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PM Narendra Modi inaugurates Lyfius Pharma's Penicillin-G Facility at Kakinada, Andhra Pradesh

Mumbai, India: Lyfius Pharma announces the inauguration of its state-of-the-art Pen- G manufacturing facility, at Kakinada, Andhra Pradesh. With an annual production capacity of 15,000 metric tonnes (MT), the facility was virtually inaugurated by Hon'ble Prime Minister Shri. Narendra Modi in the presence of Shri. Jagat Prakash Nadda (Union Minister of Chemicals & Fertilizers, Health & Family Welfare), Dr. Mansukh Mandaviya (Union Minister of Labour & Employment, Youth Affairs & Sports), Anupriya Patel (Union MoS Chemicals & Fertilizers, Health & Family Welfare), Prataprao Jadhav (Union MoS (IC) Ayush, MoS Health & Family Welfare) and Sushri Shobha Karandlaje (Union MoS Labour & Employment, Micro, Small & Medium Enterprises).

This facility represents a strategic investment of ₹2,500 crores, under the Government of India's PLI Scheme, and exemplifies how private sector participation can significantly contribute to national growth, drive innovation, and enhance healthcare security. The PLI scheme for the pharmaceutical sector aims to strengthen domestic manufacturing capabilities in critical KSMs, DIs, and APIs.

M.V. Rama Krishna, Director Lyfius Pharma, said "The launch of our Pen- G facility is a significant milestone in our efforts to enhance local production and reduce import dependency for critical pharmaceutical ingredients. This investment underscores our commitment to support the government's vision of 'Atmanirbhar Bharat', establishing India as a global pharmaceutical manufacturing hub."

Dr. Rajesh Gokhale highlighted BRIC's significant role in enhancing the value of biotechnology research

New Delhi, India: With Cabinet approval, the Department of Biotechnology (DBT), Ministry of Science and Technology created, Biotechnology Research and Innovation Council (BRIC) by subsuming the 14 Autonomous Institutions (AIs) on 10th November, 2023. Under the exemplary leadership and vision of the Minister of State (IC) for Science & Technology, Dr. Jitendra Singh, BRIC is pivotal in driving excellence and innovation in biotech sector.

The first foundation day of BRIC was celebrated at BRIC-National Institute of Immunology (NII) on 9th – 10th November, 2024. Shri Amitabh Kant, India's G20 Sherpa was the Guest of Honor for the event and also delivered the foundation day lecture. Dr Anand Deshpande, Persistent Systems was the Special Guest. Dr. Rajesh S Gokhale, Secretary, Department of Biotechnology and DG BRIC, Directors of iBRIC and Officials from DBT and BIRAC, researchers and students from various iBRIC Institutions participated.

On 9th November, 2024, a competition named as "Race from Science to Entrepreneurship (RaSE) was organized to encourage young talent pool being nurtured in iBRIC+ institutes to develop their entrepreneurial skills by exposing them to issues involved in commercialization of biosciences especially in the thematic areas mentioned in BioE3 (Biotechnology for Economy, Environment and Employment) Policy. Students from all the fifteen iBRIC+ Institutes participated in the Competition.

BRIC has been instrumental in bringing together scientists and researchers across the institutions and is expected to achieve laudable outcomes for catapulting the Indian Biotechnology sector.

Speaking at the occasion Dr Gokhale mentioned that "BRIC is playing a pivotal role in enhancing the value and impact both in the context of bringing research synergy, enhancing and transforming the power of Science, Technology and Innovation". Guest of Honor Sh Amitabh Kant appreciated the efforts of the Department and mentioned that "BRIC would be a landmark institution for the country".

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Modi 3.0 "science push" aimed at realising "Viksit Bharat": Dr Jitendra Singh

Union Minister, Dr. Jitendra Singh

New Delhi, India: Union Minister Dr. Jitendra Singh laid out the government's bold and strategic vision for India's science and technology sectors and said that Modi 3.0 "science push" is aimed at realising "Viksit Bharat".

From launching a ₹1,000 crore venture capital fund to support Space StartUps to introducing the Bio E3 policy aimed at creating a bioeconomy, the Modi government's major initiatives in the first 100 days of its third term signify its commitment to advancing India's role on the global innovation stage, the Minister said.

The Minister highlighted that these initiatives not only bolster India's scientific prowess but also contribute to a sustainable, self-reliant economy that can withstand global shifts in industry and resources.

Dr. Jitendra Singh opened by emphasizing the speed at which India has embraced major reforms in science and technology. "In the first 100 days of Prime Minister Modi's third term, we have laid the groundwork for transformative changes in science, technology, and innovation," he said. He pointed out that the Prime Minister's vision prioritises long-term, out-of-the-box initiatives to ensure India's leadership in critical domains like biotechnology, and meteorology.With the Bio E3 policy, Dr. Jitendra Singh underscored a vision for a "bio-driven" future, asserting that the next industrial revolution will stem from bioeconomy initiatives rather than traditional manufacturing.

Dr. Jitendra Singh closed by emphasizing that the government's science and technology initiatives are rooted in a commitment to self-reliance and global leadership. By strategically investing in space and biotechnology, India is not only fostering economic growth but also aligning with the sustainable goals needed to tackle future challenges. These policies, he asserted, reflect the country's ambition to lead in domains that impact both economic resilience and the well-being of the public.

Telangana emerges as a Global Life Sciences Hub with Over ₹ 36,000 crores in investments

Hyderabad, India: In a remarkable testament to Telangana's growing prominence on the world stage, the state government announced unprecedented progress in the life sciences sector, securing over ₹ 36,000 crores in investments from over 140 projects over the last year. These investments are set to create 51,000 direct jobs and an estimated 1,50,000 indirect jobs, solidifying Telangana's status as a powerhouse in the global life sciences industry.

Speaking on the state's achievements, Hon'ble Minister for Industries and Commerce, Shri Duddilla Sridhar Babu, highlighted that Telangana has become a focal point for both international and domestic life sciences companies, with Hyderabad serving as the epicenter for innovation. The minister attributed this rapid growth to the proactive, business-friendly policies championed by the Hon'ble Chief Minister and the government's strategic focus on life sciences and healthcare.

Shri Duddilla Sridhar Babu Minister of Industries and Commerce, Government of Telangana said, "We have witnessed a surge of investments from several international and domestic companies, who have chosen Telangana as their gateway to India's rapidly growing life sciences ecosystem. This momentum not only includes significant investments from new entrants but also additional investments by companies that have already seen the value in expanding in Telangana."

This upcoming policy is designed to address the evolving needs of the life sciences industry, ensuring Telangana consolidates its position as an important node in the global life sciences value chain.

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WHO prequalifies Zydus's Typhoid Vi Conjugate Vaccine, ZyVac TCV

Ahmedabad, India: Zydus Lifesciences Limited has received in principle acceptability from World Health Organisation (WHO) for ZyVac® TCV. ZyVac® TCV is now eligible for purchase by United Nations (UN) agencies. ZyVac® TCV is indigenously developed and manufactured at the Zydus Biotech Park, Ahmedabad.

ZyVac® TCV is indicated for active immunization against Salmonella typhi infection in the age group of 6 months to 65 years. This prequalification for ZyVac® TCV makes it eligible to be part of UN agencies procurement programme. Annually over 150 million doses of the typhoid conjugate vaccine is procured by UN agencies to prevent this infectious disease in geographies where it is most prevalent, such as India, Africa and Southeast Asia.

Typhoid fever is systemic febrile illness caused by ingestion of the bacterium Salmonella enterica serovar typhi (S. typhi) through contaminated water and food. In South Asian region, India alone contributes for 75% of incidence and mortality due to typhoid fever. As per GAVI (2022) it is estimated that Typhoid accounts for an estimated 11 to 21 million cases of febrile illness and 117,000 to 161,000 deaths are attributed to the disease each year.

Indian pharmaceutical market continues to deliver mid-single digit growth

Mumbai, India: India Ratings and Research highlights that the Indian pharmaceutical market (IPM) continued to deliver mid-single digit growth for the last three consecutive months at 5.3% in September 2024 (August 2024: 6.3%; September 2023: 2.4% yoy; source: AIOCD-AWACS), on account of price growth (5.3% yoy) and new launches (2.4% yoy), while the volume growth (negative 2.4% yoy) remained weak.

Key therapies such as cardiac (9%), anti-infectives (6%), anti-diabetic (6%), and central nervous system (CNS; 10%) outperformed the IPM growth, while gastro (3.0%), vitamins (3%), and respiratory (negative 2%) recorded lower growth in September 2024. During January to September 2024, the IPM reported average growth of 7.7% yoy (monthly) with average volume growing negative 0.9% yoy. The agency expects the IPM growth to be 8%-9% yoy in FY25 (FY24: 6.5% yoy; FY23: 9.9% yoy).

"Over the past 12 months, the IPM reported mid-single digit growth, primarily driven by the growth in price and new launches but the volume growth remained a challenge. The rating agency expects the IPM growth to be at 8%-9% yoy for FY25," says Vivek Jain, Director, Corporate Ratings, India-Ratings. The domestic formulations business under Ind-Ra's coverage has yet to report its 2QFY25 performance. India Ratings highlights that it delivered healthy revenue growth at 10.5% yoy in 1QFY25 (4QFY24: 10.6% yoy), on account of growth in the key therapies such as cardiac, gastro-intestinal, anti-infective and anti-diabetic. The agency highlights that India business accounted for around 45% of the coverage companies over FY19-FY24.

Lupin launches First Generic of Pred Forte in US


Vinita Gupta, CEO, Lupin

Mumbai, Naples: Global pharma major Lupin Limited announced the launch of the first generic version of Pred Forte® (Prednisolone Acetate) Ophthalmic Suspension USP, 1% in the United States. Being the first generic to be approved and launched, the company is entitled to 180-day competitive generic therapy (CGT) exclusivity. Prednisolone Acetate Ophthalmic Suspension USP, 1% is a generic equivalent of Pred Forte Ophthalmic Suspension, 1% of AbbVie, Inc. and is indicated for the treatment of steroidresponsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe. Pred Forte had estimated annual sales of USD 198 million in the U.S. (IQVIA MAT August 2024).

"The launch of Prednisolone Acetate Ophthalmic Suspension is a milestone and is aligned with our commitment to enhancing access to innovative, affordable and quality healthcare solutions," said Vinita Gupta, CEO, Lupin. "This will strengthen our ophthalmic portfolio and will benefit patients seeking effective treatment for steroid-responsive inflammation."

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Ichnos Glenmark Innovation announces First Presentation of Data from Phase 1 Study of the Trispecific ISB 2001

New York: New York headquartered, Ichnos Glenmark Innovation (IGI), a global fully-integrated clinical-stage biotech company developing multispecifics in oncology announced today that it will present first-time data from its Phase 1 study of ISB 2001 in an oral presentation at the 66th American Society of Hematology (ASH) Annual Meeting in San Diego, CA. ISB 2001 is IGI's first-in-class trispecific antibody targeting BCMA and CD38 on myeloma cells and CD3 on T cells, currently investigated in relapsed/refractory multiple myeloma (r/r MM).

"Although recent advancements have brought new therapeutic options to multiple myeloma patients, resistance mechanisms continue to limit their efficacy, necessitating multiple lines of treatment for many patients," said Lida Pacaud, M.D., Chief Medical Officer at IGI. "We are encouraged by the early data from our Phase 1 study of ISB 2001, which shows a remarkable response rate and demonstrates potential to address these challenges in heavily pretreated patients."

Rubicon Research gets SEBI nod for IPO

Mumbai, India: Rubicon Research Ltd has received market regulator Securities and Exchange Board of India ("SEBI") nod for IPO launch. The company's Initial Public Offering (IPO) is a combination of a fresh issue of equity shares worth Rs 500 crore and an Offer For Sale (OFS) of shares valued at Rs 585 crore by promoter, General Atlantic Singapore RR Pte Limited, according to the Draft Red Herring Prospectus (DRHP) filed in July 2024.

The company proposes to utilise proceeds from the fresh issue to the tune of Rs 310 crore for payment of debt. Also, funds will be used for supporting inorganic growth through unidentified acquisitions as well as other strategic initiatives and general corporate purposes.

Rubicon Research is a pharmaceutical formulations company, driven by innovation through focused research and development, with an increasing portfolio of speciality products and drug-device combination products targeting regulated markets and in particular the United States.

As on March 31, 2024, Rubicon Research had a portfolio of 69 products approved by the USFDA, 19 new drugs awaiting USFDA's nod and 46 products in various stages of development. Axis Capital, IIFL Securities, JM Financial and SBI Capital Markets are the book running lead managers to the issue.

Medicamen Organics enters French West African market

New Delhi, India: Medicamen Organics Limited (MOL), a leading Indian pharmaceutical company, has announced its entry into the French West African (FWA) market through a new strategic partnership. The company signed a Memorandum of Understanding (MOU) with Vaibhav Kashinath Chaudhari (VKC) and Mistycube Analytics (MA), paving the way for the formation of a new entity, Grande Etoile Pharmaceuticals Ltd. (GEPL). This collaboration is set to expand MOL's reach into key markets across Senegal, Mali, Ivory Coast, and other FWA nations.

Under the terms of the MOU, MOL will hold a 51% stake in GEPL, with a capital investment of ₹5 crores. The new venture will focus on establishing a robust distribution network for pharmaceutical products in the region. GEPL plans to register products across FWA markets and source additional products from various manufacturers to meet local demand.

Ashutosh Gupta, Whole-time Director of Medicamen Organics, emphasized the significance of this move, stating, "This partnership is a key step in Medicamen's long-term strategy to penetrate emerging markets, particularly in French West Africa, where we see immense growth potential."

Vaibhav Kashinath Chaudhari, who brings a wealth of experience in African markets, said, "This collaboration allows us to leverage our knowledge of the local market and scale operations effectively."

Harsh Mittal, Proprietor of Mistycube Analytics, added, "Our expertise in data analytics and team management will play a crucial role in optimizing operations for Grande Etoile Pharmaceuticals in these regions."

Alkem Laboratories signs licensing agreement with US-based Sonnet BioTherapeutics


Dr. Akhilesh Sharma, President and CMO, Alkem

Mumbai, India: Alkem Laboratories Ltd. has entered into a licensing agreement with US-based Sonnet BioTherapeutics Holdings, Inc ("Sonnet") to develop, manufacture and commercialise the drug candidate "SON-080" for the treatment of diabetic peripheral neuropathy in India.

"SON-080" is Sonnet's proprietary version of "atexakin alfa". It has shown encouraging data in phase 1b clinical trial. The drug candidate was demonstrated to be well-tolerated and the pain and quality of life survey results suggested a potential for rapid improvement of peripheral neuropathy symptoms and post-dosing durability, compared to placebo controls.

Under the licensing agreement, Alkem will carry out the clinical development of "SON-080"in India with support from Sonnet and enable global and India regulatory filings. Alkem has exclusive rights to develop, manufacture and commercialise the drug in India.

Dr. Akhilesh Sharma, President and Chief Medical Officer of Alkem said, "We are pleased to partner with Sonnet for this programme. We believe "SON-080" is a unique asset that has demonstrated promising disease modifying potential for diabetic peripheral neuropathy withtranslational studies showing nerve regeneration. There is a large prevalence of diabetic peripheral neuropathy in India, which we believe underscores the need for the drug development in this territory and potential value."

Aurobindo Pharma arm receives EMA Nod for Biosimilar facility

Hyderabad, India: CuraTeQ Biologics Private Limited, a wholly owned subsidiary of Aurobindo Pharma Limited, has received a GMP certificate of compliance for its biosimilars manufacturing facility from the EMA. The GMP inspection, conducted by EMA representatives from April 8th to April 12th, 2024, assessed mammalian and microbial drug substance manufacturing facility sections, prefilled syringes and vials filling, packaging, and QC testing and release laboratories.

Dr. Satakarni Makkapati, Director of Aurobindo Pharma Limited and CEO of Biologics, Vaccines, and Peptides, stated, "The EU GMP certification marks a significant milestone in CuraTeQ's commitment to manufacturing high-quality biosimilars for patients worldwide. This inspection outcome paves way for securing approvals for our three biosimilars in Europe, currently under review by the Agency, within the next two to five months."

K. Nithyananda Reddy, Vice-Chairman and Managing Director of Aurobindo Pharma Limited, added, "Our portfolio comprises fourteen biosimilars in development across oncology and immunology segments. We are dedicated to building a sustainable biosimilars portfolio and bringing these essential therapies to patients."

Granules India's Unit V Facility Secures US FDA EIR with 'No Action Indicated' Status


Dr. Krishna Prasad Chigurupati, CMD, Granules India

Mumbai, India: Granules India Limited, a leading pharmaceutical manufacturing company, is pleased to announce that it has received an Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA) for its Unit V facility located at Jawaharlal Nehru Pharma City (JNPC), Anakapalli District, Parawada Mandal, Andhra Pradesh. This follows an inspection conducted by the US FDA from April 8 to April 12, 2024.

The US FDA inspection classified the facility as "No Action Indicated" (NAI), indicating compliance with current Good Manufacturing Practices (cGMP) standards and confirming that no further regulatory action is required. This outcome reflects the facility's high standards in the production of Active Pharmaceutical Ingredients (APIs) and Finished Dosages(FDs) for both oncology and non-oncology therapeutic areas.

During the inspection, the FDA conducted a comprehensive Pre-Approval Inspection (PAI) and cGMP audit, which concluded with zero Form

483 observations, underscoring Granules India's commitment to stringent quality control, regulatory compliance, and operational excellence.

"The successful completion of this US FDA inspection with zero observations and the subsequent receipt of the EIR with NAI status reflects our unwavering commitment to maintaining the highest quality standards in our manufacturing operations," said Dr. Krishna Prasad Chigurupati, Chairman & Managing Director.

Granules India's Unit V facility plays a pivotal role in the company's mission to deliver high-quality and accessible pharmaceuticals globally by prioritizing regulatory compliance, operational excellence, and value delivery to stakeholders. The company remains dedicated to producing top-quality pharmaceutical products that meet global health standards.

Novel molecules Developed to treat Alzheimer's Disease

New Delhi, India: Scientists have designed and synthesized novel molecules through a blend of synthetic, computational, and in-vitro studies for treating Alzheimer's Disease (AD). These non-toxic molecules could be effective in the treatment of the disease.

Neurons are specialized cells in the brain that form the nervous system. The nervous system communicates between the brain and the rest of the body. Alzheimer's disease (AD) disrupts this communication, causing limitations in learning and memory and changes in adaptive behaviour. AD occurs due to an imbalance in certain hormones.

AD is the most common form of dementia and constitutes around 75% of all dementia cases. Of the about 55 million people worldwide with dementia, 60% to 70% are estimated to have AD. The disease most commonly affects people over the age of 65. The causes mainly include a combination of age-related brain changes and genetic, environmental, and lifestyle factors. The treatment may be able to slow dementia and improve quality of life, but these conditions are progressive, and symptoms of the disease worsen over time.

To date, treatment options available to cure AD are limited to one N-methyl-D-aspartate receptor antagonist (Memantine) and three anti-cholinesterase drugs (Donepezil, Rivastigmine, Galantamine). However, approved anti-cholinesterase drugs suffer from limitations of short-term benefits and serious side effects that restrict their clinical applications.

Recently, Dr. Prasad Kulkarni and Dr. Vinod Ugale (SERB TARE Fellow), scientists from Agharkar Research Institute, Pune, an autonomous institute of Department of Science and Technology, have developed a rapid one-pot, three-component reaction with high synthetic yields to generate novel molecules.

Venus Remedies expands reach in ASEAN region

Saransh Chaudhary, President, Global Critical Care, Venus Remedies

Mumbai, India: Venus Remedies Limited, a leading exporter of affordable generic drugs with presence in more than 80 countries, has achieved a major regulatory milestone by receiving Good Manufacturing Practices (GMP) approval with Pharmaceutical Inspection Co-operation Scheme (PIC/S) accreditation from the National Pharmaceutical Regulatory Agency (NPRA) of Malaysia for its state-of-the-art robotic pre-filled syringe (PFS) facility at its Baddi unit.

This marks the first PIC/S GMP accreditation for Venus Remedies' PFS facility, adding to the GMPs already secured by the company from more than 25 regulatory authorities, including the WHO, European Union and Saudi Arabia. The company has more than 35 marketing authorisations for its flagship PFS drug, enoxaparin, from various important markets like Saudi Arabia, Azerbaijan, Philippines, Myanmar, Kenya, Moldova, and Nepal.

Saransh Chaudhary, President, Global Critical Care, Venus Remedies and CEO, Venus Medicine Research Centre, said, "Securing the PIC/S GMP accreditation from Malaysia's NPRA is a significant milestone and a testament to our commitment to quality and technological innovation in pharmaceutical manufacturing. The major technological upgrades and investments we've made in our PFS facility over recent years have culminated in this recognition, reinforcing our team's dedication and excellence."

The approval process for the facility, completed within six months of a rigorous audit in April 2024, underscores the high compliance standards and world-class quality control measures at Venus Remedies' Baddi facility.

Thermo Fisher Scientific signs MOU with Government of Telangana to establish a Bioprocess Design Centre

Mumbai, India: Thermo Fisher Scientific, the world leader in serving science, announced the signing of a Memorandum of Understanding (MoU) with the Government of Telangana to establish a Bioprocess Design Centre (BDC) in Genome Valley, Hyderabad.

The event was graced by Shri Duddilla Sridhar Babu, Minister for Information Technology, Department of Electronics & Communications (ITE&C), Department of Industries & Commerce (I&C) and Legislative Affairs, Jayesh Ranjan IAS, Special Chief Secretary, Department of I&C and Shri Shakthi Nagappan, CEO, Telangana Lifesciences, Govt. of Telangana.

Shri Duddilla Sridhar Babu, Minister for ITE&C and I&C Departments, commented, "The establishment of this Bioprocess Design Centre reflects the state's progressive policies and collaborative approach to building a robust biopharma infrastructure. We are thrilled to partner with Thermo Fisher, the world leader in serving science, in this transformative initiative that will advance the future of healthcare."

Shakthi Nagappan, Director of Lifesciences and Pharma, Government of Telangana, stated, "This partnership with Thermo Fisher marks a significant milestone in our efforts to build a first-of-its-kind bioprocessing facility for biologics manufacturing in India. The centre, featuring single-use bioreactors, will enhance the biopharma sector by offering pay-per-use infrastructure, technical expertise, and cutting-edge research solutions, helping companies reduce their time to market."

Use technology in remote monitoring, and maintenance 24 by 7: Y. Nagi Reddy

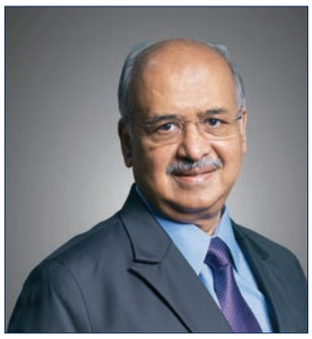
Hyderabad, India: In a two-day National Seminar on Fire, Electrical, Security and Automation (FESA) 24 for Pharma Industry, Y. Nagi Reddy, IPS, Director General of Fire Services stated that fire is important in industrial safety in Pharma. In the past 10 years, 97 major fires broke out in Pharma industries, and Rs 93 crore worth of property was lost. In another incident that occurred a day before yesterday, a property worth Rs 30 crore got burnt, he said.

Handling fire in the pharmaceutical industry is difficult due to the different kinds of gases and chemicals used. He explained the Telangana Fire Service Act 1999. Section 13 of this act requires that buildings and hazardous industries must get an NOC (No Objection Certificate) from the Fire Department. According to another section, 19, the owner or the occupant is responsible for the fire system in the establishment.

Pharmaceutical industries pose additional hazards compared to other industries, especially from the use and transfer of solvents. Hazards in this industry include fires or explosions in solvents or dusts. Several areas such as Cleanrooms; Laboratories; Warehouses; Utility/mechanical service rooms; Chemical rooms and Production areas need to be paid attention to he said. The regular fire safety Audit is a must he told 300 plus gathering. It has to be voluntary in the interest of the company, he said. You must use technology for remote monitoring, maintenance and 24 by 7 vigilance, he told.

Speaking on the occasion Jayesh Ranjan said accidents of any kind derail an industry. Many Pharma companies are under the watchlist of many European Regulators for non-compliance of ESG guidelines, which are low in those companies.

Sun Pharma Q2 net profit rises 28%



Dilip Shanghvi, CMD, Sun Pharmaceutical Industries

Mumbai, India: Sun Pharmaceutical Industries Limited reported financials for the second quarter ending September 30th, 2024. The company's Net profit for Q2FY25 was ₹ 30,402 million, up 28% YoY, while Gross sales was at ₹ 132,642 million, growth of 10.5%.

Dilip Shanghvi, Chairman and Managing Director of the Company said, "Sun has recently strengthened its specialty pipeline through an agreement with Philogen for commercializing late stage candidate Fibromun, upon approval. With Fibromun, our product basket for dermatologists has expanded further. We shall continue to leverage our strong cash position to strengthen our pipeline with products that are close to market." The company's formulation sales in India were ₹ 42,652 million for Q2FY25, growing by 11% over Q2 last year and accounting for approximately 32% of

total consolidated sales, while formulation sales in the US were US$ 517 million for Q2FY25, growing by 20.3% over Q2 last year and accounting for approximately 33% of total consolidated sales. Formulation sales in Emerging Markets were US$ 293 million for Q2FY25, growing by 3.2% over Q2 last year and accounting for approximately 18% of total consolidated sales.

The company said that Consolidated R&D investment were ₹ 7,929 million for Q2FY25 or 6% of sales as compared to ₹ 7,734 million for Q2 last year.

Cadila Pharmaceuticals launches innovative iron supplement 'Militol'

Ahmedabad, India: Cadila Pharmaceuticals, a leader in the pharmaceutical industry has launched Militol, an innovative iron supplement designed to provide a precise combination of nutrients that maximise absorption and enhance tolerance, effectively addressing iron deficiency.

Militol's unique formula incorporates carefully selected ingredients to enhance iron absorption and improve overall health. The supplement contains Ferric Maltol, an innovative low-dose form of Ferric iron complexed with Maltol. Militol also includes Folic Acid to promote red blood cell production, Vitamin B12 for neurological health and red blood cell formation, Vitamin C to enhance iron absorption and support immune health, and Vitamin D to boost calcium absorption and promote bone health.

Militol sets itself apart by combining a novel non-salt complex of Ferric iron Maltol, optimising absorption and minimising gastrointestinal side effects commonly associated with iron supplements. Militol offers comprehensive nutrient support with Folic Acid and multiple vitamins, providing a holistic approach to supplementation. The formulation enhances the absorption of iron and also supports a broad spectrum of nutritional needs, making it both highly effective and well-tolerated for a wide range of patients.

Cipla Q2 net profit rises 17%

Mumbai, India: Cipla Limited announced its unaudited consolidated financial results for the quarter ended September 30th, 2024.The company's income from operations stood at ₹ 7051 crore, while net profit stood at ₹ 1303 crore, up 17%.

"I am pleased to share that we continue to make considerable progress across our focused markets. In

Umang Vohra, MD and Global CEO, Cipla Ltd

Q2 FY25, we recorded a revenue growth of 9% over last year with a highest-ever EBITDA margin of 26.7%, driven by mix and other operational efficiencies. Our One-India business was impacted during the quarter due to changed seasonal pattern, however key chronic therapies in Branded Prescription business continued to grow faster than the market. Consumer health business grew at a strong 21% YoY. With our concentrated focus in differentiated portfolio, the US business posted a revenue of USD 237 Mn. In South Africa, we recorded a solid growth of 22% YoY in local currency terms, led by Private Market. Emerging Markets and Europe delivered a robust revenue growth of 18% YoY on the back of deep market focus strategy. Going ahead, focus will be on growing our key markets, further building our flagship brands, investing in future pipeline as well as focusing on resolutions on the regulatory front", stated Umang Vohra, MD and Global CEO, Cipla Ltd.

The company's One India Business grew at 5% YoY, while Branded Prescription business continued to outpace the market in key Chronic therapies, while company's North America delivered quarterly revenue of USD 237 Mn up by 4% YoY supported by continued positive traction in differentiated portfolio.

Zydus Lifesciences Q2 net profit up 14%

Dr. Sharvil Patel, MD, Zydus Lifesciences Ltd.

Ahmedabad, India: Zydus Lifesciences Ltd. announced its unaudited consolidated financial results for the quarter and half year ended September 30th, 2024.

The company's Revenue from operations stood at ₹ 52,370 mn, up 20% over last year, while Net Profit for the quarter was at ₹ 9,112 mn, up 14% YoY. The company's EBITDA for the quarter was at ₹ 14,614 mn, up 28% YoY. EBITDA margin for the quarter stood at 27.9% which is an improvement of 170 bps on a YoY basis.

In Formulations business, the company registered revenues of ₹ 14,569 mn, up 9% y-o-y, while company registered revenues of ₹ 24,168 mn, up 30% y-o-y and down 22% q-o-q for US Formulation business. In API business, the company Registered revenues of ₹ 1,194 mn, down 15% y-o-y. "Sustained growth momentum across our businesses along with enhanced profitability drove our strong Q2 performance. Execution success of our differentiated pipeline in the US and outperformance of our India Geography business were particularly noteworthy. With a focus on quality excellence, we will continue to align our processes and strengthen compliance. We are on course to achieve our growth aspirations for FY25 and are committed to investing in sustainable growth initiatives and innovative solutions, keeping patient centricity at the core.", stated Dr. Sharvil Patel, Managing Director - Zydus Lifesciences Limited.

Glenmark Pharma Q2 net profit stood at ₹ 3,545 mn

Mumbai, India: Glenmark Pharmaceuticals Ltd, a research led, global pharmaceutical company, announced its financial results for the second quarter ended September 30,2024. For the second quarter of FY 2024-25, Glenmark's consolidated revenue was at ₹ 34,338 Mn as against ₹ 32,074 Mn recording an increase of 7.1% YoY. The company's EBITDA was ₹ 6,019 Mn in the quarter ended September 30, 2024, as compared to ₹ 4,623 Mn in the previous corresponding quarter, registering growth of 30.2%. The company's Profit After Tax (PAT) for the quarter ended September 30, 2024 was at ₹ 3,545 Mn, with PAT margin of 10.3%. Commenting on the results, Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd. said, "This quarter, we have maintained a strong growth trajectory, driven by robust performances in the India and Europe markets. Our flagship respiratory brand, RYALTRIS®, continues to perform well across all key regions, reaffirming its position as a leading treatment option. Additionally, we have strategically in-licensed innovative products in our priority therapeutic areas, further strengthening our commitment to addressing unmet medical needs and improving patient outcomes."

"Our novel biologic asset, ISB 2001, developed by Ichnos Glenmark Innovation (IGI), has shown promising efficacy and safety in Phase 1 trials, and we look forward to presenting these encouraging first-time data at the 66th American Society of Hematology (ASH) Annual Meeting next month," he added. The company's Sales from the formulation business in India in Q2 FY 2024-25 was at ₹ 12,817 Mn as against ₹ 11,252 Mn in the previous corresponding quarter, recording growth of 13.9% YoY.

Wockhardt Q2 revenue stood at ₹ 818 Crore

Mumbai, India: Wockhardt Limited, the Pharmaceutical and Biotechnology major, reported its 2nd Quarter Results for Financial Year 2024-25. The company's Revenue for Q2FY25 of ₹ 818 Crore as compared to ₹ 762 Crore in the previous year, while EBITDA for Q2FY25 of Rs. 139 Cr compared to ₹ 81 crore in the previous year.

The company's EBITDA for Q2FY25 of ₹ 139 Crore as compared to ₹ 81 Crore in the previous year.

The Company has completed the pivotal Phase 3 pneumonia study of its antibiotic Nafithromycin WCK 4873 (MIQNAF) and has received favourable recommendation from Subject Expert Committee (SEC) of Central Drugs Standard Control Organisation (CDSCO) for treatment of Community Acquired Bacterial Pneumonia (CABP).

The company's Insulin and Glargine business has demonstrated remarkable growth driven by increasing volumes across key markets such as Thailand, Algeria, Latin America and India. This robust expansion in emerging markets has been further fueled by strategic partnerships and new deal acquisitions, accelerating our presence and reach.

The company's US Business stood at Rs.31 crore in Q2FY25 and ₹ 60 crore in H1FY25 contributing 4% of the Global Revenue respectively.

Syngene International Q2 net profit stood at ₹ 106 crores

Jonathan Hunt, MD and CIO, Syngene International Limited

Mumbai, India: Syngene International Limited announced its second quarter and half year financial results. The company's Revenue from operations increased sequentially by 13%, down 2% year-on-year to ₹ 891 crores, down 3% on constant currency basis. The company reported profit after tax, after exceptional items, for the quarter was down 9% year-on-year to ₹ 106 crores.

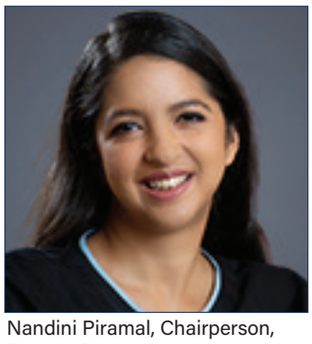
For the half year ended on 30th September 2024, revenue from operations was down by 2%, around 4% decline in constant currency, and reported profit after

tax after exceptional items was down by 13% to ₹ 182 crores compared to the same period last year.

Commenting on the quarter, Jonathan Hunt, Managing Director and Chief Executive Officer, Syngene International Limited, said, "Performance in the second quarter and first half of the year was broadly flat, in line with our expectations. I am pleased with the early positive signs of recovery in Discovery Services, largely driven by collaborations on pilot projects with large and mid-sized biopharma clients looking for alternatives to China to rebalance their supply chains. I am also encouraged to see healthy interest from clients in biologics. We have proven capabilities in biologics and additional manufacturing capacity coming online in the second half of the year. With a strong third quarter already underway, we expect to see a positive change in revenue trajectory in the third quarter and remain on track to deliver within our guidance range for the full year."

Sibaji Biswas, Executive Director and Chief Financial Officer, Syngene International Limited added, "With improving sequential revenues, our operating EBITDA margin came in at 27% for the quarter compared to 22% in the first quarter and broadly within range year-on-year. With recent investments in the research and CDMO businesses, we are in a good position to leverage opportunities to drive medium to long-term growth. The Company maintains a robust balance sheet with strong net cash position, enabling us to invest in strategic areas including digitization, commercial capabilities and new technology to support growth."

Piramal Pharma Q2 revenue up 17%



Nandini Piramal, Chairperson, Piramal Pharma

Mumbai, India : Piramal Pharma Limited, a leading global pharmaceuticals and wellness company, announced its standalone and consolidated results for the Second Quarter (Q2) and Half Year (H1) ended 30 the September 2024.

The company's Revenue from Operations grew by 17% YoY, primarily driven by robust growth in CDMO business, while EBITDA grew by 28% YoY with EBITDA margin of 18%, a YoY improvement of about 150bps, driven by operating leverage, cost optimization initiatives and superior revenue mix

Nandini Piramal, Chairperson, Piramal Pharma Limited said, "We continue our momentum of delivering healthy revenue growth accompanied by YoY EBITDA margin expansion. This has been primarily driven by consistent growth in our CDMO business which has witnessed a good pick-up in innovation related work and on-patent commercial revenues. To sustain this growth momentum and to capitalize on rising demand for sterile fill-finish capabilities, we have announced a US$80Mn expansion plan at our Lexington facility which is expected to get complete by end FY27."

RPG Life Sciences Q2 revenue from operations up 12%

Yugal Sikri, MD, RPG Life Sciences Ltd

Mumbai, India: RPG Life Sciences Limited has announced its unaudited financial results for the second quarter and half year ended September 30, 2024.

The company posted a jump in PBT before exceptional items of 22% Y-o-Y and 18% Q-o-Q for Q2 FY25, maintaining the upward trajectory in EBITDA margins, Yugal Sikri, Managing Director, RPG Life Sciences Ltd. said, "In Q2 FY25, the overall performance of the Company continued to be strong. Revenue and PBT before exceptional items grew by 12% and 22% respectively Y-o-Y. EBITDA margin retained its 5-year long upward trajectory growing from 25.5% to record 27.8% Y-o-Y. The Company continues to remain debt-free."

The company also announced that Yugal Sikri, the Managing Director of the Company, will superannuate at the close of business hours on April 30, 2025.

To facilitate smooth and structured transition, Ashok Nair is appointed by the Board on the recommendation of the Nomination and Remuneration Committee as Managing Director (Designate) of the Company w.e.f. January 7, 2025. He will assume office of Managing Director w.e.f. from May 1, 2025, subject to necessary approval by the shareholders of the Company.

Strides Pharma Science Q2 PAT stood at ₹937mn

Arun Kumar, Founder & Executive Chairperson, Strides Pharma Science

Bangalore, India: Strides Pharma Science Ltd announced its consolidated financial results for the quarter (Q2FY25) ended September 30, 2024.

The company's Revenues stood at ₹12,011m, grew 17.0% YoY, while the company's PAT was at ₹937mn.The company stated that US revenues at a historic high of USD 75m in Q2FY25, grew 26.2% YoY

Arun Kumar, Founder & Executive Chairperson, and Badree Komandur, MD & Group CEO, commented on the performance and said, "We continue to deliver on the momentum built over several preceding quarters and delivered another strong quarter. Q2FY25 demonstrated sustained growth across all markets fueled by new product launches. US operations reported highest ever quarterly revenue of $75m in Q2FY25. Strong YoY improvement in absolute EBITDA and EBITDA margin reflects our continued focus on operational efficiency and profitability.

Indoco Q2 revenues stood at ₹ 3,946 mn

Aditi Panandikar, Managing Director, Indoco Remedies Ltd

Mumbai, India: During the second quarter of FY 2024-25, revenues of Indoco Remedies are at ₹ 3,946 mn, as against ₹ 4,652 mn, same quarter last year. The company's EBIDTA to net sales for the quarter is 13.4 % at ₹ 529 mn, as compared to 15.6% at ₹ 724 mn, same quarter last year. The company's Profit After Tax to net sales is 3.2 % at ₹ 128 mn, compared to 7.1% at ₹ 331 mn, same quarter last year.

Aditi Panandikar, Managing Director, Indoco Remedies Ltd. said, "While a good performance by our Domestic Formulation business helped grow revenues, supply constraints have impacted the performance of the International Formulation business. Some of the sites supplying to US and Europe are under structured shutdowns to increase efficiency."

The company announced the receipt of final approval from the USFDA for Abbreviated New Drug Application (ANDA) for Cetirizine Hydrochloride Tablets USP, 10 mg (OTC), a generic equivalent of the Reference Listed Drug, Zyrtec Allergy Tablets, 10 mg of Johnson & Johnson Consumer Inc.

Torrent Pharma Q2 revenue up 9%

Mumbai, India: Torrent Pharmaceuticals posted results for the second quarter ended September, 30, 2024. The company's Revenue stood at ₹ 2,889 crores grew by 9%, while Net Profit after tax was at ₹ 453 crores, up by 17%.

The company's Insulin revenues were impacted this quarter due to scheduled shutdown taken in the month of August for maintenance activities. The facility will be released for manufacturing in December. Shortfall is significantly planned to be recovered in Quarter 4 of this year and consequently there will not be any impact on a full year basis.

The company's India revenues was at ₹ 1,632 crores were up by 13% led by outperformance in focus therapies, while US business revenues was at ₹ 268 crores, were up by 8%.The company added that Brazil revenues was at ₹ 263 crores, were up by 4%.

Laurus Labs Q2 revenue stood at ₹ 1224 crore

Dr. Satyanarayana Chava, Founder & CEO, Laurus Labs

Hyderabad, India: Laurus Labs Ltd , a leading research and development driven pharmaceutical and biotech company in India announces its Q2 & H1 FY25 results. The company's CDMO-Synthesis business reported revenues of ₹ 513 Crore, during H1FY25; increased by 8%, while API business reported revenues of ₹ 1,221 crore, during H1FY25.

Dr. Satyanarayana Chava, Founder & Chief Executive Officer commented;"We are pleased to see sustained demand in our CMO/CDMO services, supported by

ongoing operational excellence and expanding platform capabilities. Opening of new R&D center significantly advances our one-stop 'D & M' capability in meeting global partner diverse needs and growing early phase enquiries. Q2 results demonstrates continued resilience in financial health, led by strong growth in CDMO vertical offset by lower sales in ARV and Oncology API business. Looking at industry fundamentals, we are well positioned to capture value by maintaining our focus on solving customer complex needs and deliver long-term stakeholder value".

V V Ravi Kumar, Executive Director & Chief Financial Officer commented; "During Q2, we delivered ₹ 1,224 Crore in revenues and ₹ 182 Crore EBITDA, resulting to 14.9% margin. Gross margins maintained healthy at 55.2% due to favorable CDMO mix and process optimization. Operating results affected from lower utilization of assets as we continue to prioritise resources towards delivering several complex projects at various clinical phases."

JB Chemicals & Pharma Q2 revenue rises 13%

Nikhil Chopra, CEO and Wholetime Director, JB Pharma

Mumbai, India: JB Chemicals & Pharmaceuticals ltd, one of the fastest growing pharmaceutical companies in India, announced its financial results for the quarter ended 30th September, 2024.

JB Pharma recorded revenue of ₹ 1001 crores in the second quarter of FY25 registering growth of 13% from INR 882 crores in Q2 FY24. Operating EBITDA* (Earnings before Interest Depreciation and Taxes) improved by 13% to ₹ 285 crores. The company's Profit after Taxes registered strong growth of 16% to ₹ 175 crores as against ₹ 151 crores in Q2 FY24.

The company's Domestic business continued its momentum and registered YoY growth of 22% to ₹ 588 crores, while International business revenue grew at 3% to ₹ 413 crores as against ₹ 401 crores. JB Pharma's revenue crossed ₹ 1000 crores in a quarter for the second consecutive time.

Commenting on the financial results, Nikhil Chopra, CEO and Wholetime Director, JB Pharma mentioned, "We maintained a healthy pace of growth in Q2, achieving Rs. 1,000 crore revenue for the quarter. EBITDA margins at 28% are at the higher end of our guidance range, given a favourable product mix and cost optimization initiatives. JB's domestic business continued to out-perform the market with all our major brands posting strong growth. We have steadily driven strong volume growth for our large brands, including the acquired portfolios. On the international front, our formulations business performed well in Q2 and CDMO division growth will pick up in H2 as we come out of a seasonally muted Q2."

Alembic Pharma Q2 PAT up 12%

Shaunak Amin, MD, Alembic Pharmaceuticals Limited

Vadodara, India: Alembic Pharmaceuticals Limited reported its consolidated financial results for the second quarter ended 30th Setember, 2024. The company's net Sales increased by 3% to Rs.1648 Crores, while EBITDA up 18% to ₹. 257 Crores. The company's EBITDA Margin at 15.6% of Sales, while Net Profit was up 12% to ₹ 153 Crores.

Shaunak Amin, MD, Alembic Pharmaceuticals Limited said "India's Branded Business continues to enhance execution capabilities in both quality and scale, with the Specialty and Animal Health segments showing good growth. The USFDA successfully inspected our Oncology Formulation Facility (F-2) without any form 483 observations."

The company's India Branded Business grew 6% to ₹ 609 Crores for the quarter, while Animal Health business grew 20% for the quarter with basket of strong brands driving outperformance. The company's US Generics grew 5% to ₹ 467 Crores for the quarter, while 9 ANDA approvals were received during the quarter.

Sanofi India reports 8% growth in net sales for Q3-2024

New Delhi, India: The Board of Sanofi India Limited approved its standalone and consolidated financial results, for Q3 and year to date ended on September 30th, 2024, after the demerger of its consumer healthcare business effective from June 1st, 2024.

Diabetes portfolio reported a high single digit growth with a good performance of Toujeo, Lantus and the successful launch of Soliqua reinstating confidence and strength in our comprehensive diabetes portfolio. The recently announced partnerships for CNS (Central Nervous System) and the CV (Cardiovascular) brands have established their foundation for acceleration and expansion in reach.

The company delivered 6% growth in operating profit (*). The Profit from Operations for Q3- 2024 was at ₹ 110 crores as against ₹ 104 crores Q3-2023.

Rodolfo Hrosz, Managing Director, Sanofi India Limited said, "Fueled by our resolve to bring best-in-class and first-in-class innovative products to India, we successfully launched Soliqua - our best-in-class diabetes drug for the premix segment. Soliqua is showing immense promise in significantly reducing the complexities of living with diabetes. Encouraged by positive patient outcomes, we already have the faith and confidence of thousands of doctors who continue to prescribe it. Our recently announced partnerships for Cardiovascular and CNS (Central Nervous System) categories have shown initial positive results, as our iconic established brands in these categories begin to expand their presence across the country.

Hester Biosciences Q2 net profit rises 108%

Rajiv Gandhi, MD & CEO, Hester Bioscience

Ahmedabad, India: Hester Biosciences Limited, one of India's leading animal health company, manufacturing vaccines and health products has reported consolidated net profit of Rs. 8.39 crore in Q2FY25 ended September 2024 as against a net profit of ₹ 4.04 crore in Q2FY24, growth of 108%. The company reported revenue from operations of ₹ 83.69 crore for Q2FY25, growth of 19% Y-o-Y as compared to revenue from operations of ₹ 70.46 crore in Q2FY24. EBITDA during Q2FY25 ended September 2024 was reported at ₹ 21.96 crore, 15% growth Y-o-Y from ₹ 19.12 crore in Q2FY24. EPS for Q2FY25 was reported at ₹ 9.86 per share.

Akums Drugs and Pharmaceuticals Q2 PAT up 16% from previous quarter

Sanjeev Jain, MD, Akums Drugs and Pharmaceuticals

New Delhi, India: Akums Drugs and Pharmaceuticals Ltd. India's largest contract development and manufacturing organization (CDMO), has announced its consolidated financial results for the quarter ending September 30, 2024, marking 16% increase in profit after tax (PAT) on sequential quarter-on-quarter basis.

For Q2, Akums reported a consolidated total income of ₹10,466 million, representing a sequential growth of 2%. Adjusted EBITDA was recorded at ₹1,347 million, a 3% rise over the previous quarter, while the adjusted PAT stood at ₹667 million, a 16% increase. The company's adjusted EBITDA margin of 12.9% and PAT margin of 6.4% reflect operational efficiency and a focus on profitable growth.

Sanjeev Jain, Managing Director, also shared his views, stating, "Short term volatility apart, we continue to see strong secular demand for outsourced drug development and manufacturing. We will continue to invest in building world-class capabilities to help our clients launch new formulations and therapies, and drive their growth. The company is taking long term measures to further strengthen its leadership position in the CDMO space."

Sandeep Jain, Managing Director, stated, "Our focus continues to be on the development of innovative products and platforms, exploring more markets towards our larger objective of driving profitable growth. Q2 business performance reflects the muted volume demand and low API prices. We remain committed to our long term vision of being a global CDMO player". ■

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OneSource Specialty receives equity commitments of ₹ 8,010 mn

Bangalore, India: Strides Pharma Science Limited announced that its associate company, OneSource Specialty Pharma Limited (formerly known as Stelis Biopharma Limited),Group's Specialty Pharma CDMO, has received confirmed commitments for fundraising of ₹ 8,010 mn(~USD 95 mn) from marquee domestic and foreign institutional investors and family offices, in the pre-listing round.

The share subscription agreements are being executed at a pre-money equity value of USD 1.65 bn, delivering to Strides' shareholders an embedded value of ₹ 663 per share of Strides' holding in OneSource representing an ~82% premium over the previous embedded value of Rs 364 per share as per the Scheme of Arrangement announced earlier in September'23. The strong interest from leading investors reflects growing confidence in our capabilities and the immense potential of the CDMO sector emerging out of India. This fundraise is in line with the Scheme of Arrangement announced in September'23 and the investment is subject to customary closing conditions, including receipt of necessary regulatory approvals.

Arun Kumar, Founder of Strides Group, and Neeraj Sharma, CEO of OneSource in a statement said, "We are delighted to have received an overwhelming response to the pre-listing fundraise from a marquee set of investors on our cap table prior to our listing. Their strong support is a testament to the confidence they have in our vision and strategic direction. This fundraise will enable us to accelerate our growth plans, right-size our debt book, and commit significant new capex for a strong order book across our 3 platforms."

Badree Komandur, MD & Group CEO of Strides said, "We are pleased to have successfully received equity commitments for OneSource, ensuring its future growth. The transaction will unlock ₹ 61,000 mn (~USD 725 mn) of value for Strides'shareholders. The significant premium that will be achieved from this transaction for Strides' shareholders is a testament to our continued value creation for our stakeholders."

Rentschler Biopharma announces single investment at headquarters in Germany

LAUPHEIM, Germany: Rentschler Biopharma SE, a leading global contract development and manufacturing organization (CDMO) for biopharmaceuticals, including advanced therapy medicinal products (ATMPs), announced the construction of a new state-of-the-art buffer media station at its company headquarters in Laupheim. The new facility aims to further increase production efficiency and modernize the site, ensuring that the evolving needs of clients and patients are anticipated and fully met, both now and in the future.

"This investment underscores our commitment to the long-term development of our Laupheim site, a key part of Germany's biotechnology landscape. This expansion will strengthen our competitive position in one of the world's fastest-growing industries. As a company with 150 years of tradition, Rentschler Biopharma has always embraced forward-looking, strategic planning, enabling us to grow sustainably as an independent family-owned company. I would like to thank all colleagues involved in the planning and execution of this significant project," said Benedikt von Braunmühl, Chief Executive Officer of Rentschler Biopharma. "Government support for a German national pharmaceutical strategy is an important signal for the industry as a whole. While our focus remains on strengthening global partnerships, this investment in our German site plays a crucial role in ensuring supply chain reliability and advancing our long-term growth strategy."

The state-of-the-art, four-story buffer media station, covering 34,000 square meters, is set to be operational by 2028. The new facility will be seamlessly integrated with the existing infrastructure, offering faster and more efficient processes, as well as ergonomically designed workstations, providing an optimal working environment for employees. The new building, along with all technical systems, will meet the highest quality and automation standards, and, through its state-of-the-art equipment, support Rentschler Biopharma's environmental and sustainability goals. ■

Advanced analytical techniques in a rapidly changing regulatory landscape

Analytical technology is the mainstay of all scientific processes for the precise control over desired output. It serves as a cornerstone for evaluating identity, purity, potency, and stability of the drugs throughout their life cycle, from development to manufacturing and during post-market surveillance. With the recent advancement of instrumentation and computing science, regulatory bodies have been more and more demanding for analytical efficiency.

Dr. Sujay Rajhans, President – Research & Development, JB Pharma outlines the notable trends of widespread adoption of spectroscopic techniques such as Mass spectroscopy, Raman spectroscopy and near infrared (NIR) spectroscopy.

There is a clear shift in the expectations from analytical efforts with the availability of technological advancements. A welcome change of growing harmonization of regulatory policies across the globe has triggered the fading of a popular misnomer of semi regulated or less regulated status of various regulatory territories with the unified voice towards quality of drug products.

Advancements in analytical techniques have enabled more accurate, efficient, and comprehensive characterization of drug substances and products. With the increasing complexity of drug formulations and the evolving regulatory landscape, the need of advanced analytical techniques has been unprecedented during recent years.

Non-destructive techniques offer rapid, real-time analysis of pharmaceutical samples with minimal sample preparation, making them valuable tools for process monitoring, quality control, and counterfeit detection. Additionally, the integration of spectroscopic imaging modalities allows spatially resolved analysis of heterogeneous samples, facilitating deeper insights into drug distribution and formulation homogeneity.

Mass Spectrometry

Recently, Mass spectrometry (MS) has emerged as a key instrument in every pharmaceutical laboratory, offering unparalleled capabilities for the identification, quantification, and characterization of drug molecules and their metabolites.

Recent advancements in MS instrumentation, including high-resolution mass analysers, ion mobility spectrometry, and tandem MS configurations, have expanded the scope and sensitivity of MS-based assays, enabling comprehensive analysis of impurities, degradation products and trace-level contaminants or cancer-causing substances in food and drug products.

Mass spectrometry plays important role in identifying detailed structural information and quantitative data with high sensitivity and specificity. Recent innovations in MS instrumentation, such as orbitrap mass analysers, quadrupole time-of-flight (Q-TOF) analysers, and hybrid quadrupole-Orbitrap systems, offer improved resolution, mass accuracy, and dynamic range for complex sample analysis. Moreover, the coupling of MS with orthogonal separation techniques, such as

ion mobility spectrometry (IMS) and supercritical fluid chromatography (SFC), enables comprehensive characterization of drug metabolites, impurities, and degradation products.

Over the past decade, mass spectrometry has undergone tremendous technological evolution allowing its application to drugs, proteins, carbohydrates, DNA, peptides, and many other biologically relevant entities. Due to ionization sources such as electrospray ionization and matrix-assisted laser desorption/ ionization (MALDI), mass spectrometry has become an irreplaceable tool in the biological sciences.

Raman Spectroscopy

Raman spectroscopy enables non-destructive identification and characterization of pharmaceutical formulations, offering rapid analysis with minimal sample preparation.

Surface enhanced Raman spectroscopy (SERS) and Coherent Raman Spectroscopy have significantly enhanced analytical techniques for pharmaceutical analysis. These advancements have revolutionized the field by providing rapid, non-invasive, and precise methods for quality control and analysis in the pharmaceutical industry.

One key advancement is the integration of Raman spectroscopy into pharmaceutical quality control processes. The European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopoeia (USP) have updated their chapters to include Raman spectroscopy as a recommended technique for various analyses, such as microbiological quality control, polymorph, crystallinity, and chemical imaging reflecting the growing recognition of Raman spectroscopy as a valuable tool for ensuring drug quality and safety.

Innovations in Raman modalities, system configurations, and technical components have enabled more reliable and precise measurements, especially in on-site applications within the pharmaceutical industry.

The introduction of handheld Raman devices has further expanded the accessibility of this technology, allowing off-line, at-line, on-line, and in-line measurements and playing a crucial role in pharmaceutical applications by providing insights into chemical composition, concentration ranges, particle size distributions, and spatial distribution of components within materials.

Raman is used in material science for characterization of molecular structure, phase identification, and monitoring chemical reactions with high sensitivity and specificity. It is also employed in characterisation of nanomaterials, polymers and semiconductors and valuable information about molecular structure. Raman spectroscopy also offers non-destructive and label-free analysis of biological samples, enabling the study of cells, tissues, and biomolecules with minimal sample preparation.

It has applications in disease diagnosis, drug screening, tissue engineering, and understanding biological processes at the molecular level. In environmental science, Raman spectroscopy is employed for the detection and characterization of pollutants, contaminants, and hazardous substances in air, water, and soil. It has remarkable contribution towards rapid identification, crystallinity, chemical composition and quantification of pharmaceutical compounds.

Near Infra-Red Spectroscopy [NIR]

Illuminating the Invisible Realm of Molecular Analysis Near Infra-Red (NIR) spectroscopy is a versatile analytical technique that harnesses the interaction between near-infrared light and the matter to provide valuable insights into molecular composition, structure, and properties. Since its inception, NIR spectroscopy has found widespread applications in various industries such as pharmaceuticals, agriculture, food, and environmental monitoring due to its non-destructive nature, rapid analysis capabilities, and versatility.

Near Infra-Red (NIR) spectroscopy stands at the forefront of modern analytical techniques, offering a unique window into the molecular composition and properties of diverse materials operating within the near-infrared region of the electromagnetic spectrum, typically ranging from 780 to 2500 nanometres. This region corresponds to wavelengths slightly longer than visible light but shorter than mid-infrared radiation.

The interaction of near-infrared light with molecular bonds results in the absorption and scattering of photons provides unique spectral signatures characteristic of the molecular composition and structure of the sample. NIR spectroscopy primarily detects overtones and combinations of vibrational modes, as well as electronic transitions. It's non-destructive and rapid analysis capabilities have made it an indispensable tool for researchers, scientists, and industry professionals alike.

The quantitative analysis in NIR spectroscopy relies on the Beer-Lambert law, which relates the absorption of light by a sample to its concentration and path length. By measuring the intensity of transmitted or reflected light across a range of wavelengths, NIR spectroscopy enables the quantification of analytes and the prediction of various chemical and physical properties.

Modern NIR spectrometers feature high-performance detectors, such as indium gallium arsenide (InGaAs) arrays, that offer improved sensitivity and spectral resolution. Additionally, advancements in light sources, such as light-emitting diodes (LEDs) and tuneable diode lasers, have expanded the spectral range and enhanced the signal-to-noise ratio of NIR spectra. Moreover, the development of robust and portable NIR spectrometers has facilitated on-site and in-line analysis, enabling real-time monitoring and quality control in various industries.

NIR applications spread across diverse industries, ranging from pharmaceuticals and agriculture to food and beverage analysis. Its non-destructive nature and rapid analysis capabilities make it ideal for process monitoring and quality control in pharmaceutical manufacturing. In food industry it is employed for the analysis of various constituents, including moisture, fat, protein, and sugar content, in raw materials, ingredients, and finished products.

Even, it is effectively utilized for soil analysis, crop monitoring, and the assessment of grain quality. NIR spectra of agricultural samples provides information about nutrient levels. Predict crop yields and optimise agricultural practices for enhances productivity and sustainability. One of the interesting applications of NIR is for rapid and Realtime analysis of drug formulations, including content uniformity, blend uniformity, and moisture content determination.

Conclusion

The integration of cutting-edge analytical tools such as LC-MS, GC-MS, Raman spectroscopy, NIR spectroscopy, UHPLC, LC×LC, and hyphenated techniques has significantly improved the speed, accuracy, and sensitivity of pharmaceutical analysis. These techniques enable the identification, quantification, and characterization of drug compounds, metabolites, and impurities in complex matrices, ensuring the safety, efficacy, and quality of pharmaceutical products.

Recent advances in analytical techniques have brought a paradigm shift offering new opportunities for innovation and improvement in drug discovery, formulation, and manufacturing processes.

With enhanced understanding of drug behaviour and product quality, these techniques contribute to the continuous improvement of healthcare delivery and patient outcome. Moving forward, continued investment in research and development will further propel the field of pharmaceutical analysis, ultimately benefiting both the industry and public health.

A new dimension of use of artificial intelligence in analytical chemistry to handle heterogeneous and complex data has opened a plethora of opportunities. The integration of AI with analytical techniques is a historical milestone in the field of science and technology, transforming data analysis and interpretation. Traditionally, the analysis of such data would require extensive time and expertise. However, with AI algorithms, it's possible to extract most relevant information quickly and more efficiently. Although AI has transformed many scientific disciplines, it has offered remarkable advances in the interpretation of complex spectra and in the optimization of chromatographic methods in pharmaceutical analysis. In future, AI will continue reshaping the outcome of analytical techniques and will go hand in hand with the advancement in analytical instrumentation giving wholesome solution towards highly accurate, rapid and precise analytical results. ■

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Contract Development and Manufacturing Organizations in India's Pharma Sector: A Growth Catalyst

India's pharmaceutical market (IPM) has witnessed rapid growth, recording a 9.0% CAGR over the last five years, with projections indicating a 9.6% CAGR until FY28. The market is expected to grow from ₹ 1,317.5 billion in FY19 to ₹ 2,852.6 billion by FY28, driven by an increasing chronic disease burden, urbanization, and a growing aging population. These factors have made India an attractive destination for pharmaceutical companies seeking cost-efficient and reliable manufacturing solutions.

Arushi Jain, Director - Growth and Excellence, Akums Drugs and Pharmaceuticals emphasizes about CDMO industry playing an important role in driving innovation in existing therapies to address unmet needs. She also spoke about the challenges and outlook for India's CDMO sector.

Contract Development and Manufacturing Organisations (CDMOs) play a pivotal role in supporting this growth. Offering cost reductions, scalability, and compliance with global standards, Indian CDMOs enable pharmaceutical companies to focus on core activities such as R&D and marketing. Leading firms like Akums are driving innovation, particularly in complex formulations and emerging therapeutic areas like injectables and oral solid dosages, which dominate the domestic market.

CDMOs also help multinational corporations overcome India's unique regulatory landscape, providing a streamlined approach to market entry and production. Most of the leading pharmaceutical companies In India are now increasingly rely on CDMO partners to meet growing demand, highlighting the sector's crucial role in India's pharma ecosystem. With a focus on efficiency and quality, Indian CDMOs are well-positioned to continue their growth trajectory, contributing to the country's status as a global pharmaceutical manufacturing hub.

Scaling Global Impact

In the global CDMO landscape, companies of various scales bring unique strengths to the industry. For instance, Lonza, a prominent CDMO, serves over 7,000 customers worldwide, highlighting its extensive capacity. Regional players like Procaps Group, with a focused client base of around 120, demonstrate the impact of a more specialized approach. Likewise, Indian CDMOs such as Akums have achieved notable growth, now reaching over 1,500 clients. Catalent, another key player, serves approximately 1,200 customers, illustrating the breadth of service models that contribute to the sector's ability to meet diverse customer needs worldwide.

Why third-party manufacturing is important

Third-party manufacturing, particularly through CDMOs, is vital for pharmaceutical companies looking to stay competitive. Outsourcing the manufacturing process enables these companies to focus their resources

on core areas such as research, development, and marketing. CDMOs offer the expertise, infrastructure, and scalability required to meet the high demands of drug production. This model has become increasingly important in the global pharmaceutical landscape, and India's CDMO sector is at the forefront of this evolution.

India offers an up to 40% reduction in operational and production costs compared to other global regions, making it a go-to destination for pharmaceutical companies looking to optimise expenses while maintaining quality and adhering to regulatory standards. Multinational corporations have been particularly attracted to India for this reason, especially as the country's regulatory environment continues to improve, further enhancing its appeal as a manufacturing hub.

The rising demand for injectable drugs, particularly in oncology and other high-value therapeutic areas, has driven the need for specialised CDMO services. Injectable formulations offer higher returns due to their therapeutic efficacy, which makes them attractive for both pharmaceutical companies and manufacturers alike. The complexity of producing these formulations underscores the growing importance of CDMOs, who possess the requisite skills and infrastructure to meet these specialised production demands.

Indian CDMOs are also playing a crucial role in supporting late-stage clinical trials, particularly for pharmaceutical products destined for highly regulated markets like the US and Europe. The Drug Technical Advisory Board's (DTAB) decision to waive late-stage clinical trial requirements for certain drugs from these markets has significantly lowered costs, making India an attractive destination for pharmaceutical outsourcing and innovation.

Accelerating innovation in pharma

India's CDMO industry plays an important role in driving innovation in existing therapies to address unmet needs. The sector is increasing focus on manufacturing by engaging in research and development, focusing on improving therapeutic options and patient outcomes. By utilizing new technologies and expertise, Indian CDMOs contribute to developing solutions that meet the changing demands of healthcare, helping to ensure that patients have access to effective treatments tailored to their specific needs.

A notable instance of innovation includes the recent development of India's first Advanced Anti-Reflux Antacid, a Sodium Alginate + Potassium Bicarbonate Chewable Tablet, approved by the Drugs Controller General of India (DCGI). This formulation offers effective relief for acid reflux patients. Also, the launch of Rabeprazole + Levosulpiride SR Capsules marks a breakthrough for gastrointestinal tract (GIT) disorders, being the first time such a formulation has been made available in India. Both products reflect how CDMOs are playing a pivotal role in bringing novel treatments to the market.

Another example is the approval of Hydroxyurea Oral suspension by Akums. Akums is advancing pharmaceutical innovation with its production of Hydroxyurea, a key medication used in the management of sickle cell anemia. By leveraging its cutting-edge manufacturing facilities, Hydroxyurea exemplifies therapeutic advancements and addressing unmet medical needs in both domestic and international markets. Similarly, the development of Estradiol + Progesterone Capsules for menopause relief, the first FDA-approved bio-identical combination hormone therapy, scores a major advancement in women's health.

Growing demand for nutraceuticals in preventative health

Nutraceuticals and functional foods are gaining momentum as global demand for preventative health solutions rises. These products, ranging from vitamins to gummies, cater to various demographic groups, addressing health concerns such as immune support, cognitive function, and overall wellbeing. Nutraceuticals designed specifically for women, children, and the elderly are becoming increasingly popular. CDMOs in our country have been pivotal in introducing innovative products, especially for women in prenatal and postnatal phases. These include prenatal vitamins containing essential nutrients like folic acid, calcium, and DHA, which are critical for fetal development. Postnatal supplements help nursing mothers replenish vital nutrients like vitamin D and iron and even support breast milk production. Additionally, CDMOs have

developed nipple sore creams to address common issues faced by breastfeeding mothers, offering relief and helping prevent cracked skin.

The market for nutraceuticals has also expanded into skincare, with products infused with collagen and hyaluronic acid witnessing popularity for promoting healthy skin and hair. Probiotics and prebiotics, essential for digestive health, are also on the rise. New forms like mouth-melt powders and gummies are preferred for their convenience, taste, and rapid absorption. Gummies, in particular, are popular among children, often featuring playful designs and natural sweeteners like stevia.

CDMOs facing challenges in India

India's CDMO sector is on a growth trajectory, with immense potential for expansion. However, like any dynamic industry, it faces opportunities for improvement. Adhering to stringent regulatory requirements, particularly for quality control and approvals of small molecules and biologics, encourages CDMOs to enhance their standards.

Rising raw material costs present challenges, but this also creates an opportunity for CDMOs to innovate, optimize processes, and increase cost-efficiency. Investing in technological upgrades and operational improvements is crucial for staying competitive. Moreover, with stronger support from both government and private sectors, the industry can unlock further potential in research and development. Such initiatives will empower CDMOs to introduce novel therapeutics and specialized formulations, propelling India's role as a global pharmaceutical leader.

Future prospects and path ahead

The outlook for India's CDMO sector is promising, with several factors contributing to its continued growth. The COVID-19 pandemic significantly spiked the demand for vaccines, antiviral drugs, and medical products, prompting pharmaceutical companies worldwide to turn to Indian CDMOs for expanded production. Additionally, geopolitical tensions such as the Russia-Ukraine war disrupted global supply chains, yet Indian CDMOs have shown resilience by diversifying sources and concentrating on domestic production capabilities.

The rising demand for biologics, injectables, and advanced therapies, coupled with increased investments in the sector, will likely sustain future growth. Government initiatives like the Production Linked Incentive (PLI) scheme provide financial support, promoting the production of essential starting materials (KSMs), active pharmaceutical ingredients (APIs), and other components. This initiative strengthens India's position as a global manufacturing hub while encouraging growth across both large corporations and SMEs.

Collaboration between private companies and government bodies is further fueling the CDMO sector. Strategic partnerships within the pharmaceutical industry, along with public-private partnerships (PPPs), are enhancing India's global competitiveness in drug development and production.

By adapting to trends like personalised medicine and sustainable practices, CDMOs that invest in advanced technologies will be well-positioned to thrive. As the global healthcare landscape evolves, Indian CDMOs will remain crucial in driving medical innovation and ensuring the efficient production of life-saving treatments. ■

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Biotechnology: Today and Tomorrow

Biotechnology, a field rooted in ancient practices like plant & animal domestication, alcohol fermentation using yeasts, Sauerkraut preparation, pickling, bread manufacture, Cheese fermentation etc. has evolved dramatically with modern advancements and high level of automated systems. Today, it encompasses a wide range of applications, from genetic engineering, sequencing, metagenomics, CRISPER technology, manufacture of protein therapeutic molecules using recombinant clones and cell therapies to nanotechnology.

Dr. Vishal G. Warke, Director, Cell Biology, HiMedia Laboratories Pvt. Ltd and Dr. Girish B. Mahajan, Senior Vice President, Microbiology, HiMedia Laboratories Pvt. Ltd emphasizes about how Biotechnologies is essential in addressing human needs across medicine, agriculture, forensics, bioremediation, and biosecurity.

Recognized as a major contributor to India's goal of a USD 5 trillion economy by 2047, India's BioE3 Policy aims to foster innovation and sustainability through initiatives in bio-based chemicals, precision biotherapeutics, climate-resilient agriculture, and advanced marine research, positioning India as a global biotechnology leader by enhancing economic, environmental, and employment impacts. Let us walk through some aspects of Biotechnology today and in future.

History and Evolution of Biotechnology

Biotechnology has evolved through centuries, beginning with ancient fermentation techniques used to make bread & alcohol and selective breeding in agriculture. In 1865, Gregor Mendel's discoveries in genetics established fundamental laws of heredity. The field took a quantum leap in 1953 with Watson and Crick's discovery of the DNA double helix, sparking advances in genetic research. The 1970s marked the development of recombinant DNA technology, which allowed scientists to splice genes and laid the groundwork for genetic engineering. The 1980s brought transformative tools like the Polymerase Chain Reaction (PCR), which enabled the amplification of DNA sequences, and the first genetically modified organism (GMO), showing the potential of transgenic technology in agriculture.

In 2003, the Human Genome Project successfully mapped the human DNA sequence, accelerating research in genomics and precision medicine. By 2010, synthetic biology achieved the creation of the first synthetic cell, highlighting the potential to design life at a genetic level. In 2012, CRISPR-Cas9 emerged as a groundbreaking gene-editing tool, allowing precise genetic modifications and opening new possibilities in medicine and agriculture. In 2015, CAR-T cell therapy provided a revolutionary approach to treating certain cancers by reprogramming patients' immune cells. The development of lab-grown meat in 2016 represented a major milestone in food biotechnology, with potential to address food security and sustainability.

In 2018, the creation of the first CRISPR-edited babies in China sparked global ethical debates on human genetic modification. From 2019 to 2021, mRNA vaccines, notably used in the COVID-19 pandemic, demonstrated the power of rapid, scalable biotechnology solutions for global health crises. In 2023, artificial intelligence integrated into biotech, accelerated drug discovery and diagnostics. Biotechnology today

encompasses a continuum from ancient fermentation practices to cutting-edge genetic engineering and biopharmaceutical innovations. It plays a transformative role across sectors like healthcare, agriculture, and environmental sustainability, positioning itself as an indispensable tool for addressing complex global challenges and advancing scientific progress.

Today's Advancements in Biotechnology

Biotechnology, an evolving blend of biological and technological sciences, is at the forefront of addressing some of the world's critical challenges. Rooted in applications across agriculture, healthcare, cosmetic & other industry, and the environment, biotechnology uses sophisticated techniques like synthetic biology and CRISPR gene editing to revolutionize numerous sectors, with promising advances emerging across various specialized fields. Core Areas of Biotechnology today include following.

Synthetic Biology

It focuses on the design and engineering of new biological systems, leveraging genetic modifications and DNA editing. Notable advancements include CRISPR, a tool revolutionizing genome editing. Expected to gain traction in 2024-25, CRISPR-based treatments for conditions like sickle cell anemia and gene editing workflows from several companies hold potential to transform healthcare. An application of synthetic biology is, also in creating biofuels. Typically, this is done by hacking a microbe's metabolism to transform plant waste into fuel. For example, a common yeast, *Pichia pastoris,* has been modified to break down renewable carbon sources into fuel.

Agricultural Biotechnology

Biotechnology plays a critical role in improving agricultural productivity. Through genetic modifications, scientists have developed crop variants with enhanced resistance to pests, weeds, and extreme climates. Such innovations reduce dependence on harmful pesticides and improve yields, offering sustainable food production solutions. Biopesticides, derived from natural materials like plants, animals, and minerals, represent a safer alternative to synthetic pesticides, promoting environmentally friendly practices in farming. Transgenic Bt corn is an outstanding example of successful application of genetic engineering in agriculture. It produces its own insecticide and contains a gene from the bacterium *Bacillus thuringiensis.*

The use of Bt varieties has dramatically reduced the amount of chemical pesticides applied to cotton. Golden Rice is produced by inserting two genes from daffodil and one gene from a bacterium into rice plants so that the rice becomes capable of synthesizing β-carotene, the precursor of vitamin A. Biotechnology researchers at the University of Pennsylvania have discovered that the overexpression of a gene, GRP8, increases the production of root hairs and thus, increased the surface area for water and nutrient absorption. The overexpression of this glycine-rich RNA-binding protein has also been found to improve plant tolerance to phosphate starvation, enhancing resistance to environmental stresses and reducing the need for fertiliser.

Environmental Biotechnology

Extending beyond agriculture, environmental biotechnology focuses on ecosystem conservation and restoration. It encompasses strategies for the safe disposal of farm waste and the development of sustainable crops. Through bioremediation techniques, contaminants in soil and water are mitigated, contributing to healthier ecosystems and aiding in climate change mitigation. Environmental biotechnology is widely adopted by the modern industrial sector for

cost-efficient green production and to reduce the environmental hazards. Some major processes and applications include biomarkers, bioenergy, agriculture, pulp and paper industry, and bioremediation and biotransformation. Eight promising biotechnology tools were selected by experts as potentially impactful game changers: (i) the Wood–Ljungdahl pathway, (ii) carbonic anhydrase, (iii) cutinase, (iv) methanogens, (v) electro-microbiology, (vi) hydrogenase, (vii) cellulosome and, (viii) nitrogenase. Their respective roles were well explained in review by Werner Fuchs et al (2023, https://doi.org/10.3390/microorganisms11061514).

Industrial Biotechnology

Combining sustainability and industrial utility, this branch aims to replace conventional industrial processes with eco-friendly alternatives. Biofuel production, ranging from ethanol and biodiesel to methane, exemplifies this effort. Additionally, scientists are creating biodegradable materials from renewable resources like starch and cellulose, replacing conventional plastics and reducing environmental pollution. Missouri and Kansas, with their agricultural and manufacturing strengths, exemplify regions where such innovations can drive sustainable economic growth, generate jobs, and reduce fossil fuel dependence. Environmental biotechnology is widely adopted by modern industrial sector for cost-efficient green production and to reduce the environmental hazards. Some major processes and applications include biomarkers, bioenergy, agriculture, pulp and paper industry, and bioremediation and biotransformation. India is among the top 12 destinations for biotechnology worldwide. The Department of Biotechnology (DBT), under the Ministry of Science and Technology, has placed great emphasis on developing an ecosystem for the development of excellence and research in a variety of biotechnology fields in India.

By creating and using a variety of tools at its disposal, such as vaccines, antivirals, diagnostic tests, and other tools, the biotechnology industry has been at the forefront of the fight against the Covid-19 pandemic.

Medical Biotechnology

In healthcare, biotechnology is pioneering approaches like precision medicine, which tailors treatments based on a patient's genetic makeup. Biopharmaceuticals, such as bi-specific antibodies and oligonucleotide therapeutics, are advancing cancer and genetic disease treatments, marking significant progress in personalized medicine. These therapies target diseases at a molecular level, offering new hope for conditions previously deemed untreatable. Cancer treatment holds a dominant position in the medical biotech market, with companies like Pfizer and IBM leading in areas like immuno-oncology research.

Developing new medicines is a complex, costly, and time-intensive endeavor, with only a small percentage of drugs ultimately gaining regulatory approval. To improve efficiency, AI and machine learning are increasingly used to enhance early-stage predictions about a molecule's performance, potential effectiveness, and toxicity. Even a minor increase in success rates can translate into significant cost savings for biotech companies. Personalization has become a key trend in modern healthcare, where genomic medicine, particularly pharmacogenomics, enables customized treatment by analyzing the relationship between individual genetic variations and drug response. This collective effort across biotech teams—scientists, researchers, and data technology experts—is driving transformative advances in products and therapies that positively impact the health and lives of millions worldwide.

Ethical and Societal Considerations

With biotechnology's profound capabilities come ethical considerations, particularly in areas like gene editing and stem cell research. Ethical guidelines underscore the importance of protecting human subjects in clinical trials, ensuring affordability and accessibility of biotech solutions, and safeguarding genomic privacy. Addressing potential bioterrorism threats and navigating sensitive areas like stem cell research require careful adherence to ethical standards to maintain public trust and foster responsible innovation.

Biotechnology in Tackling Global Issues

Biotechnology is instrumental in addressing global issues like food security and climate change. Modified crops are being developed to withstand harsh conditions, while animal breeders are using biotechnology to enhance livestock traits, both contributing to a more resilient food supply chain. In the energy sector, methane capture from agricultural waste exemplifies how biotechnology can provide renewable energy sources while reducing greenhouse gas emissions. As climate change intensifies, biotechnology's role in mitigating environmental impacts and promoting sustainable practices becomes increasingly vital.

Future Scope in Biotechnology

Synthetic Biology is a way of engineering living systems for creating bio-based materials, sustainable alternatives, and programmable organisms. It is a rapidly advancing field within bioengineering and is driven by cutting-edge innovations in laboratory techniques and equipment. This discipline enables microbiologists and geneticists to design new biological systems with unprecedented speed and precision by streamlining living cells into simplified forms known as chassis. Real-world applications of synthetic biology are already making significant impacts across diverse sectors, from cosmetics to the development of sustainable fuels. Each industry is leveraging synthetic biology's versatile potential to pioneer novel, application-specific solutions.

In the area of Gene Therapy and Regenerative Medicine, the rapid advancement of biological methodologies over the past decade has generated substantial interest in the regeneration of human tissues. Breakthroughs in stem cell research, gene therapy, and tissue engineering have significantly propelled tissue and organ regeneration technologies forward. However, despite notable progress, several technical challenges remain, particularly regarding the clinical application of gene therapy. The goals of gene therapy include enabling cells to produce essential proteins, silencing the expression of overactive proteins, and genetically modifying or repairing cellular functions that impact disease conditions.

Nanobiotechnology involve use of nanomaterials for drug delivery, enhancing plant growth in agriculture, and next-generation vaccines. Researchers and companies are pioneering novel nanomaterials and expanding the applications of nanotechnology across various fields. The development of green nanotechnology and cost-effective solutions will further support the integration of these advancements. In healthcare, nanobots enable precision surgeries and significantly improve patient care, while nanotechnology also enhances the efficiency and targeting of drug delivery systems.

Biotechnology in space exploration, including synthetic biology for life support systems and space agriculture for long-term space missions. Unraveling the mysteries of space is no longer confined to science fiction; biotechnology has become instrumental in advancing space exploration by addressing critical challenges like astronaut health, and food and water scarcity. By merging biology, engineering, and space science, biotechnology provides innovative tools and techniques that enhance astronauts' adaptability and resilience in extreme environments. This fusion supports sustainable and efficient exploration, enabling higher-impact missions beyond Earth's orbit.

Further trends and scope in biotechnology

Several forward-looking trends signal biotechnology's evolving landscape. Artificial intelligence (AI) and machine learning (ML) are being integrated into biotech research, enabling advancements in data analysis, drug discovery, and personalized medicine. Bioprinting and tissue engineering are pioneering developments with the potential to address organ shortages and advance regenerative medicine. Mergers and acquisitions are expected to shape the industry's financial landscape, increasing consolidation among biotech companies. Additionally, firms are increasingly partnering with specialty contract research organizations (CROs) to expedite innovation while managing costs.

In a recent interview with Labiotech, Bill Coyle, Principal at ZS, shared insights on 2023 biotechnology trends and priorities. He highlighted cancer, antimicrobial resistance, and sepsis as key areas of transformative potential, while also noting biotech's expanding role beyond life sciences, with promising applications in tackling climate change and enhancing food security. Despite challenges, ground breaking health initiatives driven by biotechnology are poised to reshape our future, addressing critical global issues across health, medicine, and agriculture. ■

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Nitrite and Nitrate Analysis in Excipients: Monitoring Precursors to Nitrosamine

Pharmaceutical excipients are inactive substances used in the formulation of medications alongside the active pharmaceutical ingredient (API) that have been appropriately evaluated for safety and are intentionally included in a drug delivery system.

Niranjan Kothandaraman, Product Manager – Ion Chromatography, Metrohm India Pvt. Ltd. shares insights about the method for nitrite and nitrate determination in excipients, using ion exchange chromatography.

The excipients enable the drug substance to be applied to the patient in the right form and support the way and place of action without being active themselves. They serve various functions, including binding agents, fillers, disintegrants, colouring agents, stabilizers, lubricants and preservatives. Common examples of excipients include starch, lactose, microcrystalline cellulose, povidone, gelatin, magnesium stearate, croscarmellose, methylcellulose, HPMC, talc etc.

Reliable and robust trace analysis using ion exchange chromatography (IEC)

FDA (U.S. Food and Drug Administration) issued a guidance for industry, Control of Nitrosamine Impurities in Human Drugs (possible mitigation strategies to reduce the risk of nitrosamine drug substance-related impurities in drug products). This will help ensure the safety of the U.S. drug supply by recommending steps manufacturers of active pharmaceutical ingredients (API) and drug products should take to detect and prevent objectionable levels of nitrosamine impurities in pharmaceutical products. The guidance also described conditions that may introduce nitrosamine impurities and described a three-step mitigation strategy.

The strategy includes risk assessment (Step I), confirmatory testing if risks are identified (Step II), and reporting changes implemented to prevent or reduce the presence of nitrosamine impurities in drug products in approved and pending new drug applications (NDAs) and abbreviated new drug applications (ANDAs) (Step III)

Recently, the FDA has received additional reports of certain types of nitrosamine impurities that formed in several drug products. These Nitrosamine Drug Substance-Related Impurities (NDSRIs) are a class of nitrosamines sharing structural similarity to the API. NDSRIs can be generated during manufacturing or during the

shelf-life storage period of the drug product. In some cases, the root cause of NDSRI formation has been attributed to nitrite impurities present in excipients at parts-per-million amounts (ppb). Nitrite impurities have been observed in a range of commonly used excipients (as well as water).

Nitrites and nitrates can be naturally occurring or introduced during the medicine manufacturing process. They can originate from raw materials, the synthesis of excipients, or contamination during handling and storage. While nitrites and nitrates are not typically used as excipients themselves, they may be present as impurities in some excipient materials or formulations. Certain preservatives or stabilizers could also contain these compounds.

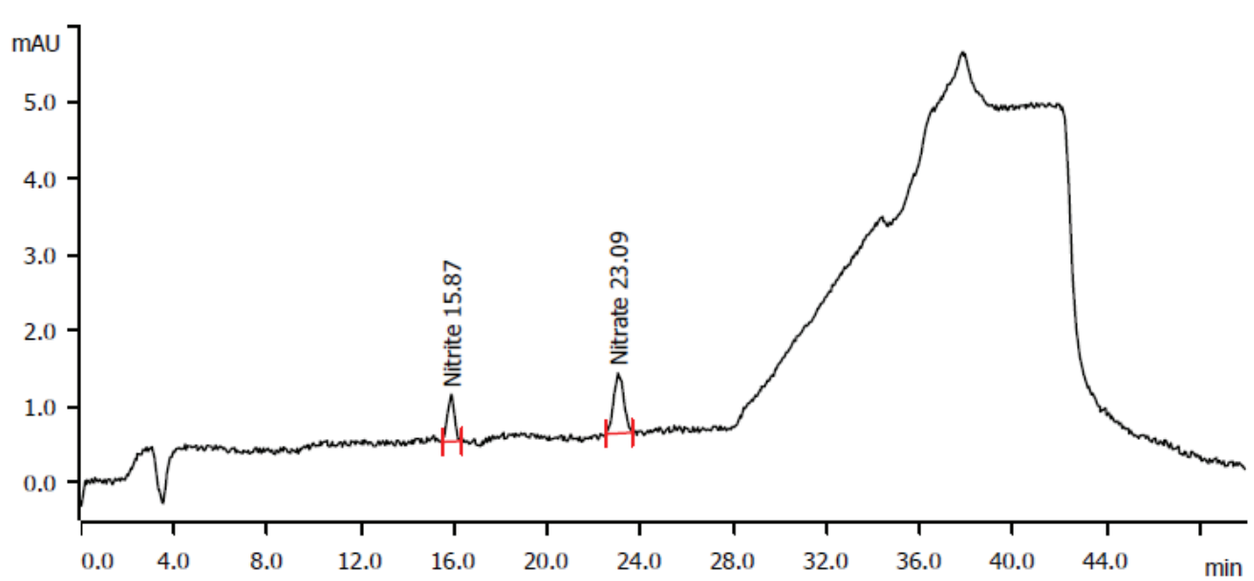
Under acidic conditions, nitrites and nitrates may decompose and react with amines (which can be part of some excipients or APIs), leading to the formation of nitrosamines. The nitrosamines are a class of chemical compounds known for their potential carcinogenic effects. Their presence in pharmaceutical products, including excipients, has raised concerns, particularly in relation to regulatory scrutiny and patient safety.

Monitoring the level of nitrite and nitrate in excipients

will be helpful for risk assessment and risk mitigation strategies. There is a highly selective, sensitive, and reliable determination of trace-level nitrite and nitrate contents in pharmaceutical excipients using ion exchange chromatography.

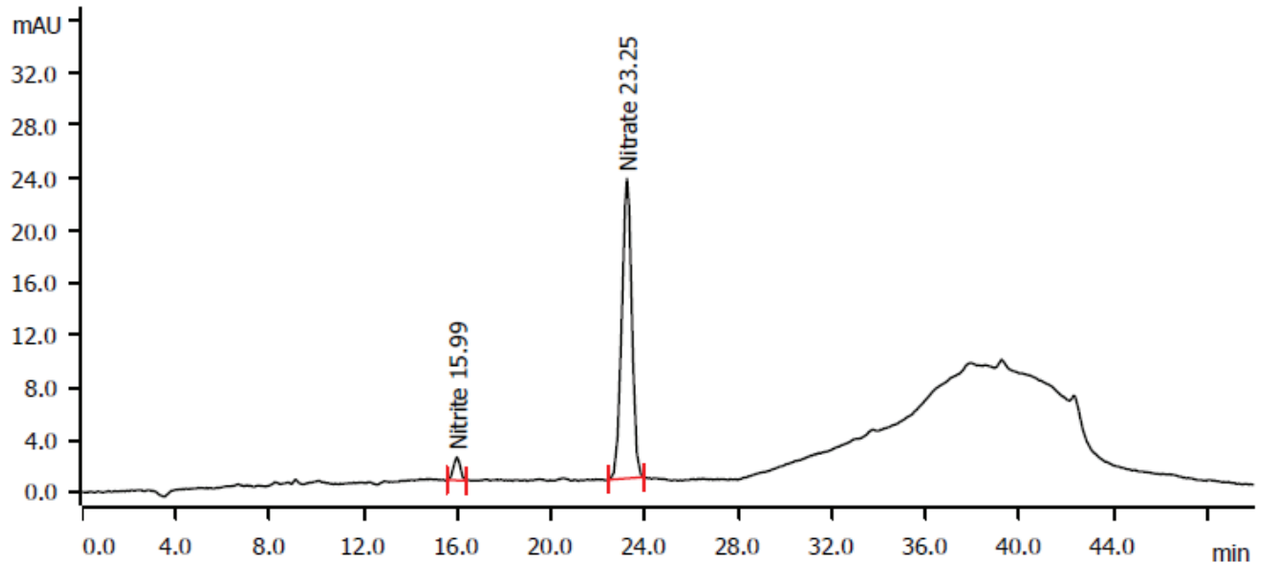
Ion Exchange Chromatography (IEC) is the separation of inorganic and organic ionic species by ion exchange chromatography followed by conductivity detection. The separation of anions is accomplished via anion exchange chromatography. The separation of cations is by cation exchange chromatography.

Sample ID: Purified water-Daman_GPW13 + Standard level 1 (5.0 µg/L of nitrite and 10.0 µg/L of nitrate



Component name	Retention time min	Height mAU	Area (mAU) x min
Nitrite	15.87	0.62	0.213
Nitrate	23.09	0.78	0.391

Sample ID: Microcrystalline Cellulose USP-NF/Avicel pH 112_Normal grade



Component name	Retention time min	Height mAU	Area (mAU) x min	Concentration µg/kg
Nitrite	15.99	1.77	0.584	542.820
Nitrate	23.25	22.91	11.255	10826.217

Ion Chromatography is a very specific and selective technique. Once the instrument is configured for specific analysis, it will carry out the analysis of those ions, irrespective of the presence of other classes of ions. For example, during an analysis of ANIONS, only anions will be detected and estimated, irrespective of the presence of CATIONS & TRANSITION METALS.

The detection in the ion chromatography (IC) technique involves mostly conductivity detectors. Since all the ions have conductivity given the conditions, either high or low they can be detected using this detector. In fact, conductivity detectors are also called universal detectors. The majority of anions, cations, organic acids (C1-C8), amines, transition metals, and speciation studies of ions can be determined.

The technique can be connected to other detectors like diode array detectors UV VIS, fluorescence detectors, electrochemical detectors, and mass spectrometry detectors.

Minimum Detection Limit is usually parts per billion (ppb), without any need for additional equipment. An ideal instrument for trace-level analysis. Per sample analysis, cost is very low as compared to any other existing technique. No shelf life for any of the components.

The following chromatogram shows the quantification of nitrite and nitrate in purified water samples (WFI) and one of the excipients widely used in the pharmaceutical industry.

Conclusion

This article presents a straightforward and sensitive method for nitrite and nitrate determination in excipients. Both the conductivity and UV VIS detectors can be used (individually or in tandem) for the determination in this matrix. The method is quite robust and ensures consistent results. ■

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Metrohm India Pvt. Ltd.

Pharma Analysis Made Easy: Key Insights and Evaluation Metrics

The Indian pharmaceutical industry is highly resilient, largely unaffected by economic fluctuations. It includes branded and generic products, finished dosage formulations and over-the-counter (OTC) medicines. Historically, the global market has been dominated by the USA, Western Europe, and Asia-Pacific countries, with the USA, UK, France, Germany, Italy, Spain, and Japan being primary growth drivers. Emerging markets are expected to significantly contribute to growth in the next five years.

D. Naveen Kumar, Associate Director, CARE Ratings Ltd and Pulkit Agarwal, Director, CARE Ratings Ltd emphasizes about the Indian Pharmaceutical industry, therapeutic Segments and spoke about geographical diversification, R&D focus and regulatory compliance.

Several factors have driven domestic market growth, including increased demand in both acute and chronic segments, pricing revisions by the National Pharmaceutical Pricing Authority (NPPA), and the introduction of new products. Therapies for cardiac conditions, diabetes, and central nervous system (CNS) disorders saw lower double-digit growth, with other therapeutic areas also performing well.

Indian pharmaceutical companies face challenges such as regulatory issues and the need to enhance domestic manufacturing of bulk drugs, intermediates, and key starting materials (KSM) to reduce dependence on imports. The Indian government has introduced measures like a production-linked incentive scheme and dedicated bulk drug parks to support domestic manufacturing. However, reliance on imports, especially from China, remains high.

Key Determinants of Credit Risk

CARE Ratings Limited evaluates companies in the manufacturing sector through a detailed methodology. This includes assessing of the below factors in detail with respect to Indian pharmaceutical industry.

- **Business/Operational Risk**
- **Financial Risk**
- **Environmental, Social, and Governance (ESG) Risk Factors**
- **Business/Operational Risk**
- **Business Segment and Product Portfolio**

It is important to understand the segment in which the Pharma company is operating. Indian Pharmaceutical companies are classified broadly into bulk drug/Active Pharmaceutical Ingredients (APIs) manufacturers, formulation manufacturers, or those with integrated operations and Contract Research & Manufacturing Services (CRAMS). Bulk drugs are APIs used to manufacture formulations.

Therapeutic Segments

Evaluation of the therapeutic segmentation of products into Acute (e.g., anti-infective, pain management) and Chronic (e.g., cardiovascular, oncology, diabetes) is critical. Acute segments dominate domestic and less-regulated markets, while chronic segments are prominent in regulated markets. Companies with a strong presence in chronic segments are viewed favorably for long-term revenue sustainability. It

is crucial to consider the company's presence in different therapeutic segments, revenue percentage from top segments, market share, and strategies for diversification.

Product Portfolio: Analysing the number of products, revenue from top products, product diversity, and the pipeline for future growth is essential in understanding the fundamental stability of company Yearly growth rates of existing products, expected new product launches, market size, and revenue growth from new products also needs to be considered. Companies producing specialty or complex products like injectables and biosimilars are viewed favorably.

Formulation Companies: For formulation companies, market positioning, market share in therapeutic segments, and product portfolio diversification are assessed to evaluate growth stability. The marketing and distribution setup is crucial for market penetration and growth prospects. Formulation companies are classified into patented, branded generic, and generic formulations. Indian companies have a significant presence in branded generics, which command higher margins and better market positioning.

Bulk Drug/API Companies: These companies are capital-intensive and face threats from cheaper imports. Analysing cost efficiency, technical upgrades, manufacturing capabilities, third-party tie-ups, customer base diversification, and product concentration plays critical role from business operations point of view. Over-dependence on a particular country or few suppliers for raw materials can create significant supplier concentration risk. Indian pharma companies are heavily dependent on China for raw materials, with imports accounting for 66-68% of total imports from FY18-FY24. During the COVID-19 pandemic, supply disruptions due to lockdowns in China accentuated the need for supplier base diversification.

Geographical Diversification

Indian pharmaceutical companies derive revenue from both domestic and export sales almost equally. Companies with diversified revenue streams, particularly those exporting to various markets, are viewed favorably as this diversification offers growth opportunities and mitigates regulatory risks.

Export Markets: Indian pharmaceutical companies export to either regulated or semi-regulated markets. Regulated markets have stringent regulations, while semi-regulated markets have less stringent ones. Exporting to regulated markets involves higher compliance with patent and drug laws but offers significant growth opportunities in the generic segment due to upcoming patent expirations. Therefore it is important to evaluate a company's strength in regulated markets by considering regulatory approvals, which also open opportunities in CRAMS. The number of ANDAs (Abbreviated New Drug Applications) and the product pipeline are also analysed.

Research and Development (R&D) Focus

With increasing competition and changing business dynamics, pharmaceutical companies need to focus on R&D to diversify therapeutic segments and improve product quality for sustainable growth. Its essential to assess R&D expenditure as a percentage of sales, comparing it with industry averages and peers. The company's track record in developing new molecules, dosage forms, drug delivery systems, and drug combinations also has to be considered.

Manufacturing Facilities and Regulatory Compliance

Regulatory and legal compliance is a significant challenge for Indian pharmaceutical companies, both domestically and internationally. Compliance with good manufacturing practices (GMP), good clinical practices (GCP), and good laboratory practices (GLP) is crucial due to rapid global changes.

The revenue share from specific manufacturing facilities and the impact of regulatory non-compliance are to be analysed. High legal costs and re-inspection times can affect revenue and profitability. Companies with multiple approved manufacturing plants are viewed favorably, while those with a single facility face asset concentration risks. Disruptions from force majeure incidents, warning letters, import alerts, and labor unrest are critical considerations.

Environmental Compliance

API manufacturers must comply with environmental and pollution control norms to avoid regulatory

actions, including shutdowns. Small and mid-sized API companies face higher risks compared to organized companies with investments in pollution control infrastructure. Changes in environmental rules in major economies have disrupted production and increased raw material costs. Vertically integrated companies with low import reliance have greater operational flexibility and sustained profitability.

Financial position

Financial ratios are used by CARE Ratings Limited (CARE Ratings) to make a holistic assessment of financial performance of the entity, and also help in evaluating the entity's performance vis-à-vis its peers within the industry. Financial ratios are not an 'end' by themselves but a 'means' to understanding the fundamentals of an entity. The common ratios used by CARE Ratings can be categorised into the following five types:

- **Growth ratios**
- **Profitability ratios**
- **Leverage and coverage ratios**
- **Turnover and liquidity ratios**

ESG risk factors

In the current evolving environment ESG plays a critical role in understanding the stance of the management and their responsibility towards Environment, Social and Governance.

Environmental Risks

Pharmaceutical companies, especially those in the API business, must comply with stringent pollution control norms. Non-compliance or stricter regulations can adversely impact operations. Companies investing in infrastructure to reduce environmental impact are to be viewed favorably.

Social Risks

High social risks include consumer safety, regulatory audit track records, litigation instances, and product recalls. Reputation risks related to product quality, compliance with labour laws, worker safety, customer privacy, and fair marketing practices are also considered.

Governance Risks:

Evaluation of the board composition, legal and statutory compliance track record, financial disclosure quality, related party transactions, and transparency in information sharing to gauge corporate governance practices plays critical role.

Conclusion

The overall credit risk profile of companies in the pharmaceutical sector is driven by their relative position in the domestic as well as export markets, geographical diversification and presence across therapeutic segments, their product portfolio, and the ability to handle the regulatory challenges and its focus on R&D.

CARE Ratings in its analyses considers each of the above factors to arrive at the overall assessment of the credit quality of the Issuer. Credit rating is a futuristic assessment, and the rating outcome is ultimately an assessment of the fundamentals and the probabilities of change in the fundamentals in future. Moreover, for arriving at the rating outcome, CARE Ratings also considers future estimation of the company's financials based on past trends and future strategies, competition, industry trends, economic conditions, and other considerations. ■

Authors

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Conductivity Measurement in Pharma: Ensuring Quality and Safety

Conductivity measurement is a critical aspect of pharmaceutical manufacturing, particularly in the production of Active Pharmaceutical Ingredients (APIs). This analytical parameter plays a vital role in monitoring the purity of water used in formulations, validating cleaning processes, and controlling chemical concentrations. The accuracy and reliability of conductivity measurements are paramount, requiring careful selection of appropriate sensors for various production steps.

Importance of Conductivity Measurement

In API production, the primary objective is to create safe and effective therapeutic molecules. Therefore, it's crucial to obtain pure products devoid of contaminants that could compromise downstream purification processes or harm patients. Conductivity serves as an essential indicator in several pharmaceutical operations:

- **Monitoring Purity of Pharmaceutical Grade Waters:** Conductivity helps detect ionic impurities in water used for formulations.
- **Cleaning-in-Place (CIP) and Sterilization-in-Place (SIP) Efficiency:** It verifies that cleaning solutions are effective and that residues are eliminated.
- **Controlling Phase Separation and Chemical Concentration:** Accurate measurements enable optimal control during various production processes.

Selecting the Right Conductivity Sensor

Choosing the appropriate conductivity sensor is vital for accurate readings. Conductivity sensors are categorized into two main types: contacting (with electrodes in direct contact with the sample) and inductive (operating without electrodes).

Key Selection Criteria

Conductivity Range

- **Low Conductivity:** For pharmaceutical waters (0.001 – 2,000 µS/cm).
- **Medium Conductivity:** For buffer formulations, CIP/SIP processes (0.02 – 500 mS/cm).

- **High Conductivity:** For chemical concentration control and phase separation (0 – 2,000 mS/cm).

Cell Constant: The cell constant, a geometric factor indicating the ratio of distance between electrodes to their area, must align with the expected conductivity range of the measurement medium. For low conductivity, a low cell constant (e.g., 0.1 cmS^{1}) is necessary, while higher constants are suited for medium and high conductivity readings.

Temperature Considerations: Since conductivity is temperature-dependent, it's essential to select sensors with integrated temperature probes. This feature enables temperature compensation for more accurate results, especially crucial for compliance with regulatory standards such as USP <645> and USP <1644>.

Construction Materials: For sanitary conditions, materials like 316L stainless steel are preferred. In corrosive environments, alternatives such as PEEK or PFA are more suitable for sensor longevity.

Sensor Length and Fitting: The sensor must reach an optimal measurement point within the process to provide representative readings. Various lengths and fittings (e.g., NPT, DN, Tri-Clamp) are available to meet facility-specific requirements.

Conductivity Measurements Across API Production Steps

Production of Pharmaceutical Waters (Low Conductivity)

Conductivity measurement is vital for controlling ionic impurities in pharmaceutical grade waters. Continuous monitoring through online sensors is recommended to eliminate contamination risks associated with grab sampling. An example of a suitable sensor is the UniCond 2-E, which features Plug and Measure functionality and an integrated measuring circuit.

CIP/SIP Processes and Formulation (Medium Conductivity)

In CIP processes, conductivity measurements confirm the required strength of cleaning liquids and ensure no residues remain. A 4-electrode sensor, such as the InPro 7100i, is ideal due to its minimal polarization effects and reduced susceptibility to fouling, ensuring reliable measurements.

Phase Separation and Chemical Concentration Control (High Conductivity)

Conductivity sensors are crucial in phase separation processes, where readings indicate when to interrupt flow and allow for optimal separation. The InPro 7250 inductive sensor, designed with no wetted metal parts, offers excellent chemical resistance and is suitable for aggressive environments.

Conclusion

Conductivity measurement is indispensable in the pharmaceutical industry for ensuring product quality and safety. By selecting the appropriate sensors based on conductivity range, temperature considerations, construction materials, and process requirements, manufacturers can achieve accurate and reliable results. This, in turn, helps maintain compliance with regulatory standards and supports the production of safe therapeutic products. As the pharmaceutical landscape continues to evolve, the importance of precise conductivity measurement will only increase, underscoring its critical role in modern manufacturing processes.

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. ■

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The exciting potential of digitalization in cell culture manufacturing

When we experience the ease of online shopping or banking, we're benefiting from the digitalization of the fast-moving consumer goods industry. For example, in some supermarket warehouses you'll find robots picking products chosen by a customer online at home, ready for tracked next day delivery. For biotech and biopharma companies advancing the next generation of cell-based medicines, forecasting is more challenging.

Rajan Sankaran, General Manager, Bioprocess, APAC, Cytiva emphasizes about the potential of digitalization in cell culture manufacturing and challenges faced by Biopharma. He also stated that Collaboration is essential to transform biopharmaceutical manufacturing in the biopharma 4.0 era.

Biopharma and biotech manufacturers face many challenges in the biopharma 4.0 era, with speed, access to talent, risk mitigation, and cost control being at the top of the list. In addition, biomanufacturing inefficiencies still exist today for cell culture manufacturing. While there are pockets of digital adoption, the biopharma industry lags in digital maturity, ranking at a Level 2 out of 5 on the Digital Plant Maturity Model (DPMM). Fortunately, recent advancements in digitalization can help address and overcome these challenges.

Over the last several years, the industry has been moving toward adopting digital and automation solutions in tandem with increasing single-use technology solutions, expanding capacity by using scalable and flexible solutions, and manufacturing "in region, for region" to meet growing demand for products and services. Adaptation, innovation, and collaboration are the essential characteristics the life sciences industry needs to enable fast, flexible, and reliable bioprocess development to move toward discovering and delivering future therapeutics.

I want to share four key technology advances that are available today to help manufacturers transition to and solve Biopharma 4.0 challenges in cell culture manufacturing:

- In-Silico process development to speed development of high performance, flexible processes;
- Predictive batch: digitally enhancing consumables and process data to feed advanced process control models and drive predictable outcomes for the drug batch.
- Overall equipment effectiveness, to decrease customer downtime via predictive and remote maintenance; and
- Adaptive plant, to reduce transfer cost where, for example, Cytiva's virtual reality training systems allows personnel to learn processes in advance.

Process development is an intense and time-consuming part of making a therapy. To build a bioprocessing operation that's flexible and scalable for the future, companies can strengthen digital capabilities in

bioprocessing through in-Silico process development. In 2021, we included German scientific software maker GoSilico into our portfolio. In-Silico simulation builds digital twins of downstream processing, thereby revealing how process parameters affect attributes. The result is a scalable and robust solution within about one week, a reduction in experiment materials and, more impactfully, more confident decision-making.

The use of predictive batches enables digital enhancement of consumables and process data to feed advanced process control models and drive predictable outcomes for the drug batch.

With the use of predictive batches, biotechs can reduce the frequency of failed or underperforming batches. This is because cell culture media, resin lots, and bags come with eCOA (Certificate of Analysis) and genealogy, in an electronic format. This combined with process information can enable fast, high-confidence release of on-spec products.

In 2022, predictive modeling output was successfully used in two regulatory filings. Our downstream predictive modeling software, which determines optimal purification conditions through simulation or simulated data, is used by companies to achieve better process yield, higher product purity, and faster regulatory filings. Our upstream predictive modeling software was used by UMass Medical Gene Therapy Center to achieve right-first time scale up from 50L to 200L production of AAV vectors.

There's also so much potential around data sharing by making equipment 'smarter.' This is where effective equipment comes in. Stronger integration, data collection, and analysis are crucial to creating a manufacturing platform capable of core data management. To bolster our biopharma 4.0 offering, we implemented an Augmented Reality solution, OptiRun View and My Equipment, to decrease equipment downtime and speed up repairs. We're exploring how we can help customers save time, money, and increase output by understanding what happened in every stage of a process.

Lastly, an adaptive plant can accelerate speed to market as well as reduce costs and error. Our FlexFactory configurable manufacturing train provides access to Current Good Manufacturing Practice (cGMP) biomanufacturing capacity in the shortest time possible by utilizing bioprocess equipment with pre-configured and pre-verified automation software.

The latter mitigates risk by reducing implementation, documentation, testing, and validation effort and time and human error. In turn, it allows for flexible implementation of manufacturing execution system (MES). As manufacturers strive to build digital maturity with enterprise automation, Cytiva's Figurate automation software offers a robust platform to streamline manufacturing operations and capture valuable data to improve process control.

Training

In the 2023 Global Biopharma Resilience Index, the data reveals that companies find it hard to find mature talent and train fresh hands. Training personnel in person creates fundamental challenges in bioprocessing. These challenges include regional barriers as well as limited access to equipment and trainers. In search of a solution, we've turned to virtual reality. This virtual training system is strategic collaboration with our customers as part of their digital strategy. Through it, we can train our customers without having them shut down commercial production or maintain equipment used only for training.

Innovation and digitalization, especially in data management, is a bright spot for biopharma manufacturers to bring the next generation of medicines. I'm excited about the adoption of digital solutions to enable flexible, reliable bioprocess development. ■

Author

Rajan Sankaran
General Manager, Bioprocess, APAC
Cytiva

IoT based Laboratory Monitoring and Controlling System

Digitization is revolutionizing the world we live in, and Laboratories and Research buildings are no different. **Shine Chandran, Business Head – Kewaunee 4.0 (IoT Business Unit), Kewaunee International Group** emphasizes about Lab Digitization and how data analytics can help fuel innovation.

Continuous Monitoring of lab equipment is crucial to prevent malfunction, reduce downtime, improve efficiency, and ensure product safety.

The insights from equipment monitoring can help to optimize equipment usage so that the assets run at peak performance, avoiding excessive energy consumption caused by equipment working overtime and also help to improve energy efficiency in any lab through schedule management.

Why Lab Digitization?

Lab digitization enables scientists and analysts to work in safe, controlled environments free from contaminants, equipped with high-throughput technologies. This allows labs to streamline R&D and accelerate innovation in core research, enhancing the speed, cost management, and efficiency of testing—empowering them to focus on their expertise.

Digitization and automation categorically can also assure better quality and compliance by reducing manual errors and variability. They enable faster and more effective problem resolution and a risk-based approach to optimizing testing volume, tools, and methods.

The latest technologies and digital solutions can make quality control faster, more agile, more reliable, more compliant, and more efficient.

Also, Let's understand how data analytics can help fuel innovation and could be a game-changer.

Data is the fuel for unlocking value through digital technology. More data and accurate data are vital for a better solution.

However, as the amount of digital data grows it's a burden to manage data and provide accurate results. Regardless of the type of laboratory, discovery, research, or industrial, the accuracy of results and insight are critical to creating new products or driving forward scientific discoveries.

Furthermore, quality assurance and quality control are of utmost importance at all stages of a pharmaceutical product's development to ensure the safety & compliance of products before these reach the market

and finally to consumers.It is a fact that digitalization has the potential to enhance pharmaceutical quality assurance and quality control significantly.

For example, a typical pharma lab does not have the advanced analytical capabilities needed to get the maximum value from its data sources. As a result, the labs collect a lot of useful data but fail to generate insights that could prevent problems, improve test methods, or optimize testing volumes.

However, with digitalization IoT Powered Integrated Laboratory Monitoring Solutions can communicate with each other and share data, giving insight and thus allowing them to automatically identify potential quality control issues.

Application of new technology

The emerging technologies that characterize Industry 4.0—from connectivity to advanced analytics, robotics, and automation—have the potential to revolutionize every element of the pharma-manufacturing labs. Enabling the R&D industry to achieve sustainability, harvest the fast-growing wealth of data, and turn it into actionable insights for a better solution and enhanced financial results.

Kewaunee's LabAsimo (IoT Powered Integrated Laboratory Monitoring and Controlling Solution) is the way to realize your dream of a complete solution for monitoring and reporting in regulated and critical environments. It's important to maintain acceptable levels in the internal atmosphere of a lab, such as temperature, humidity, volatile organic compounds (VOCs) and CO_2/O_2 levels along with Monitoring of essential common services like Gases, Energy monitoring and optimization.

LabAsimo offers continuous monitoring for a wide range of parameters like Monitoring the Lab environment including VOC's and CO_2, Laboratory HVAC Monitoring and automated controlling, Comfort index for Laboratory users, Monitoring fume hood performance and IoT based modernization , Monitoring of essential common services like cameras, lighting and water in the lab, Energy monitoring and optimization. ■

Author

Shine Chandran
Business Head – Kewaunee 4.0 (IoT Business Unit), Kewaunee International Group

Romaco to showcase portfolio at CIPM 2024 in China

Karlsruhe, Germany: Romaco will take advantage of this year's CIPM, China International Pharmaceutical Machinery Exposition, to show its key technologies for manufacturing and packing pharmaceutical solids. The one stop solutions supplier's portfolio covers the entire process chain – from powder to pallet.

From granulation, tableting and coating to primary and secondary packaging, Romaco offers the right technology for every process step. The one stop solutions supplier's portfolio covers everything from smart solutions for research and development to high-performance production machinery. The manufacturer combines premium quality with excellent value for money. All machines are extremely versatile and very easy to operate. Due to their systematic reduction of power and material consumption, Romaco technologies are not only sustainable but also cost-efficient.

At the Romaco China Process Centre (RCPC) at the production site in Changsha, users and prospects have the opportunity to test their products on Romaco equipment. The modern laboratory environment is the perfect place for all development activities related to granulation, tableting and coating of pharmaceutical solids. Selected Romaco packaging technologies are likewise available there for demonstration purposes. ■

Nikon India inaugurates India's First Experience Centre dedicated to its healthcare Range

Mumbai, India: Nikon India Private Ltd., a 100% subsidiary of Nikon Corporation today inaugurated India's first experience centre dedicated exclusively to the healthcare product range at its headquarters in Gurgaon. The Healthcare Business is one of the largest Business Segments of Nikon Corporation that owes the responsibility to lead a Life Science Market through core Optics and Image analysis technologies.

Nikon has been a significant player in the Indian market for over four decades, primarily through its imaging and precision technologies. With the launch of this healthcare experience centre, Nikon India aims to provide a hands-on experience to healthcare professionals, researchers, and academic institutions to explore and utilize its cutting-edge microscopy solutions. This Experience Centre will also focus on microscopy workshops and trainings for skill development of the latest microscopy technologies in this region.

Speaking at the inauguration, Mr. Sajjan Kumar, Managing Director of Nikon India Pvt. Ltd., said, "Nikon's century-old legacy in manufacturing microscopes has always set benchmarks for quality and precision. The launch of India's first experience centre dedicated to healthcare technology reaffirms our commitment to supporting the scientific research and pathological, clinical communities with world-class solutions. This facility will serve as an important touchpoint where professionals can explore and experience our advanced healthcare products firsthand before making informed purchasing decisions. We believe this initiative will help elevate the standards of Scientific research and Pathology across the country." ■

Asahi Kasei Medical launches Planova FG1 next-generation virus removal filter

Tokyo, Japan: Asahi Kasei Medical has launched the Planova FG1, a next-generation virus removal filter featuring higher flux for the manufacture of biotherapeutics, in October 2024.

The bioprocess business of Asahi Kasei Medical comprises Planova™ virus removal filters and equipment used in the manufacturing process of biotherapeutic products such as biopharmaceuticals and plasma derivatives, biosafety testing services, and biopharmaceutical CDMO operations. It is one of the Asahi Kasei Group's businesses to drive future growth.

Sold since 1989, Planova had its product lineup expanded in 2009 with the launch of Planova BioEX hydrophilic PVDF hollow-fiber membrane filters, and in 2022 with the launch of Planova™ S20N next-generation cellulose hollow-fiber membrane filters, meeting heightened standards for the viral safety of biotherapeutics around the world. The new Planova™ FG1 is expected to further contribute to improved productivity as demand for monoclonal antibodies and other biopharmaceuticals steadily grows by 5–10% per year.

Developed to maximize productivity in the process of manufacturing biopharmaceuticals, Planova FG1 provides high performance in terms of the filtration speed and robustness in virus removal capability. Its high flux is approximately 7 times that of Planova™ BioEX, enabling virus filtration time to be shortened, and it features less risk of virus breakthrough when the filtration process is suspended. Customer evaluation in the development stage of Planova™ FG1 confirmed high protein filtration and virus removal performance under various conditions using several solutions, even without a prefilter to remove aggregates. Planova FG1 is also compatible with standard cleaning in place (CIP) and sterilization in place (SIP) processes, allowing it to be used with many types of existing equipment for biopharmaceutical manufacturing. ■

Thermo Fisher Scientific introduces transmission electron microscope

WALTHAM, Mass: Thermo Fisher Scientific Inc., the world leader in serving science, introduced a groundbreaking transmission electron microscope to a packed room of attendees at the recent European Microscopy Congress 2024 in Copenhagen, Denmark. As a fully integrated multimodal analytical solution, the Thermo Scientific Iliad (Scanning) Transmission Electron Microscope, (S) TEM, gives scientific pioneers deeper insights about the chemical nature of the most sophisticated modern materials, down to the atomic level.

"A revolutionary new platform like this only comes around once in a decade," said David Wall, vice president and general manager of Materials Science at Thermo Fisher Scientific. "Beginning with its unveiling at EMC, Iliad has already received a positive and energetic reception from researchers and industry leaders across the globe. This is the culmination of years of investment and hard work, but in many ways it's just the beginning of unlocking the full potential of integrated microscopy technology." Iliad (S)TEM is featuring the new Thermo Fisher Scientific EELS Spectrometer and Energy Filter, as well as the NanoPulser — the new electrostatic beam blanker for the electron dose optimization. Multimodality and the integration of energy dispersive spectroscopy (EDS), EELS and the NanoPulser ensures the advanced and effective approach for precise chemical and structural investigations of broad classes of modern materials. ■

INDIA

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

Asia Pharmacon Expo 2024

Dates: 6-7 December, 2024

Venue: Bengaluru, India

Details: Asia Pharmacon Expo is the Asia largest pharmaceuticals exhibition. It will provide an opportunity to the participating companies to display or showcase the product among the global crowd coming from the different part of the world. The Expo will simultaneously provide opportunity to the visitors to know about the recent advancement and discoveries going on now a days.

Email: info@asiapharmaconexpo.com
Website: www.asiapharmaconexpo.com.

World Congress on Advanced Pharmacy and Clinical Research

Dates:14th December, 2024

Venue: Chennai, India

Details: WCAPCR-24 will create a global platform to researches, scientists, academicians, policymakers, industry experts to share experiences, discuss research findings and acquire and the desired knowledge in the subject from around the world with many networking opportunities.

Contact: 9677007228
Email: info@sfe.net.in
Website: www.sfenet.in

International

Drug Discovery Chemistry Europe (DDCE)

Dates: 03- 05 Dec 2024

Venue: Barcelona, Spain

Details: Drug Discovery Chemistry Europe is a premier event designed for medicinal and biophysical chemists in pharma, biotech, and academia. This dynamic conference focuses on addressing the discovery and optimization challenges of small molecule drug candidates.

Contact: 7819725400
Email: chi@healthtech.com
Website: www.drugdiscoverychemistry.com

Pharmaceutical and Medical Meeting Planners' Summit 2024

Dates: 2-3rd December, 2024

Venue: Boston, USA

Details: Pharmaceutical and Medical Meeting Planners' Summit convenes senior meeting management professionals from the life sciences, medical, and health care industries to discuss the latest innovations in medical meeting management and strategies to effectively and creatively execute both in-person and virtual meetings while complying with Federal and State regulations.

Contact: 7819392618
Email: Sean.Edwards@thinc360.com
Website: www.thinc360.com

17th World Drug Delivery Summit

Dates: December 05-06, 2024

Venue: Dubai, UAE

Details: The 17th World Drug Delivery Summit, scheduled for December 05-06, 2024, in Dubai, UAE, offers a premier platform for global experts in drug delivery to converge and exchange insights at the forefront of pharmaceutical sciences.

Contact: 1-650-889-4686
Email: contact.omics@omicsonline.org
Website: www.drugdeliveryeurope.com, www.pharmaceuticalconferences.com

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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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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

FACTS & FIGURE 2024

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

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