific models in their fields.

Contact: 8754929172
Email: info@iarfconference.com
Website: www.iarfconference.com

International Conference on Biochemical Pharmacology and Clinical Pharmacy (ICBPCP-2024)

Dates: 14th November 2024
Venue: Medina, Saudi Arabia

Details: The aim of the Conference is to provide a platform to the researchers and practitioners from both academia as well as industry to meet the share cuttingedge development in the field.

Contact: 9789129171
Email: team@isar.org.in
Website: www.isar.org.in

International Conference on e- Health and Bioengineering 2024

Dates: 14-15th November 2024
Venue: Lasi, Romania

Details: The IEEE International Conference on e-Health and Bioengineering is a premier interdisciplinary event that highlights the latest advancements in e-health, bioengineering, and biomedical engineering. It unites experts across fields such as medical robotics, bioinformatics, medical informatics, and digital health to share and discuss innovative research and technologies. The conference aims to foster advancements in medical devices, biosignal processing, wearable systems, AI in medicine.

Contact: +40-7455 567 193
Email: gladiola.petroiu@bioinginerie.ro
Website: www.ehbconference.ro

Jefferies London Healthcare Conference 2024

Dates: 19-21st November 2024
Venue: London, UK

Details: The Jefferies London Healthcare Conference is the largest healthcare-dedicated conference in Europe. Our conference will again feature leading public and private companies from the pharmaceuticals, biotechnology, medical technology, and healthcare services sectors from the Americas, Europe, Middle East, Africa, Asia, and Australia.

Contact: (212) 284 2300
Email: mediacontact@jefferies.com
Website:ir.jefferies.com

Syntegon to Highlight Settle Plate Changer SPC 1000 at PACK EXPO International 2024

Syntegon, a leading provider of pharmaceutical packaging solutions and process technology, will be highlighting its innovative new patented Settle Plate Changer SPC 1000 at PACK EXPO International, to be held November 3-6, 2024 at McCormick Place, Chicago, IL, Booth W-16099. Also on display will be the GKF 60 R&D ProTect capsule filling machine and the Range Manual Assembly (RMA) machine, designed for small batches and clinical trials.

The Settle Plate Changer SPC 1000 on display won the German Packaging Award 2024 in the packaging machines category. It offers automated viable monitoring in the aseptic filling process, which reduces manual interventions for environmental monitoring by 80 percent. With its 24-hour operation, the SPC 1000 increases machine availability by up to three hundred hours per year. An energy-free adhesive gripper technology ensures precise handling of settle plates during production.

The Settle Plate Changer SPC 1000 features a standardized interface for transferring exposure data to upper layer systems. Optional barcode scanning offers increased process safety and traceability. The SPC 1000 helps customers comply with the latest EU GMP Annex 1 requirements for both new and existing equipment. Quick and easy retrofits are available for Syntegon machines as well as all other machine brands, types, and controls. ■

Thermo Fisher Scientific unveils pilot-scale 65-liter high shear granulator (HSG)

Thermo Fisher Scientific Inc. has unveiled New, pilot-scale 65-liter high shear granulator (HSG), which is part of the new HSG and fluid bed processing suite.

The company is expanding its oral solid dose (OSD) footprint with a $22-million total investment since 2021 in its Cincinnati, Ohio, and Bend, Ore. sites. Together, these expansions will enable research and development (R&D), manufacturing and testing of OSD drug formulations – doubling the Bend site's existing footprint and continuing a multi-year investment plan in Cincinnati – to bolster capabilities across the company's global Contract Development and Manufacturing Organization (CDMO) and Contract Research Organization (CRO) network.

OSD formulations have long been the most prescribed dosage form in the world and, today, make up 84% of all medications on the market due to storage stability and ease of administration. To meet the increasing demand for small molecule OSD solutions, Cincinnati adds dedicated flexible R&D space, supporting pre-clinical early development of OSD formulations through rapid project initiation and the use of next-generation technologies for data-informed decision-making, which can solve for drug development challenges and help companies avoid costly trial-and-error cycles.

The Bend expansion is focused on R&D manufacturing and testing, including bench and pilot scale spray drying, hot-melt extrusion and dry granulation. These additions to the site bolster capabilities at the company's center of excellence for early development and advanced drug delivery, including solubility and bioavailability enhancement solutions and digital modeling. These capabilities address some of the largest challenges for pharma and biotech customers to help accelerate pre-clinical oral drug product development and reduce timelines to GMP production of clinical trial materials. ■

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ChemTECH WORLD EXPO 2026

SPECIALTY ChemiCAL WORLD EXPO 2026

Bio Pharma World Expo 2026

32nd International Exhibition and Conferences

3-6 February 2026

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

Concurrent Events

EPC 2026 | Specialty ChemiCAL | Refining & Petro Chemicals 2026 | Bio Pharma | Industry Automation & Control 2026 | PVF | WaterEX WORLD EXPO 2026 | Surface Engineering Coating & Corrosion WORLD EXPO 2026 | Chlor-Alkali World Expo & Conferences 2026

Scope for ChemTECH World Expo 2026

- Plant Machinery & Industrial Consumables
- Engineering Consultants
- OEMs for Chemicals & Pharmaceutical Processing Equipment
- Metals & Metallurgy
- Bioprocessing Equipment
- Construction Services Providers
- Plant Maintenance Services Providers
- Logistics & Supply Chain Solutions Providers
- Instrumentation & Process Control
- Industry Automation (Process & Factory)
- Systems Integration & ERP Solutions Providers
- Water & Waste Water Treatment Consultants
- Environment Solutions Providers
- Waste Management Consultants
- Financial Institutions
- Fire & Safety Solutions Providers
- Material Handling Solutions
- Certification Bodies
- Welding Solutions
- Quality Health & Environment Solutions
- Analytical & Laboratory
- Packaging Materials, Machinery & Systems
- Business Consultants

Scope for Specialty Chemicals World Expo 2026

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

Scope for Biopharma World Expo 2026

- Materials Processing
- Pharma Machinery
- Pharma Ingredients
- Plant Engineering, Process Plants & Equipment
- Laboratory & Analytical Solutions
- Process Measurement & Inspection
- Sterilization & Clean Room Solutions
- Biopharma R&D And Manufacturing
- IT Solutions
- Water & Waste Treatment Solutions

FACT & FIGURES 2024

- **750** EXHIBITORS FROM 15+ COUNTRIES
- **25871** VISITORS FROM 53 COUNTRIES
- **8** TECHNICAL CONFERENCES
- **250+** GLOBAL SPEAKERS
- **1500+** BUSINESS DELEGATES
- **2500+** ENGINEERING PHARMA & SCIENCE STUDENTS AT STUDENT OUTREACH PROGRAM FROM 28 STATES & UNION TERRITORIES
- SCALE@CHEMTECH World Expo 2024: 60+ GLOBAL CLIMATE TECH STARTUPS FROM 20 COUNTRIES; 40 TECHNICAL PRESENTATIONS
- BRICS WORKING GROUP BRAIN STORMING SESSION

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R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month. Poster Registration No: MCS/207/2023-25
Posted at Patrika Channel Sorting Office, Mumbai 400001. On 27th every month. Total Pages 50

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HIGHLIGHTS OF BIO-PHARMA WORLD EXPO 2024

Bio Pharma World Expo 2024

NAVIGATING THE PATH TO LEADERSHIP IN BIOPHARMA EXCELLENCE

(L to R) Guest of Honour Dr Krishna Ella , Executive Chairman, Bharat Biotech International Ltd, Prof (Dr) Samir Kulkarni , Head, Department of Biological Sciences & Biotechnology, Coordinator, DBT – ICT Centre, Dr Rajesh Gokhale, Secretary , DBT, Ministry of Science & Technology, Govt. of India & Chief Guest, Mr Suresh Prabhu Former Union Minister, Govt. of India & Chief Patron & Brand Ambassador, ChemTECH World Expo 2024

Biotech is one of the fastest-growing industries in the world right now, especially in India. The Indian bioeconomy registered a remarkable 28% growth in 2022. The past three years have been enormously successful, especially considering the challenges posed by the COVID-19 pandemic. The Indian bioeconomy is forecasted to reach USD 300 billion by 2030, a significant increase from its current valuation of USD 140 billion, which constitutes 4% of the total GDP of our country's growth. The BioPharma industry contributes approximately 43% to the economy and extends beyond pills; it encompasses aspects of healthcare, wellbeing, and cognitive enhancement. To capitalize on green growth and the bio economy, we are establishing Bio enablers in the form of Bio manufacturing hubs through Public-Private Partnerships.

Dr Rajesh Gokhale
Secretary, DBT, Ministry of Science & Technology, Govt. of India

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