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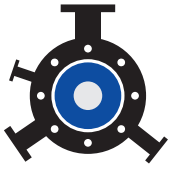
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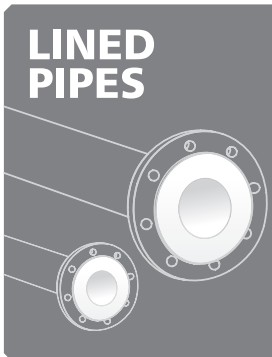
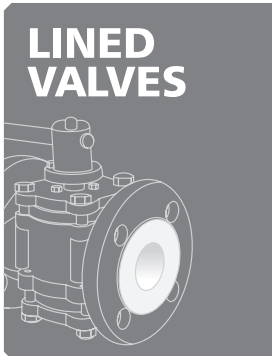
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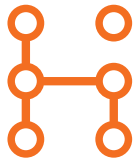


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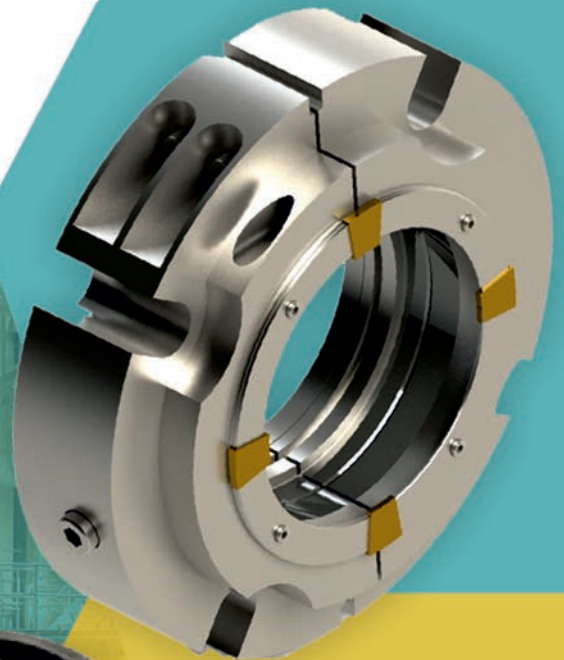
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Budget reflects Govt's strong commitment to 'A Developed and Self-Reliant India': Smt. Anupriya Patel

New Delhi: Union Minister for Chemical and Fertilizers, Shri J. P. Nadda, has lauded the Union Budget 2026-27 presented by Union Minister of Finance & Corporate Affairs Smt. Nirmala Sitharaman as a 'Viksit Bharat Budget' with a long-term vision under the leadership of Prime Minister Shri Narendra Modi.

Commending the emphasis on advancing the Biopharmaceutical ecosystem in the country, the Minister has stated, "Under the Biopharma Shakti Initiative, the Government has proposed an outlay of ₹10,000 crore over the next five years. This will enhance domestic production of advanced biologic medicines and biosimilars. Establishment of three new institutes and the upgradation of seven existing institutes will usher in a new era of growth, innovation, and global competitiveness for India's pharmaceutical sector. Three new dedicated Chemical Parks in states will enhance domestic chemical production", he added.

Minister of State for Chemicals & Fertilisers Smt. Anupriya Patel, while welcoming the Union Budget 2026-27, said that "this budget marks the beginning of a new era in the Health and Pharma sector. From the ₹10,000 crore 'Biopharma Shakti' initiative to three new National Institutes of Pharmaceutical Education and Research (NIPERs) and a new NIMHANS in North India, this Budget reflects the Government's strong commitment to 'a Developed and a Self-Reliant India'.

India-EU FTA unlocks access to \$572.3 billion EU pharmaceuticals & medical devices market

New Delhi: India and the European Union (EU) announced the conclusion of negotiations for a Free Trade Agreement (FTA), an important milestone in one of India's most strategic economic partnerships. Designed as a modern, rules-based trade partnership, the FTA responds to contemporary global challenges while enabling deeper market integration between the world's 4th and 2nd largest economies.

The FTA unlocks access to the \$572.3 billion EU pharmaceuticals and medical devices market giving impetus to the Indian Pharmaceuticals sector. This would enable pharma industries to scale, generate employment, and reinforce India's positioning as

a reliable partner in the pharmaceuticals sector underlining its growing stature as the pharmacy of the world. It is expected to expand skilled jobs, industrial employment, stronger Micro Small and Medium Enterprises (MSME) participation and strengthen global supply chain integration.

The highlights of Free Trade Agreement for the pharmaceuticals and medical devices sector include liberalised tariffs for key 'Made In India' medical devices; growth across inorganic and organic chemicals, fertilisers, pharmaceuticals, cosmetics, soaps and detergents; capacity expansion and MSME cluster development to drive sectoral growth and major expansion opportunities across hubs in Gujarat, Maharashtra, Karnataka and Andhra Pradesh.

Coastal export hubs will be able to scale Export-led growth to support employment and processing intensive sectors. Aligned with India's vision of "Viksit Bharat 2047", the India-EU FTA reinforces shared values, fosters innovation, laying the foundation for inclusive, resilient and future-ready growth for both India and Europe.

Economic Survey 2025-26 highlights India's shift towards high-value pharma and innovation

New Delhi: The Economic Survey 2025-26 has observed that, the pharmaceutical industry in India is shifting from a volume-driven approach to a value-driven approach, to move up the value chain with greater emphasis on complex generics, biosimilars and innovation.

The survey has stated that India's medical devices sector is rapidly becoming globally competitive, with exports to 187 countries in the financial year 2025. The industry now manufactures high-end equipment, including MRI and CT scanners, linear accelerators, cardiac stents, and ventilators. The survey noted that this expansion into sophisticated imaging and life-support technologies marks a significant shift toward high-tech medical manufacturing.

India currently ranks 11th globally in pharmaceutical exports by value, with a 3 per cent share and medical devices exports have grown significantly from USD 2.5 billion in FY21 to USD 4.1 billion in FY25. The survey states that there exists substantial scope for further expansion and adds scaling up the medical devices sector necessitates reducing import dependence through the adoption of advanced manufacturing technologies such

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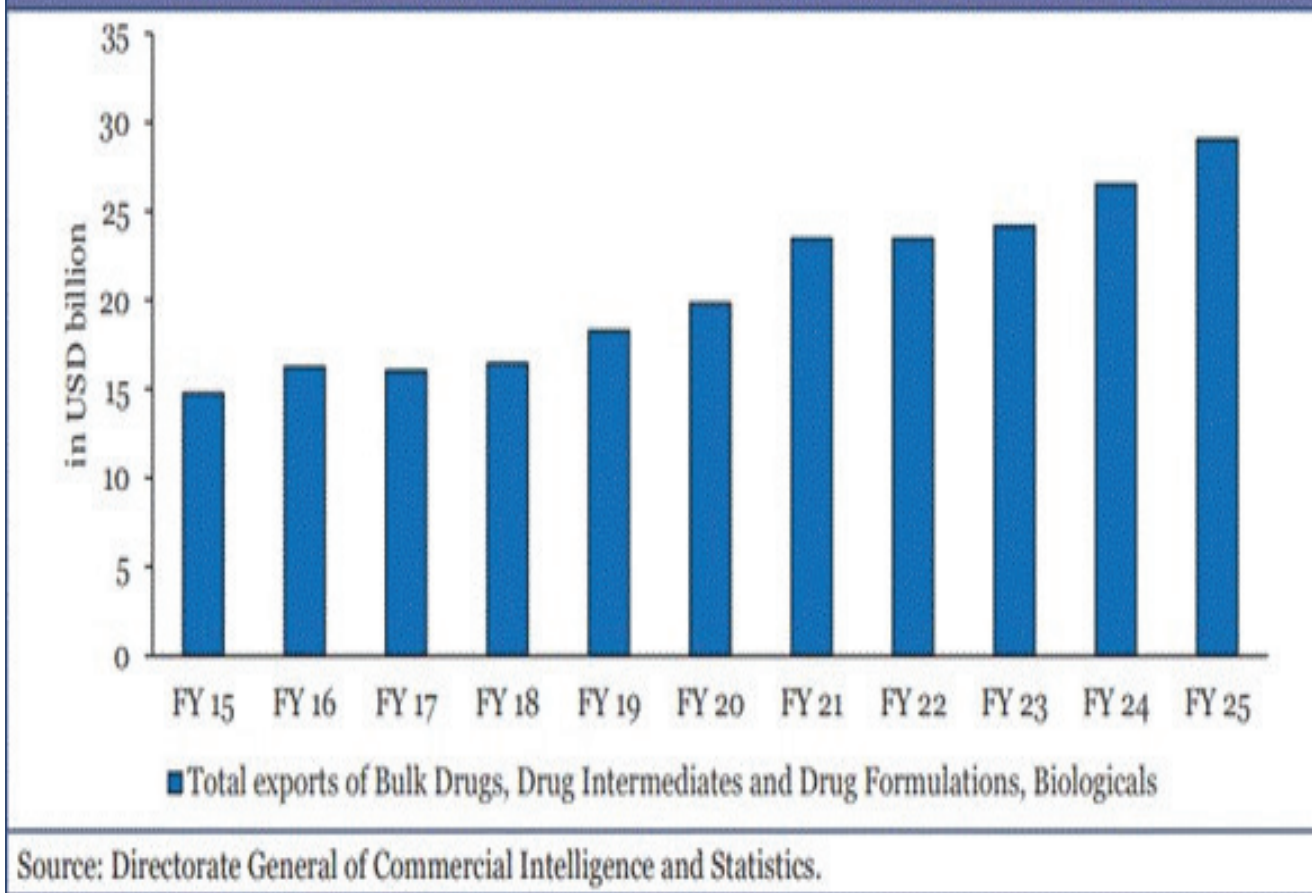


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Chart VIII.17: Growing exports of the pharmaceutical industry



Steady rise in India's Pharmaceutical Exports (FY15–FY25)

as AI and 3D printing, along with streamlining global certification processes to strengthen international market access.

DoP launches 7 Centres of Excellence

New Delhi: The Department of Pharmaceuticals (DoP) has established seven Centres of Excellence (CoEs), one each at seven National Institute of Pharmaceutical Education and Research (NIPERs), under Component A of the Promotion of Research & Innovation in MedTech Sector (PRIP) scheme. A total amount of ₹183.46 crore has been released for setting up these centres till 31.1.2026.

A total of 710 research projects, were received from industry, start-ups and Micro Small and Medium Enterprises (MSMEs) by the closing date of 19.11.2025, including projects in priority areas that are eligible for higher financial support under the PRIP scheme. Approval for financial assistance under the scheme, including full funding assistance and higher funding assistance to eligible projects is provided after a multi-stage appraisal process, as prescribed under the

scheme guidelines.

Info on import of high end and high value used medical equipment

New Delhi: As per the information provided by the Ministry of Health and Family Welfare, the medical devices are regulated under Drugs and Cosmetics Act, 1940 and the Medical Device Rules, 2017 made thereunder. In order to have control over the refurbished medical devices, the Ministry of Health and Family Welfare has constituted a committee on 'Policy on regulation of refurbished medical devices,' to examine the scope of refurbished medical devices, methodology to evaluate the safety, performance, and remaining useful life of refurbished medical devices & suggest guidance for waste disposal of such refurbished devices.

Non-inclusion of cancer medication under price control

New Delhi: The prices of drugs including oncology drugs are regulated as per the provisions of Drugs

(Prices Control) Order, 2013 (DPCO, 2013). Ministry of Health and Family Welfare publishes the National List of Essential Medicines (NLEM) which is incorporated as Schedule-I of DPCO, 2013 by Department of Pharmaceuticals. The medicines under Schedule-I are mentioned according to their therapeutic category. Anti-cancer formulations are listed in the Schedule-I of DPCO, 2013 under the Section-7, "Anti-cancer agents including Immunosuppressives and Medicines used in Palliative Care".

The National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling prices of 131 anti-cancer scheduled formulations as listed in Schedule-I. All manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA.

NPPA also fixes retail price of 'new drug' as defined under para 2(1)(u) of DPCO, 2013 as on 27.01.2026, NPPA has fixed the retail price of 54 drugs under the Anti-Cancer therapeutic category. Further, in case of non-scheduled formulations, their prices are monitored and manufacturer of such formulations are required to not increase the maximum retail price of that formulation by more than 10 per cent of the maximum retail prices during the preceding 12 months. Accordingly, prices of all oncology medicines are covered under DPCO, 2013 either by way of price control by fixation of ceiling / retail price or by regulating the increase of price under para 20 of DPCO, 2013.

Novo Medi Sciences launches 'G.A.U.R.I.' – A nationwide missed call movement to ensure no girl misses her right to immunization

Mumbai, India: Novo Medi Sciences Pvt. Ltd. (Novo Group) has announced the launch of G.A.U.R.I. (Generating Awareness on Underprivileged Girls' Right to Immunization), a nationwide awareness-led vaccination mission designed to spotlight and support the immunisation rights of underprivileged girl children across India. At its heart, G.A.U.R.I. is built on a powerful yet understated belief: *'Protecting a girl child's health should never depend on privilege, geography, or circumstance.'*

G.A.U.R.I. invites citizens to participate in a collective public health effort by leaving a missed call at 9555-466-000. The missed-call awareness phase of G.A.U.R.I. started from 24th January 2026 (National

EVERY GIRL DESERVES HEALTHY FUTURE. EVERY ACTION COUNTS, put your phone on 'Do Good Mode'.

Protect an underprivileged girl with just a missed call.

NO COST. NO FORM. NO APP.
Every missed call strengthens Novo Medi Sciences vaccination pledge.
Give her 2X care. Give her 2X protection.

Give a missed call on 9555-466-000

An initiative by Novo Medi Sciences Pvt. Ltd.

G.A.U.R.I.
Generating Awareness on Underprivileged Girl's Right to Immunization

From the Makers of NEXIPOX PLUS

Girl Child Day) will continue till 30th March 2026, allowing sustained participation over several weeks. Every participant will receive an acknowledgement via a thank-you voice message and an SMS, directing them to the microsite, ensuring transparency, and reinforcing that each individual action contributes to real-world change. (www.gauribynovo.com)

Through this campaign, Novo Medi Sciences (Novo Group) aims to transform awareness into action, starting with something as simple as a missed call. At the end of this campaign, Novo Medi Sciences hopes to reach millions of Indians and will provide vaccination to thousands of underprivileged girl children across the nation with NEXIPOX PLUS® against the deadly chickenpox disease.

While G.A.U.R.I. begins with awareness on underprivileged girls' right to Immunization, its impact is rooted in responsible execution. The vaccination phase, which will follow the awareness drive, will be supported by qualified healthcare professionals to ensure vaccines are administered safely and ethically, in accordance with medical guidelines. Healthcare professionals will also play a vital role in community engagement, helping families understand the importance of immunisation and guiding them towards appropriate care.

This missed call serves as a silent signal of support for G.A.U.R.I., helping ensure that underprivileged girls do not miss out on their right to health protection. When thousands of such small individual actions come together, they turn into a collective statement—one

that says no girl should ever miss her chance at a healthier future, simply because of the circumstances she was born into.

Zydus receives USFDA Orphan Drug Designation for Desidustat for treatment of Sickle Cell Disease

Ahmedabad, Gujarat: Zydus, a leading, discovery-based, global pharmaceutical company has announced that the USFDA has granted Orphan Drug Designation (ODD) to Desidustat, a novel oral HIF-PHI, for the treatment of Sickle Cell Disease (SCD). The USFDA's Office of Orphan Drug Products grants orphan status to support development of medicines for the treatment of rare diseases that affect fewer than 200,000 people in the United States. Therapeutic options for management of Sickle Cell Disease are limited. Hydroxyurea, reduced frequency of painful crisis in SCD, but is not universally effective and associated with side-effects like neutropenia and thrombocytopenia. Blood transfusions are expensive, not uniformly accessible, and are accompanied by risks including alloimmunization, hemolysis, and transfusion iron overload. A Phase II, double blind, randomized, placebo controlled, parallel, multi-centre, proof-of-concept study to evaluate the efficacy and safety of Desidustat oral tablet for treatment of SCD has been completed, and data will be published in medical journal.

Orphan drug designation by the USFDA for Desidustat, provides eligibility for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and a potential seven-year marketing exclusivity upon the USFDA approval.

Evinova announces tie-ups with Astellas, AstraZeneca & Bristol Myers Squibb to accelerate global clinical development via AI

BAAR, Switzerland: Evinova has announced strategic collaborations with global life sciences companies Astellas Pharma Inc, AstraZeneca and Bristol Myers Squibb to accelerate their global clinical development using Evinova's AI-native platform. Each partner company has opted in to share operational data with Evinova, enabling the platform to provide benchmarks

and smarter recommendations intended to further accelerate clinical trials and improve patient outcomes.

Clinical development is often slowed by fragmented systems and manual processes that delay timelines and increase costs. Evinova's AI-native platform addresses these challenges through intelligent optimization, faster end-to-end workflows and recommendations for improvements. The platform, now enhanced with multi-agent AI capabilities, empowers partners to innovate, adapt, and achieve better outcomes.

Evinova's AI-Native platform accelerates clinical development while ensuring the user has full control of decision making, supporting compliance and confidence across every phase of the trial lifecycle. The globally scaled platform features a flexible architecture that enables a multi-model partner approach, provides access to the most advanced AI models and trained agents with deep enterprise expertise as well as smarter operational insights through an opt-in data sharing mechanism. Evinova's platform has delivered transformative value, unlocking 5 to 7 per cent savings minimum per study, adding to hundreds of millions of dollars for top 10 pharma across their portfolio.

With 17% YoY export growth to Brazil, Pharmexcil's India-Brazil healthcare meeting, signals next growth phase

New Delhi: The Pharmaceutical Export Promotion Council of India (PHARMEXCIL) supported the India-Brazil Healthcare Business Gateway held in New Delhi, bringing together Indian pharmaceutical manufacturers, regulatory authorities, and Brazilian healthcare leaders. Organized by Amoveri Farma during the official visit of the Brazilian delegation, the closed-door meeting focused on expanding cooperation in oncology medicines, biosimilars, complex therapies, and hospital technologies, while facilitating structured access to the Brazilian market.

The meeting included participation from Amoveri Farma leadership, ANVISA representatives, and regulatory specialists, underscoring the strategic importance of India-Brazil cooperation in healthcare innovation and access. Discussions also addressed compliance with ANVISA requirements and pathways to accelerate responsible market entry.

India's pharmaceutical exports to Brazil have shown significant growth, with the country currently ranked as the second-largest destination for Indian pharma

exports by share. Brazil accounts for approximately 2.88 per cent of India's total country-wise pharmaceutical exports. The majority of exports between Apr'25 – Jan'26 are driven by formulations and biologicals, which saw the highest growth during this period.

Veeva and BioMarin form long-term strategic partnership

Pleasanton, California, and San Rafael: Veeva Systems and BioMarin Pharmaceutical Inc. have announced a long-term enterprise agreement that builds upon their long-standing relationship.

The expanded partnership will help BioMarin increase speed, agility, operational efficiency, and optimize the healthcare professional and patient experience by further leveraging and providing strategic input into Veeva's software, data, services, and consulting products.

"This strategic partnership marks an important next step in our digital evolution," said Alexander Hardy, President and Chief Executive Officer of BioMarin. "We are excited by the opportunity to combine our scientific capabilities with Veeva's technological leadership that we believe will enable us to bring our transformative medicines more quickly to patients around the world."

"Our partnership with BioMarin has always been guided by a shared set of values, including product excellence, value realization, and customer success," said Veeva CEO Peter Gassner. "Building on this foundation, I look forward to how we can further support BioMarin as they advance important new medicines and reach even more patients around the world."

Eris Lifesciences enters tie-up with Natco Pharma for Semaglutide launch in India

Ahmedabad: Eris Lifesciences Limited, a leading Indian branded formulations company, has announced a strategic partnership with Natco Pharma Limited for the commercialization of Semaglutide in India, reinforcing Eris's commitment to expanding its leadership in the fast-growing diabetes and metabolic care segment.

Semaglutide, a GLP-1 receptor agonist, has emerged globally as a transformative therapy in the management of Type 2 diabetes and chronic weight management driven by robust clinical outcomes in glycemic control and weight reduction. With India witnessing a rapidly

growing diabetic population and increasing awareness around obesity management, GLP-1 therapies represent a high-growth opportunity within the metabolic segment.

This collaboration builds on both companies' complementary strengths: Eris's robust commercial and diabetes franchise presence, and Natco's manufacturing and regulatory prowess in complex formulations.

Natco Pharma has received approval from the Central Drugs Standard Control Organisation (CDSCO) to manufacture generic semaglutide for the Indian market, paving the way for a launch expected in March 2026. The product will target Type 2 diabetes management aligning with unmet needs in India's expanding metabolic care landscape. ■

Intas Pharmaceuticals collaborates with IntegriMedical to launch needle-free injection system for IVF & gynecology



Mr. Sarvesh Mutha, Managing Director, IntegriMedical and Mr. Durga P. Satapathy, Executive Vice President, Intas Pharmaceuticals, during signing of the agreement.

New Delhi : Intas Pharmaceuticals Limited, a leading multinational pharmaceutical company, has entered into an exclusive agreement with IntegriMedical, the technology leader behind India's first Needle-Free Injection System (N-FIS), to introduce this revolutionary technology for use in IVF and gynecology treatments across India.

This marks a significant milestone in IVF and women's health. Securing exclusivity for a first-of-its-kind needle-free injector transforms both the delivery and experience of treatment, placing patient comfort and confidence at the forefront of care.

Through this agreement, Intas becomes the first and only company in India to offer IVF and gynecology therapies with needle-free injections, setting a new benchmark for patient-centric innovative drug delivery system. The collaboration represents a decisive step in transforming how reproductive care is delivered.

By leveraging IntegriMedical's proprietary drug-delivery technology, Intas aims to reduce injection-related discomfort and anxiety while enhancing compliance and patient satisfaction. Under the agreement, Intas, in collaboration with IntegriMedical, will streamline deployment of needle-free injections across IVF clinics

and gynecology centers nationwide.

India represents one of the fastest-growing IVF markets globally. Reportedly, the current number is around 300,000 to 350,000 cycles per year, with projections suggesting this could increase to 500,000 to 600,000 cycles by 2027. At scale, this results in several million injections administered every year as part of IVF treatment in India alone. By integrating needle-free injection technology into IVF treatment pathways, the collaboration is expected to improve the treatment experience for hundreds of thousands of women annually, particularly by reducing injection-related pain, anxiety, and treatment fatigue.

N-FIS delivers medication through a high-pressure jet stream mechanism in a consistent, predictable, spray-like pattern. Medication is administered through a fine micro-orifice in the skin, enabling effective delivery without the use of needles. Unlike traditional needle-based injections, this approach minimizes tissue trauma, avoids medication pooling, and reduces the risk of cross-contamination.

Zydus Hospitals expands presence in Vadodara, acquires VINS Hospital

Ahmedabad, Gujarat: The 300-bed, Zydus Multispecialty and Cancer Hospital, Vadodara has acquired Vadodara Institute of Neurological Sciences (VINS) Hospital. With the acquisition of the 50-bed centre, Zydus Hospitals gain a dedicated centre in neurology and neurosurgery enabling it to reach out to patients needing neuro-care.

The integration will significantly strengthen Zydus Hospitals' neuroscience portfolio, bringing expertise to manage complex conditions such as brain and spinal tumours, aneurysms, movement disorders, stroke, trauma, deep brain stimulation (DBS), complete epilepsy care including surgery, among others.

VINS was founded two decades ago by Dr. Monish Malhotra and has since built a reputation for specialised care in Vadodara. Some of the renowned experts like Dr. Suresh Nayak, Dr. Rakesh Shah and Dr. Mihir Acharya will join the Zydus Hospitals team, which includes Dr.



Chaturbhuj Rathore, Dr. Bhagwati Salgotra, bringing in multiple decades of clinical experience and surgical expertise.

WuXi Biologics and Vertex sign license and research service agreement for T-cell Engager

Shanghai, China: WuXi Biologics, a leading global Contract Research, Development, and Manufacturing Organization (CRDMO), has signed a license and research service agreement with Vertex Pharmaceuticals Incorporated for an innovative trispecific T-cell Engager (TCE) for the treatment of B-cell mediated autoimmune diseases.

Under the agreement, Vertex will have exclusive global rights to develop and commercialize an innovative trispecific TCE at the preclinical stage designed for the treatment of B-cell mediated autoimmune diseases. WuXi Biologics will receive an upfront payment and is eligible to receive development, regulatory, and sales milestone payments, as well as royalty payments. In addition, WuXi Biologics will provide Vertex with contract research and development services on novel next-generation TCEs.

Thermo Fisher Scientific expands real-world data interoperability and linkage through tie-up with Datavant

Waltham, Massachusetts: Thermo Fisher Scientific has entered into a strategic data collaboration with Datavant, the data collaboration platform trusted for

healthcare, to make it easier for pharmaceutical and biotech companies to connect real-world data with clinical research — helping them generate stronger evidence, faster. Thermo Fisher's PPD™ clinical research business and Datavant will enable secure connection and analysis of Real-World Data (RWD), spanning RWD enrichment of randomized clinical trials, PPD™ CorEvitas™ Clinical Registries and PPD™ Evidera™ solutions.

Datavant enables privacy-preserving tokenization and linkage of patient-level data across more than 350 RWD partners and 80,000 U.S. hospitals and clinics. With this technology, Thermo Fisher's PPD clinical research business can securely connect de-identified research datasets and retrieve

consented electronic medical record (EMR) data for bespoke RWD generation. Integrating Datavant's encrypted token technology within Thermo Fisher's RWD infrastructure will provide biopharmaceutical and biotech customers with access to enhanced linked patient data and advanced analytics to design more connected studies, improve recruitment and accelerate evidence generation, ultimately supporting better patient outcomes.

The collaboration builds on Thermo Fisher's broader investments in digital innovation, including its strategic collaboration with OpenAI, to deliver more value and greater scientific innovation to life sciences customers. ■

UNION BUDGET 2026 - 27

Union Budget 2026-27: Transforming India into a Global Biopharma Hub

The Union Budget 2026-27 proposed Biopharma SHAKTI with an outlay of ₹10,000 crores over five years, aimed at strengthening India's ecosystem for production of biologics and biosimilars. The Union Budget 2026-27 marks a decisive shift in India's approach to pharmaceuticals by placing biopharma and biologic medicines at the centre of its healthcare and manufacturing strategy. **Pharma Bio World** presents Industry leaders' views on Union Budget 2026 and their opinion on what is in store for the pharmaceutical industry in the future.



-Dr. Sharvil Patel,
Managing Director,
Zydus Lifesciences Limited

"Thrust on Lifesciences is a Welcome Step"

"The thrust on Lifesciences is a welcome step as the Indian Lifesciences Sector looks at building capabilities for leadership and growth in the future. The Biopharma Shakti programme heralds a long-term vision that can catapult India to the next orbit of growth.

The focus on upgrading National Institute of Pharmaceutical Education & Research (NIPERs) and strengthening the talent pipeline, benchmarking regulatory infrastructure to global standards, creating a network of over a thousand accredited India Clinical Trials Sites, are all steps in the right direction.

Exempting 17 cancer drugs and 7 rare disease drugs from customs duty will greatly improve patient access. The Budget 2026 has touched upon the important pillars of accessibility, affordability and patient-centricity that are an urgent need."



-Mr. Sushil Suri,
Chairman & Managing Director,
Morepen Laboratories

"A Forward-Looking, Reform-Oriented Budget"

"We welcome the Union Budget 2026-27 and congratulate Hon'ble Prime Minister Shri. Narendra Modi and Hon'ble Finance Minister Smt. Nirmala Sitharaman for presenting a forward-looking, reform-oriented Budget that strengthens India's manufacturing and healthcare ecosystem. The strong emphasis on biopharma manufacturing, ease of doing business, infrastructure creation and export competitiveness reinforces India's position as a trusted global partner in pharmaceuticals and healthcare. At Morepen, these measures give us greater confidence to invest, innovate and expand our global footprint, while continuing to deliver quality, affordable healthcare solutions from India to the world. We remain optimistic about the opportunities ahead and aligned with the Government's vision of Viksit Bharat."

**UNION
BUDGET
2026 - 27**



-Amarjeet Singh Tak,

Microscopy Solutions, India and Neighboring Markets, ZEISS Group

“Union Budget’s ₹40,000 Crore Allocation Shows Government’s Intent to Strengthen Local Manufacturing”

“The Union Budget’s ₹40,000 crore allocation to strengthen India’s semiconductor ecosystem extends a strong signal of the government’s intent to strengthen local manufacturing and reduce dependency on global supply chains. This aligns well with the vision of “Make in India” and “Make with India,” where global collaboration meets local capability.

ZEISS India has consistently worked with academic institutions to support skilling and applied research, helping to create a workforce capable of supporting precision-led innovation. Beyond semiconductors, the government’s push to scale AI training across 500 universities reflects a forward-looking approach to building future-ready talent.

As India positions itself as a global technology and manufacturing hub, ZEISS India remains committed to supporting enterprises with advanced, efficient, and future-ready data management solutions that enable innovation at scale.”



-Dr. G. S. K. Velu,

Chairman & Managing Director, Triviron Healthcare; Maxivision Eye Hospitals & Neuberg Diagnostics

“Budget 2026 Positions India to Accelerate Transition to Value-Driven Global Leadership”

“Budget 2026 positions India to accelerate its transition from volume-driven production to value-driven global leadership across pharmaceuticals, biopharma, and medical devices, with Biopharma Shakti as its anchor and a renewed focus on regulatory and manufacturing reforms that assure reduced compliances.

The ₹10,000 crore commitment to strengthening the biopharma, biotech, and life sciences ecosystem, alongside support for the drug regulatory framework and biopharma research and development, creates a strong foundation for raising quality benchmarks and aligning Indian innovation with global standards. This integrated approach will help move ideas from the laboratory to the bedside more efficiently, while encouraging closer collaboration between industry, academia, and care providers.

At the same time, the planned expansion of the allied healthcare workforce and the enhancement of district hospital capacity point to a broader effort to strengthen healthcare delivery on the ground. Skilled professionals in optometry, diagnostics, and geriatric care, supported by improved emergency, diagnostic, and rehabilitation infrastructure, will be essential in meeting the growing demand for specialised, technology-enabled services across both urban and emerging regional centres.”

BIO-X India: A Resounding Success!



BIO-X India World Expo & Concurrent Conference 2026, organized by CHEMTECH and powered by ABLE - Association of Biotechnology Led Enterprises, was held successfully on 4th February 2026 in Mumbai.

The one-day conference themed - "Reimagining the Future of Biotech in India", was organized as part of the 52nd ChemTECH World Expo & Conferences, held from 3-6 February 2026 at the Bombay Exhibition Centre (BEC), Goregaon, Mumbai.

The conference brought together diverse perspectives across five high-impact sessions that collectively highlighted India's growing bio-innovation leadership. Discussions on "Translating the BioE3 policy rollout and Biomanufacturing Investments" focused on enabling policy frameworks and capital flows to strengthen India's bioeconomy; "Frontier Tech in Healthcare" explored breakthroughs in gene editing, mRNA platforms, and precision medicine and "Synthetic Biology in Food & Agri" examined next-generation solutions for resilient food systems. The session on "Next-Gen Bioplastics & Specialty Green Chemicals" showcased India's potential in sustainable manufacturing, while deliberations on "AI-Driven Drug Discovery and Diagnostics" demonstrated how digital intelligence is accelerating therapeutic and diagnostic innovation. Together, the sessions reflected a strong convergence of science, technology, policy, and industry collaboration shaping the future of biotechnology in India.

Pharma Bio World presents glimpses of photos taken during the inaugural session.



(L-R) Mr. Nadir Godrej, Chairperson, Godrej Industries Group and Chairperson and Managing Director, Godrej Industries; Mr. Maulik Shah, Chairman & Chief Executive, Jasubhai Group & Chemtech Foundation; Dr. P.M. Murali, Chairman, Jananom Group & President, Council of Presidents, ABLE; Mr. Hemant Shetty, CEO, Jasubhai Group & Chemtech Foundation; Dr. Rajesh S. Gokhale, Secretary, Department of Bio Technology, Government of India & Chairman - Central Advisory Board, Bio-X India World Expo & Conferences 2026, during the lighting of the lamp at the inaugural session of Bio-X India World Expo & Conference 2026.



(L-R) Mr. Hemant Shetty, CEO, Jasubhai Group & Chemtech Foundation; Dr. P.M. Murali, Chairman, Jananom Group & President, Council of Presidents, ABLE; Mr. Nadir Godrej, Chairperson, Godrej Industries Group and Chairperson and Managing Director, Godrej Industries and Dr. Rajesh S. Gokhale, Secretary, Department of Bio Technology, Government of India, & Chairman – Central Advisory Board, Bio-X India World Expo & Conferences 2026.



Dr. Rajesh S. Gokhale, Secretary, Department of Bio Technology, Government of India, & Chairman – Central Advisory Board, Bio-X India World Expo & Conferences 2026, presenting the Chairman's Address during Bio-X India Conference 2026 on 4th February 2026.



Dr. P.M. Murali, Chairman, Jananom Group & President, Council of Presidents, ABLE, making his presentation at Bio-X India Conference 2026 held on 4th February 2026, Bombay Exhibition Centre, Goregaon, Mumbai.



Guest of Honour - Shri. Nadir Godrej, Chairperson, Godrej Industries Group and Chairperson and Managing Director, Godrej Industries - while addressing the august audience, during Bio-X India Conference 2026 on 4th February 2026.

A glimpse of the august audience during Bio-X India World Expo & Conferences 2026, powered by ABLE.



“Indian Market is Cost Sensitive”



Mr. Viraj Shah

Founder
Swa Consultancy Pvt. Ltd.

Ahmedabad-based firm, Swa Consultancy, is excelling in expert insulation of thermal, acoustic and passive fire safety solutions for industrial and commercial projects. The company is leading the way with strong technical expertise and client-focused design. In an exclusive interview with *Pharma Bio World*, **Mr. Viraj Shah, Founder, Swa Consultancy Pvt. Ltd.**, shares the applications of its company products and services for the pharmaceutical industry.

Can you throw more light about the applications of Swa Consultancy products and services in pharmaceutical industry?

The BioPharma industry that is coming up requires precise temperature controls for the environment so, insulation becomes a critical design element to maintain those temperatures. Also, in traditional Pharma industry, the hot and cold lines need insulation, which can be optimized with engineered insulation.

What are the market trends in terms of thermal, acoustic and fire insulation system design that you are expecting?

Acoustics & Noise Reduction are bound to become more important as the working conditions for the workers in

Indian Market is cost sensitive and reluctant to change so, shaking it up is going to be crucial for any new entrant to succeed in the market, be it on the basis of bottom line or market penetration. With supportive economic policies, like the large capital allocation to BioPharma in the 2026 Union Budget; the market is poised for growth, especially with the government support.



Performance Is Never Accidental

the industry improve. Moreover, with the requirement of precise temperature controls in the evolving BioPharma industry, insulation designing becomes a critical aspect of the process design.

Which are the business sectors that Swa Consultancy caters to?

Swa Consultancy is a startup, with a vision to be a nodal agency with technical expertise and thought leadership in the insulation fraternity. Being a Blue Ocean, we have capability to cater to a large part of the business sectors being Buildings, Solar Manufacturing, SemiCon, Data Centers, Pharma, Oil & Gas, Chemical Industry, Cement, Power Plants etc.

What have been the challenges that you have faced in your growth journey?

Product cycle is always defined in four stages, and, we are in the introduction phase where we are looking for early adopters that would drive our take-off, as we are very confident in our offerings.

How would you describe the Indian market and its potential in the future?

Indian Market is cost sensitive and reluctant to change so, shaking it up is going to be crucial for any new entrant to succeed in the market, be it on the basis of bottom

line or market penetration. With supportive economic policies, like the large capital allocation to BioPharma in the 2026 Union Budget; the market is poised for growth, especially with the government support.

Are there any plans to make foray into the international market?

Again, as I mentioned, it is a blue ocean for us so, wherever the undercurrents take us, we will be there. ■

NIPER, Raebareli & Boehringer Ingelheim India sign MoU to advance pharmaceutical education and research in India



Dignitaries from NIPER and Raebareli & Boehringer Ingelheim India, during signing of MoU.

New Delhi: To advance pharmaceutical education and research in India, a Memorandum of Understanding (MoU) has been signed between National Institute of Pharmaceutical Education and Research (NIPER) and Raebareli & Boehringer Ingelheim India Pvt. Ltd. The MoU was signed in the presence of Shri Manoj Joshi, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers in New Delhi.

On the occasion, Cohort 2 of AMRITVA (Alliance for Medicinal Research, Innovation, Translation & Value Acceleration) to strengthen India's innovation system and enable translation of research outcomes into viable pharmaceutical products and entrepreneurial ventures was also launched.

On the occasion, Cohort 2 of AMRITVA (Alliance for Medicinal Research, Innovation, Translation & Value Acceleration) to strengthen India's innovation system and enable translation of research outcomes into viable pharmaceutical products and entrepreneurial ventures was also launched. AMRITVA is implemented by the Startup Incubation and Innovation Centre (SIIC), IIT Kanpur, in partnership with the National Institute of Pharmaceutical Education and Research (NIPER), Raebareli. This is an initiative supported under Corporate Social Responsibility (CSR) by Boehringer Ingelheim India Pvt. Ltd.

In his address, Shri Manoj Joshi underscored the role of collaborative partnerships between academia and industry in strengthening the research-to-market pipeline. He noted that such initiatives are critical for advancing domestic innovation capabilities, encouraging entrepreneurship, and ensuring wider access to cost-effective healthcare solutions.

► NEWS FEATURE

AMRITVA is implemented by the Startup Incubation and Innovation Centre (SIIC), IIT Kanpur, in partnership with the National Institute of Pharmaceutical Education and Research (NIPER), Raebareli. This is an initiative supported under Corporate Social Responsibility (CSR) by Boehringer Ingelheim India Pvt Ltd

Shri Awadhesh Kumar Choudhary, Senior Economic Advisor, Department of Pharmaceuticals; Ms. Anugraha P, Director, Department of Pharmaceuticals; and Dr. Ashutosh Agnihotri, Chief Executive Officer of SIIC, IIT Kanpur were present during the event.

As part of Cohort 2, five innovators have been selected for grant support aimed at facilitating the commercialization of their research. Financial assistance has been provided to three faculty-led projects and two research scholar-led projects.

The MoU signed between Boehringer Ingelheim India and NIPER Raebareli, including its Centre of Excellence for Novel Drug Delivery Systems (CoE-NDDS), establishes a framework to strengthen academic and research collaboration in areas such as pharmaceutical technologies, novel drug delivery systems, academic exchange, and capability-building programmes.

As part of this collaboration, Boehringer Ingelheim will provide access to its opnMe® open science platform to researchers and institutions, enabling scientific exchange and accelerating innovation in healthcare.

The Department of Pharmaceuticals is supporting the country's pharmaceutical sector to transition from a volume-driven to a value-driven sector with focused policy interventions, infrastructure development, strengthened industry-academia partnerships, and incubation-led commercialization efforts which are aligned with the broader vision of Viksit Bharat 2047. ■

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M E D I A

Showcasing the Future of Smart Manufacturing at B&R Innovations Day 2026



Inauguration of India Innovations Day

B&R India, the Machine Automation division of ABB, hosted its flagship Innovations Day 2026 in Pune, bringing together customers, OEMs, industry experts, and technology leaders to explore new possibilities that are shaping the future of machine automation and smart manufacturing. A key highlight of the event was the leadership address by Florian Schneeberger, Division President of ABB's Machine Automation division (B&R), who shared a global perspective on the future of machines and intelligent manufacturing eco-systems. This was complemented by insights from India leadership, outlining the region's growth trajectory and the increasing role of advanced automation in enabling competitive manufacturing..

"Innovations Day reflects our continued commitment to empowering manufacturers and machine builders with future-ready automation solutions. By bringing together industry stakeholders on a common platform, we aim to accelerate the adoption of intelligent technologies that drive efficiency, flexibility, and sustainable growth," said Florian Schneeberger, Division President of ABB's Machine Automation division (B&R).

The event also marked the India introduction of ACOPOS D1, B&R's next-generation servo drive, designed to

enable intelligent motion control and scalable machine performance for OEMs.

Through interactive experience zones and expert consultations, attendees gained first-hand exposure to emerging automation technologies tailored to evolving industrial needs across sectors. Innovations Day 2026 underscores B&R India's commitment to strengthening collaboration within the manufacturing ecosystem while advancing digital transformation across industries.

ABB's Machine Automation division delivers automation solutions and services for machine and factory applications across industries such as consumer-packaged goods, printing, life sciences, plastics, energy and maritime. With its B&R's product portfolio, the division delivers integrated control and software, motion control, mechatronics, and machine automation technologies designed to simplify processes and optimize factory operations. ■

Five Compliance Challenges for Pharma Exporters & How AI Simplifies Them



Sunil Kharbanda

Co-founder & COO
Trezix

In pharmaceutical exports, compliance is not a checklist, it is a system of trust. As regulatory scrutiny intensifies and cross-border operations grow more complex, exporters must shift from reactive compliance to predictive risk management, from document-heavy processes to batch-intelligent trade, and from audit anxiety to continuous regulatory readiness. **Mr. Sunil Kharbanda, Co-founder & COO, Trezix,** shares five compliance challenges that pharma exporters face and how Artificial Intelligence (AI) can help simplify them.

Artificial Intelligence (AI) does not merely streamline compliance workflows. It safeguards licenses, protects brand credibility, and enables sustainable access to global markets making it a strategic imperative for pharma exporters operating at scale. Here are five key compliance challenges pharma exporters face today and how AI is simplifying each of them.

1. Complex Product Classification across Regulatory Regimes

Pharmaceutical exports span Active Pharmaceutical Ingredients (APIs), intermediates, finished formulations, biologics, and controlled substances — each subject to distinct regulatory, licensing, and reporting requirements across jurisdictions. Classification errors, whether in HS codes, drug

schedules, or regulatory status, can result in customs delays, compliance breaches, or export license violations, particularly when trade classifications fail to reflect regulatory definitions.

AI simplifies this challenge through product intelligence models that analyze chemical composition, therapeutic application, export control lists, and country-specific drug regulations in parallel. By aligning customs classification with pharmaceutical regulatory frameworks, AI ensures products are classified correctly across markets, reducing clearance delays and minimizing regulatory risk.

2. Ever-Changing Global Regulatory & GAMP 5 Compliance

Pharma exporters must simultaneously comply with country-specific drug regulations (FDA, EMA, MHRA, CDSCO), data integrity principles such as ALCOA+, and GAMP 5 validation requirements for computerized systems. Tracking regulatory updates, maintaining validation evidence, and staying audit-ready through manual processes is no longer sustainable.

AI enables continuous compliance by monitoring regulatory changes by market and molecule, mapping updates to labelling and documentation requirements, and assessing system behavior against GAMP 5's risk-based validation principles. This shifts compliance from periodic, point-in-time checks to an always-on model.

3. Export Controls, Restricted Substances, & License Management

Many pharmaceutical products fall under dual-use controls, narcotic and psychotropic regulations, and country-specific export restrictions. Missing a required license or shipping to a restricted party can lead to severe penalties, shipment seizures, or long-term regulatory action.

AI embeds transaction-level compliance checks before shipment execution by mapping products to export control and drug control lists, automatically determining license requirements, and screening buyers, distributors, and destinations in real time. This enables compliant, uninterrupted exports while significantly reducing enforcement risk.

4. Certificate of Analysis (CoA) & Batch-Level Documentation Accuracy

Regulators and overseas buyers demand batch-specific compliance for pharmaceutical exports, including accurate Certificates of Analysis (CoA), batch manufacturing records, stability data, and test results. Any mismatch between the CoA, invoices, packing lists, or shipping documents can result in shipment rejection or prolonged clearance delays.

AI enables end-to-end batch-level traceability by linking each shipment to its corresponding batch, CoA, and quality parameters, while validating data consistency across regulatory, quality, and trade documents. Deviations are flagged in real time, creating a single, reliable source of truth across QA, regulatory, and export teams.

5. Managing Compliance at Scale without Violating GxP Principles

As pharmaceutical export volumes increase, compliance risks scale alongside them. Manual checks collapse under high transaction volumes, spreadsheet-driven processes fail audit scrutiny, and non-validated systems can directly violate GxP and data integrity expectations.

AI-driven trade orchestration platforms address this by embedding compliance into workflows by design. They maintain auditable, GAMP 5-aligned trails, enforce GxP-compliant controls across processes, and enable exception-based human intervention allowing exporters to scale without compromising validation integrity or regulatory confidence.

In pharmaceutical exports, compliance is not a checklist, it is a system of trust. As regulatory scrutiny intensifies and cross-border operations grow more complex, exporters must shift from reactive compliance to predictive risk management, from document-heavy processes to batch-intelligent trade, and from audit anxiety to continuous regulatory readiness.

AI does not merely streamline compliance workflows. It safeguards licenses, protects brand credibility, and enables sustainable access to global markets making it a strategic imperative for pharma exporters operating at scale. ■

Warehousing Reinvented: How Smart Warehouses are Becoming the Brain of India's Supply Chain



Mr. Khursheed Alam

Founder
Atmos Systems

In the fast-paced world of global commerce, warehouses no longer function merely as storage facilities but are emerging as the nerve centres of modern supply chains. Over the past decade, India's warehousing sector has evolved from static, labour-intensive storage units into dynamic, technology-led 'smart warehouses.' These next-generation facilities are driving a major logistical transformation, delivering greater agility, accuracy, and efficiency across logistics networks in industries like e-commerce, manufacturing, FMCG, pharmaceuticals, and retail.

According to a report by Knight Frank India, warehousing transaction volumes across eight major markets reached 56.4 million sq. ft. in 2024, marking a 12 per cent rise over the previous year. This growth is boosted by surging demand, improving infrastructure, and rapid digitalisation. Warehousing today is no longer about expanding space; it is about enhancing speed, reliability, and real-time responsiveness. Powered by robotics, AI, IoT, and data intelligence, smart warehouses are redefining how goods are managed, moved, and delivered across the country.

This development is especially significant for India, where e-commerce penetration continues to deepen and manufacturing momentum is accelerating under initiatives such as "Make in India." Investment trends reflect this shift as there's been a sharp rise in institutional capital inflows into warehousing and logistics, driven by increasing demand from sectors such as quick commerce and industrial manufacturing. India's total warehousing stock crossed 533 million sq. ft. in 2024, with nearly one-fifth located in Tier II and Tier III cities, highlighting a notable structural shift away from traditional metropolitan hubs.

Supply Chain 4.0

For decades, warehouses in India and worldwide followed a linear “store–dispatch–deliver” model. They functioned largely as passive repositories, with minimal integration across supply-chain stages. But with the rise of Supply Chain 4.0, this model is being replaced by a connected, data-driven, highly responsive ecosystem. In this new framework, warehouses operate as smart hubs that predict demand, optimize storage, and orchestrate logistics with precision. Real-time data flows and advanced analytics enable managers to reroute stock, recalibrate priorities, and reconfigure space almost instantly, resulting in agile, resilient, and cost-efficient supply chains.

At the centre of this evolution is the rise of intelligent warehousing. These facilities integrate advanced technologies that learn, adapt, and optimise over time. Artificial intelligence now drives everything from demand forecasting to dynamic slotting, ensuring each SKU is stored where it offers maximum efficiency. Machine learning models analyse diverse datasets including sales patterns, seasonality, campaign cycles, even weather variations to predict demand with greater accuracy. Digital twins are also emerging as powerful tools, enabling operators to test new layouts, workflows, and emergency scenarios in virtual environments before implementing them on the ground.

In addition, technologies such as automated storage and retrieval systems (ASRS), automated guided vehicles (AGVs), electric forklifts, robotic picking arms, smart conveyor systems, and IoT-enabled sensors are replacing manual, repetitive processes. These systems significantly accelerate throughput, reduce human error, and compress order-to-dispatch timelines, benefitting crucial sectors like e-commerce and q-commerce, where delivery windows are shrinking by the year.

Sophisticated hardware is only part of the story. The true engine of smart warehousing is data. IoT sensors monitor everything, from inventory movement and equipment utilisation to temperature and humidity levels for perishable goods. AI-powered warehouse management software processes this data to deliver real-time insights, automate decision-making, and forecast operational requirements. This data-intelligent layer turns warehouses from reactive spaces into proactive, learning systems capable of forecasting challenges before they arise.

Technological upgrades have further strengthened their appeal. When it comes to high-capacity lifting, the earlier concern was whether electric forklifts could match the performance of diesel machines. Today, that gap has been bridged. Lithium-ion battery technology delivers higher energy density, rapid charging, and consistent power output, ensuring uninterrupted operations. For even heavier workloads, hydrogen fuel cell solutions are being tested in ports and large-scale logistics hubs.

Smart Warehousing

Smart warehousing is also becoming a driver of sustainability and resilience. Modern warehouses increasingly integrate renewable energy, energy-efficient lighting, smart HVAC systems, and sustainable materials. Electric forklifts and AGVs are now standard across warehouses, retail, and logistics because they are eco-friendly (zero emissions), energy-efficient, quieter in operation, and require far less maintenance than conventional IC-engine machines.

Predictive analytics help reduce waste by preventing overstocking and minimising unnecessary transportation cycles. As supply chains face disruptions, from geopolitical tensions to extreme weather, smart warehouses offer continuity and operational stability through improved visibility and flexible fulfilment capabilities.

The integration enabled by smart warehousing is arguably its strongest advantage. When warehouses are connected seamlessly with suppliers, distributors, and retailers, cloud-based platforms can track performance across multiple facilities, identify emerging patterns, and optimise inventory flows with precision. This integrated ecosystem replaces lagging indicators with real-time intelligence, creating supply chains that can absorb volatility and respond faster to market shifts.

In conclusion, smart warehouses are fast becoming the “brain” of India’s supply chain, driving speed, accuracy, intelligence, and sustainability. For a diverse and rapidly growing economy like India, this evolution represents far more than an operational upgrade; it is a fundamental reimagining of how goods move from factories to the final consumer. As Supply Chain 4.0 becomes the new reality, smart warehousing will sit firmly at its core, powering the next era of logistics in India. ■



Vacuum Technology for Chemical and Pharmaceutical Processes



Ms. Meike Strasheim

Head of Market Management Content Strategy
Pfeiffer Vacuum+Fab Solutions

Vacuum technology is an essential element of chemical and pharmaceutical manufacturing. It enables key operations such as distillation, drying, conveying, and inerting, by providing process conditions that would be difficult or impossible to achieve under ambient pressure. Through this article, **Ms. Meike Strasheim, Head of Market Management Content Strategy, Pfeiffer Vacuum+Fab Solutions**, provides an in-depth comparison of conventional and dry vacuum pump technologies, with a focus on dry screw vacuum pumps. It further aims to provide process engineers and plant designers with the insights needed to specify and design vacuum systems that meet today's technical, regulatory, and economic demands.



IMPACT FEATURE ◀



Figure 1: This image shows a model from the DOLPHIN series by Busch, known for its robustness and suitability in vapor-laden and particle-rich environments. Source: Busch Group.

Vacuum requirements vary significantly across chemical processes, depending on factors such as volatility, process temperature, gas composition, and contamination sensitivity. Different vacuum technologies offer distinct advantages and trade-offs. Understanding the operating principles of each vacuum pump type is key to selecting the right solution for a given application.

Liquid Ring Vacuum Pumps

Liquid ring vacuum pumps operate using an impeller mounted off-center that rotates within a partially filled chamber. The liquid – typically water or a compatible solvent, forms a ring along the chamber wall due to centrifugal force. As the impeller rotates, it traps gas between the liquid ring and the impeller blades, compressing it as the chamber volume decreases. The liquid absorbs heat from compression and acts as a sealant, keeping internal temperatures low and reducing the risk of ignition.

These vacuum pumps are valued for their simplicity, robustness, and ability to handle saturated vapors as well as small particles. However, their achievable vacuum is relatively low (typically limited to ~33 hPa [mbar] absolute, depending on the liquid used and its corresponding vapor pressure). They are also less energy-efficient compared to dry technologies and require a continuous supply of operating fluid, which adds to utility and maintenance costs.

Rotary Vane Vacuum Pumps

Rotary vane vacuum pumps consist of a rotor mounted off-center in a cylindrical housing. As the rotor turns, vanes actuated by centrifugal force slide out to create sealed compression chambers. Gas is drawn into the expanding volume and expelled under compression as the chamber contracts. These vacuum pumps rely on oil for sealing, lubrication, and cooling – either through a closed loop system or a once-through configuration to handle chemically active or condensable media.

Rotary vane vacuum pumps are compact, easy to install, and widely used in general applications. In chemical and pharmaceutical settings, single-stage vacuum pumps are most common due to their robustness and simplicity.



Figure 2: Cross-sectional view of an R5 single-stage rotary vane vacuum pump. Source: Busch Group.

While versatile, these vacuum pumps are susceptible to oil contamination and degradation if oil is reused in a closed loop system. In continuous operation, the oil condition must be monitored, replaced regularly, and

► IMPACT FEATURE

filtered properly to avoid process interference. Their typical vacuum range spans from 100 to 1 hPa (mbar) in single-stage versions, with dual-stage configurations reaching 10^{-3} hPa (mbar) when properly maintained and operated under optimal conditions.

Dry Screw Vacuum Pumps

Dry screw vacuum pumps use two interlocking screw-shaped rotors that compress gas with no contact between the moving parts or operating fluid in the process chamber. As the rotors turn in opposite directions, gas is trapped between the twin screws and the housing, progressively compressed, and discharged. This oil-free design eliminates contamination risk, making the vacuum pumps ideal for processes involving solvents, reactive compounds, or clean environments.

They can achieve vacuum levels around 10^{-2} hPa (mbar) and are well-suited for clean, reactive, or solvent-rich environments. Their performance depends on precise thermal control to avoid condensation or polymerization, especially when operating with volatile process gases. Their higher initial investment is justified by long service intervals, low total cost of ownership, and high reliability under challenging conditions.

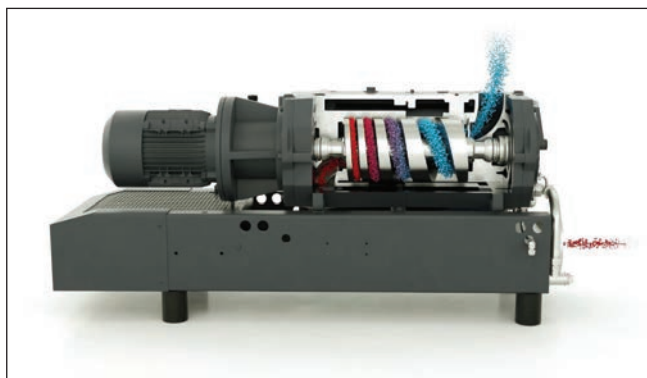


Figure 3: Cutaway view of a dry screw vacuum pump showing the internal rotor geometry. Source: Busch Group.

Design Considerations for Vacuum Systems

Designing a reliable and efficient vacuum system extends far beyond choosing the suitable vacuum pump technology. It involves careful coordination of multiple factors, ranging from process conditions and material compatibility to layout constraints and automation strategies.



Figure 4: Custom-engineered vacuum system with PANDA and PUMA vacuum boosters as the first stage and COBRA screw vacuum pumps as backing pumps Source: Busch Group.

Process Chemistry and Material Selection

The chemical composition of the process stream – especially the presence of condensables, corrosives, or reactive gases – dictates material selection and sealing technology. Stainless steel is a standard baseline for wetted components, but more aggressive environments may require specialized coatings, alloys like Hastelloy or titanium, or non-metallic materials such as PTFE. For dynamic sealing surfaces, especially around rotating shafts, double mechanical seals or magnetically coupled drives for leak-free operation might be needed.

Choosing suitable O-ring and gasket materials, such as FFKM or EPDM, is critical to prevent degradation when exposed to acids, solvents, or elevated temperatures.

System Resistance and Pressure Drop

Every valve, filter, bend, and restriction between the process and the vacuum pump introduces pressure losses. In low-pressure systems, even small pressure drops can significantly affect performance or lead to undersizing the vacuum pump. Therefore, a pressure drop analysis of the complete system from chamber or reactor to pumping unit should be part of the early engineering phase.

Thermal Management

Thermal control is crucial in vacuum systems, especially for dry screw vacuum pumps handling condensable or polymerizable vapors. The vacuum pump body must be kept warm enough to prevent internal condensation but below thermal material and safety limits. This is

typically managed through heating jackets, cooling loops, and gas-ballast systems.

In processes involving solvent-rich streams, controlling the inlet piping temperature and pre-heating during startup helps prevent sticky deposits that may compromise rotor clearance or cause corrosion. A pre-condenser can also be a solution, allowing a reduction in the amount of chemicals reaching the pumping unit.

Layout and Integration

Space constraints often dictate the form factor of the system, especially in retrofit projects. Skid-mounted, modular designs allow tighter footprints and easier maintenance access. Vertical stacking and wall-mounted control panels can help reclaim floor space. Systems must also be accessible for cleaning, inspection, and potential part replacement without requiring full disassembly.

Compliance with local safety regulations, especially in ATEX zones, will influence enclosure design, ventilation strategy, and component certifications.

Automation and Control

Vacuum systems increasingly integrate with DCS (Distributed Control Systems) or PLCs (Programmable Logic Controllers) to support advanced process control and diagnostics. Parameters such as inlet pressure, motor current, cooling flow, and seal integrity can be monitored in real time. In high-value processes, this supports predictive maintenance, early fault detection, and compliance tracking.

Modern systems use controlled valves and frequency-controlled motors to dynamically adjust vacuum generation to the process load, reducing energy consumption and mechanical stress.

Operational Challenges of Vacuum Systems

One of the most common and impactful issues is the condensation of vapors within the vacuum pump. When condensable gases fall below their dew point during compression, they can liquefy inside the vacuum pump, leading to corrosion, internal fouling, or – in severe cases – hydraulic shock. The risk is highest in dry vacuum pumps, where there are no internal

liquids to buffer phase transitions.

Related to this is the challenge of improper startup and shutdown sequences. If a vacuum pump is brought online while still cold, condensable vapors may condense immediately upon contact with internal surfaces. Similarly, stopping a process without removing residual vapors can result in unwanted deposition or corrosion during cooldown.

Another persistent challenge involves the ingress of solids and particulate matter. Dry screw vacuum pumps are especially sensitive due to their tight internal clearances. Even small amounts of powders, sticky residues, or abrasive crystals can accelerate wear or reduce compression efficiency. In processes where dust or condensable slugs are present, the vacuum pump's performance and longevity may be compromised if no pre-separation or filtration system is installed.

Maintenance presents its own set of operational concerns. While dry vacuum pumps generally offer longer service intervals, the consequences of unexpected failure are often severe. Unmonitored shifts in power draw, temperature, or vibration can signal early-stage issues that, if ignored, lead to costly repairs and unplanned downtime.

Protection Strategies and System Accessories

To ensure vacuum systems remain reliable and efficient in chemically and thermally demanding environments, protection strategies must be thoughtfully designed and implemented.

Thermal stability is one of the key prerequisites for preventing internal condensation and phase-related damage. In processes involving solvents or reactive vapors, the vacuum pump body and associated piping must be maintained above the dew point of the gases involved. This is often achieved through external heating systems or thermal jackets. Gas-ballast valves are commonly used to dilute condensable vapors, reducing the likelihood of phase change within the compression chamber.

Contaminant ingress is another major threat to vacuum equipment, particularly in systems handling solids,

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slurries, or dusty environments. Effective filtration is essential to keep abrasive or reactive materials from entering sensitive components. Depending on the process, protection may involve fine-mesh inlet screens for large particulates, high-efficiency filters for fine powders, or knock-out pots and cyclonic separators to remove droplets and slugs from vapor streams.

Corrosion resistance begins with material selection. Vacuum pumps and piping in contact with aggressive media must be made from chemically compatible materials. Stainless steel 316L is often used as a default in pharmaceutical settings, while more aggressive chemistries may require Hastelloy, titanium, or additional surface treatments such as PTFE or ceramic coatings. Elastomeric components such as seals and gaskets should be carefully matched to the media in question, with materials like FFKM, EPDM, or fluoroelastomers used depending on chemical resistance requirements.

Sealing performance plays a critical role in both environmental protection and regulatory compliance. Static seals must maintain integrity under pressure and temperature cycles, while dynamic seals – especially around rotating shafts – must ensure gas tightness without compromising mechanical efficiency. Double mechanical seals and magnetically coupled drives are frequently used in systems where leakage is unacceptable. For ultra-clean environments or processes involving toxic gases, bellows seals and encapsulated drives offer added layers of containment. These sealing strategies are often selected with compliance frameworks such as ATEX, TA Luft, or regional emissions regulations in mind.

Protective components can also support recovery and sustainability goals. Condensers positioned upstream of the vacuum pump can capture valuable solvents, reduce vapor load, and improve overall system economy. Cold traps are similarly used to recover hazardous or condensable vapors. The effectiveness of these systems depends on correct sizing and specification, including parameters such as condenser temperature, system pressure drop, and expected recovery volumes.

Finally, system protection is greatly enhanced by

intelligent monitoring and control. Sensor networks tracking pressure, temperature, vibration, and motor current can detect early signs of wear or instability. When integrated with plant automation systems, these inputs allow for automated shutdowns, maintenance alerts, and process adjustments in real time. Advanced data analytics tools further enable predictive diagnostics and long-term performance optimization.

Conclusion

Vacuum systems are more than peripheral utilities – they are critical enablers of process performance, product quality, and plant safety in the chemical and pharmaceutical industries. As regulatory standards tighten and expectations grow around sustainability, digitalization, and operational transparency, vacuum technology must evolve in both capability and complexity.

While established solutions like liquid ring vacuum pumps and steam ejectors continue to serve high-load or rugged applications, the industry's shift toward dry, oil-free technologies – particularly dry screw vacuum pumps – reflects a growing demand for clean operation, minimal maintenance, and seamless integration into automated process environments.

But selecting the right vacuum solution is more than achieving a target pressure. It requires a comprehensive understanding of the gases involved, thermal behavior, contamination risks, system layout, and utility infrastructure. Long-term success hinges on marrying the correct vacuum pump technology with effective safeguards, intelligent control systems, and well-structured operating procedures. ■

Why India Needs Therapy-Specific Regulatory Pathways for Faster Drug Approvals



Saransh Chaudhary

President - Global Critical Care, Venus Remedies and
CEO, Venus Medicine Research Centre

Modern medicine is undergoing a profound transformation. Increasingly, therapies are no longer limited to managing symptoms but are designed to intervene at the root of disease, whether at the level of genes, cells, or finely tuned molecular pathways. Gene therapies, RNA-based treatments, advanced biologics, and antibody-drug conjugates are reshaping expectations of what medicine can achieve, offering the possibility of durable remissions or even cures for conditions that were once considered lifelong. Across the world, regulatory systems are evolving to keep pace with this shift, recognizing that these new modalities cannot be assessed through the same lenses that were developed for conventional drugs.

In India, however, regulatory evolution has been slower. While the country has earned global recognition as the “Pharmacy of the World” through its dominance in generics and vaccines, the regulatory architecture governing new drug development has remained largely anchored in a framework designed for an earlier era. That framework, built when small-molecule drugs were the primary therapeutic modality,

now struggles to accommodate the scientific and developmental complexity of modern therapies.

Therapy-Specific Regulatory Pathways

To close this growing gap, India must move decisively toward therapy-specific regulatory pathways. These are not about lowering standards or accelerating

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approvals at the expense of safety. Rather, they are about aligning regulatory expectations with scientific reality, so that novel therapies can be assessed with clarity, consistency, and appropriate rigor.

The contemporary therapeutic landscape spans a wide range of platforms. Gene therapies rely on viral vectors or genome editing technologies. Biologics are produced in living systems and demand precise control of manufacturing variability. RNA-based medicines depend on sophisticated delivery technologies. Antibody–drug conjugates combine biologics with highly potent cytotoxic agents, introducing unique safety and quality challenges. Each of these approaches raises distinct questions related to manufacturing, biodistribution, immunogenicity, long-term safety, and post-treatment monitoring. Yet in India, many such therapies are still evaluated using largely generic checklists that provide limited insight into what specific evidence regulators expect for a given modality. This mismatch often results in prolonged review cycles, repeated clarification requests, and significant uncertainty for developers.

Importantly, the need for therapy-specific guidance does not apply only to advanced or emerging modalities. It is equally relevant for small-molecule drugs, particularly in complex and high-risk areas such as antibiotic development. At present, India largely relies on the New Drugs and Clinical Trials Rules, which lay out general submission requirements but offer little therapy- or indication-specific direction. As a result, developers are often left without clear guidance on the depth and nature of nonclinical or clinical evidence expected for specialized programs.

Global Scenario

In contrast, regulators in other major jurisdictions have invested heavily in detailed, therapy-specific guidance across the spectrum of drug development. In the United States and Europe, antibiotic developers have access to well-defined regulatory documents that outline expectations around preclinical infection models, pathogen selection, clinical trial design, and resistance considerations. These guidelines do not merely list documents to be submitted; they provide scientific context and rationale, helping developers design programs that are aligned with regulatory

Strengthening therapy-specific regulation would not weaken patient protections. On the contrary, a system grounded in deep scientific understanding is better equipped to identify risks early, demand appropriate long-term follow-up, and manage safety signals after approval. When regulators understand the nuances of each therapeutic pathway, they can ask the right questions at the right time, rather than relying on generic processes that may miss critical issues or create unnecessary friction.

expectations from the outset. This clarity reduces development risk, shortens timelines, and improves confidence among investors and partners.

The broader regulatory ecosystems in these regions reinforce this clarity. In the United States, the Food and Drug Administration operates multiple expedited pathways for therapies addressing serious or unmet medical needs, with clearly defined review timelines and eligibility criteria. In Europe, advanced therapies are regulated under a dedicated framework for Advanced Therapy Medicinal Products, supported by specialized scientific committees and modality-specific guidance. These systems recognize that predictable, science-based regulation is essential not only for patient safety but also for sustaining innovation.

Indian Scenario

In India, the absence of similarly codified, therapy-specific standards means that regulatory expectations can sometimes feel opaque. Even when developers believe they have complied fully with published requirements, they may encounter additional data requests that were not clearly signposted in advance. This unpredictability has consequences beyond timelines. It affects investment decisions, increases the cost of capital, and often drives companies to seek

scientific advice or regulatory validation from overseas agencies, even when their products are intended primarily for Indian patients.

This trend is particularly concerning given India's rapidly evolving innovation landscape. The country is no longer defined solely by generics. Indian companies and academic institutions are increasingly active in cell and gene therapies, biologics, RNA platforms, and novel anti-infectives. Manufacturing capabilities and cost-efficient research give India a natural advantage in making advanced therapies accessible at scale. Yet without clear, therapy-specific regulatory pathways, many promising programs risk being delayed, redesigned around foreign regulatory expectations, or launched first outside India.

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India needs publicly available guidance that clearly articulates quality, nonclinical, clinical, and pharmacovigilance expectations for different therapy classes and for complex small-molecule indications such as antibiotics. Developers should be encouraged to seek early scientific advice so that development programs are aligned with regulatory expectations before large investments are made. Review capacity must be strengthened through specialized expertise, and accelerated or adaptive pathways should be institutionalized with transparent criteria and predictable timelines.

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Way Forward

The way forward requires a deliberate shift in regulatory philosophy. India needs publicly available guidance that clearly articulates quality, nonclinical, clinical, and pharmacovigilance expectations for different therapy classes and for complex small-molecule indications such as antibiotics. Developers should be encouraged to seek early scientific advice so that development programs are aligned with regulatory expectations before large investments are made. Review capacity must be strengthened through specialized expertise, and accelerated or adaptive pathways should be institutionalized with transparent criteria and predictable timelines.

Encouragingly, there are early signs of progress. The approval of India's first indigenous CAR-T therapy based on early-phase clinical data demonstrates a growing willingness to engage with scientific complexity. Dedicated mechanisms for handling cell and gene therapy submissions have begun to take shape within the existing framework. These developments suggest that regulatory practice is evolving, even if the underlying guidance architecture has yet to fully catch up.

The next step is to convert these isolated advances into a coherent, transparent system. Clearly defined, therapy-specific regulatory pathways would reduce ambiguity for developers, restore confidence among investors, and ensure that regulatory intent is matched by regulatory execution. If India succeeds in this transition, it can move beyond its traditional role as a generics powerhouse and emerge as a global center for innovation-driven, affordable therapeutics. Most importantly, it can ensure that Indian patients gain timely access to the most advanced treatments that modern science has to offer. ■

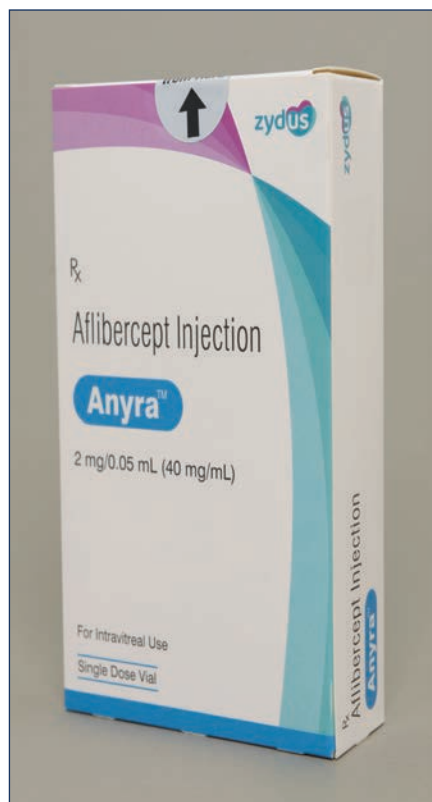
Zydus Launches 2 New Products :- PEPAIR™ - Affordable Handheld Device for Better Respiratory Health



Zydus Lifesciences Limited launches PEPAIR™, India's first affordable Oscillating Positive Expiratory Pressure (OPEP) device, featuring a 3-resistance system designed to help clear congestion and support effective mucous clearance and improve breathing in patients with COPD, Asthma, and Bronchiectasis. PEPAIR™ is an innovative, drug-free, handheld device with patented design. PEPAIR™ is being launched in agreement with AeroDel Technology Innovations Pvt. Ltd, an Indian medical device company focused on simplifying inhalation through drug-delivery, pulmonary rehabilitation. In a patient-centric approach, Zydus offers PEPAIR™ at an affordable cost of ₹990 per unit.

OPEP, a therapy using a handheld, translucent device that creates pressure and vibrations during exhalation to loosen mucous, open airways, and promote clearance. PEPAIR™ contributes to clearing up impaired mucociliary pathways, removing airway obstruction, reducing cough and delivering optimal therapeutic response. OPEP-based airway clearance is recommended in established clinical guidance but in practice, limited affordability has restricted access for a large proportion of patients; an access gap PEPAIR™ aims to address. ■

Biosimilar Aflibercept 2 mg ANYRA™



Zydus Lifesciences Ltd., an innovation-led global life sciences company, has launched Anyra™, India's first indigenously developed biosimilar of Aflibercept 2 mg. Zydus has also signed an agreement with Regeneron Pharmaceuticals, Inc. and Bayer. Anyra™ is indicated for the treatment of neovascular (wet) Age-related Macular Degeneration (AMD), visual impairment due to macular edema secondary to Retinal Vein Occlusion (Branch RVO or Central RVO), visual impairment due to Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and visual impairment due to Myopic Choroidal Neovascularization (mCNV).

Diabetic Retinopathy (DR) affects an estimated 7–8 million individuals, with many progressing to vision-threatening stages such as DME. Wet AMD impacts approximately 1.5–2 million elderly patients, while Retinal Vein Occlusions affect over 2 million individuals. Collectively, these conditions represent a large patient pool requiring timely anti-VEGF therapy to prevent irreversible vision loss. As chronic retinal diseases require repeated intravitreal injections over extended periods, affordability and continuity of treatment are of concern. Enhanced access to such therapies improves treatment adherence, reduces preventable blindness, and lowers long-term disease burden. Zydus has India's largest biosimilar portfolio with more than 13 biosimilars and complex biologic molecules developed and manufactured entirely in India. ■

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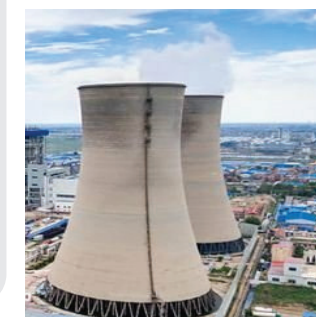
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