India Pharma Outlook
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PHARMA MANUFACTURERS & PRODUCT SOLUTIONS

ASHISH BAFNA,
EXECUTIVE DIRECTOR & CHIEF FINANCIAL OFFICER

TRIDENT LIFELINE

Building an Institution of Trust in Pharmaceutical Manufacturing

₹250

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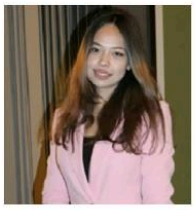

Advancing Pharmaceutical Excellence through Innovation, Quality & Patient-Centric Solutions

India's pharmaceutical ecosystem is entering a transformative phase in 2026, driven by expanding healthcare needs, manufacturing advancements, technological innovation, and the country's growing prominence in global pharmaceutical supply chains. As India continues to strengthen its position as the "pharmacy of the world," pharmaceutical manufacturers and product solution providers are emerging as vital contributors to a healthcare landscape that increasingly demands quality, affordability, accessibility, and innovation.

At the same time, the industry is witnessing a significant shift toward higher-value pharmaceutical products, advanced formulations, specialty medicines, complex generics, biosimilars, injectables, and patient-centric healthcare solutions. Increasing investments in research and development, manufacturing infrastructure, quality systems, and technology are enabling Indian pharmaceutical companies to expand beyond conventional volume-driven manufacturing and address more sophisticated domestic and international healthcare requirements.

Technology and manufacturing excellence are becoming increasingly integral to pharmaceutical competitiveness. Automation, digital manufacturing, data-driven quality management, advanced analytical systems, artificial intelligence, and smart production technologies are helping manufacturers enhance productivity, strengthen compliance, improve quality consistency, and optimize pharmaceutical operations. Alongside these developments, the growing emphasis on regulatory readiness, supply-chain resilience, traceability, and stringent quality standards is encouraging companies to build more robust and future-ready manufacturing ecosystems.

Recognizing the companies contributing to this transformation, **India Pharma Outlook** presents its '**Pharma Manufacturers & Product Solutions – 2026**' special edition, highlighting dynamic pharmaceutical manufacturers and solution providers that are redefining excellence through innovative products, advanced manufacturing capabilities, quality-driven operations, and patient-focused approaches. The edition celebrates the enterprises helping shape a more resilient, accessible, technologically advanced, and globally competitive pharmaceutical future for India.

Shiwani Pradhan
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TOP STORIES

LUPIN'S NEW DEAL COULD BE A GAME CHANGER IN OPHTHALMOLOGY

Ophthalmology is becoming a stronger specialty-care focus for Lupin as the company expands its European eye-care business through VISUfarma. Lupin announced an exclusive licensing agreement with Visus Therapeutics for YUVEZZI, a once-daily ophthalmic treatment for adult presbyopia.

The deal covers the European Union, UK, Switzerland, Norway and Iceland. It follows Lupin's acquisition of VISUfarma in April and adds a differentiated presbyopia product to its growing ophthalmology portfolio. The agreement could also strengthen Lupin's European specialty-care presence as the company expands beyond established eye care categories and targets new treatment opportunities. PO

FIRST FDA-APPROVED GSDIA GENE THERAPY COULD CHANGE TREATMENT

Ultragenyx Pharmaceutical's gene therapy Genglycos has received U.S. FDA approval for glycogen storage disease type Ia (GSDIa). The gene therapy is the first FDA-approved treatment for the rare metabolic disorder. GSDIa, also known as Von Gierke disease, affects about 1,500 to 2,500 people in the U.S.

The inherited disorder is caused by a deficiency of an enzyme needed to release glucose from the liver. This can lead to dangerous drops in blood sugar. Genglycos is designed to address the underlying cause of the disease. It helps the body break down glycogen and produce glucose. This could reduce patients' dependence on raw cornstarch to control blood sugar. PO

PERSONALIZED MELANOMA VACCINE CLEARS MAJOR PHASE 3 TEST

Merck and Moderna's personalized melanoma vaccine has met key goals in a large Phase 3 trial. The mRNA-based treatment was tested with Merck's Keytruda in high-risk melanoma patients. The companies said the combination significantly improved recurrence-free survival. It also improved distant metastasis-free survival compared with Keytruda alone.

The results mark the first successful Phase 3 test for an mRNA cancer vaccine of this kind. The Phase 3 trial enrolled 1,137 patients with surgically removed stage IIB to IV melanoma. These patients faced a high risk of their cancer returning or spreading. Patients received either Intismeran with Keytruda or Keytruda alone. Intismeran is the treatment's generic name and was earlier known as V940 or mRNA-4157. PO

GLENMARK SCORES WITH USFDA APPROVAL FOR NASAL SPRAY

The latest USFDA approval has given Glenmark Pharmaceuticals another entry into the US respiratory market with its Fluticasone Propionate Nasal spray. The company received the final approval on August 20, 2026, for a generic product equivalent to Haleon's Flonase nasal spray.

The product will add to Glenmark's respiratory portfolio in the United States. This approval gives the company access to a market that recorded about USD 295.2 million in annual sales for the 12 months, according to IQVIA data. Glenmark Pharmaceuticals will distribute the product across the US market. PO

WEGOVY PILL ENTERS NEW TRIAL TO FIND THE LOWEST EFFECTIVE DOSE

Wegovy pill has entered a new late-stage clinical trial as Novo Nordisk looks for the lowest dose that can still deliver meaningful weight loss. The study could help the company offer more flexible treatment options for people using oral semaglutide.

Novo Nordisk started the Wegovy pill study, called OASIS 5, on August 12, 2026. The trial will run for 60 weeks and is expected to continue through 2028. It will include 450 adults with overweight or obesity. The company has not disclosed the exact lower doses that will be tested. The study will compare lower doses of oral semaglutide with a placebo. It will assess weight loss and other health benefits linked to the treatment. PO

EBOLA CASES CROSS 5,000 IN CONGO AS OUTBREAK DEFIES CONTAINMENT

Ebola cases in the Democratic Republic of Congo (DRC) have crossed 5,000, marking a new and alarming phase in the country's fastest-growing Ebola outbreak. Government data showed 5,021 confirmed cases as of August 16, along with 2,378 deaths. Health officials are warning that the response is struggling to keep pace with the rapid spread of the virus.

The outbreak, which was declared on May 15, has already surpassed the 2018–2020 Ebola epidemic in both infections and deaths, making it the largest Ebola outbreak in the DRC's history. The current crisis is also the second-deadliest Ebola outbreak recorded globally, behind the 2014–2016 West Africa epidemic. **PO**

MADE IN INDIA HEART-LUNG MACHINE SET TO CHALLENGE IMPORTS

India's heart-lung machine market is set for a major shift as a homegrown device gains key regulatory approvals. The heart-lung machine developed by Mediyant Technologies has received USFDA 510(k) clearance and CDSCO approval.

The device is called the New Century Heart-Lung Machine. It is designed for use during open-heart surgeries. The machine supports blood circulation and oxygenation when the heart and lungs are temporarily stopped. Mediyant Technologies developed the device after years of work on indigenous cardiac care technology. The company has secured approval to manufacture and market the machine in India. **PO**

WHY FAKE MEDICINES PERSIST DESPITE INDIA'S DRUG CONTROL PUSH

Fake medicines remain a serious threat to India's pharmaceutical ecosystem, even as regulators continue to tighten drug-control measures and enforcement. A fresh raid near Bidadi in Karnataka has exposed how counterfeit products can move beyond illegal manufacturing into repacking, relabeling and potential hospital supply chains.

The Karnataka drug enforcement authorities seized material estimated at Rs 4.91 crore, including thousands of vials, expired medicines, counterfeit labels and packaging equipment. Reports also indicated that some seized products carried names of major pharmaceutical companies. **PO**

INDIAN SKINCARE ENTERS A NEW HORIZON WITH WIPRO'S DERMATOUCH DEAL

Indian skincare is entering a new growth phase as established consumer companies move deeper into premium and science-backed beauty. Wipro Consumer Care & Lighting's acquisition of Dermatouch marks a major step in this direction.

Wipro will initially acquire a 60 per cent stake in the Ahmedabad-based skincare brand and take the remaining 40 per cent over three years. The deal gives Wipro its first digital-first brand and a direct entry into India's premium skincare segment. The transaction also highlights growing corporate interest in India's fast-expanding dermal and specialized skincare categories. **PO**

AMYLYX DRUG CUTS DANGEROUS LOW BLOOD SUGAR EPISODES BY 55 PERCENT

Amylyx Pharmaceuticals' low blood sugar drug avexitide has delivered strong results in a late-stage trial. The experimental treatment cut hypoglycemic episodes by 55 percent versus placebo. The results came from a 78-patient trial involving people who had undergone weight-loss surgery.

The trial met its main goal after 16 weeks. The results also pushed Amylyx shares more than 45 percent higher during Tuesday trading. The stock reached USD 31.72 in morning trading. The jump could add about USD 1.15 billion to the company's market value. **PO**

ANALYSIS

ADVANCED SAFETY PRACTICES FOR PHARMACEUTICAL MANUFACTURING WORKERS

Pharmaceutical manufacturing workers form the backbone of resilient domestic and global drug supply chains. They operate in highly regulated, sterile environments to produce, package, and ensure the quality of essential medicines, from everyday generics to complex biologics and potent therapies. In an era of geopolitical tensions, pandemics, and raw material vulnerabilities, these frontline professionals maintain production continuity, prevent shortages, and safeguard patient access to life-saving drugs. Their expertise in adhering to Good Manufacturing Practices (GMP), quality controls, and safety protocol Guide directly supports supply chain integrity, enabling timely delivery across borders while minimizing disruptions from quality issues or contamination events. Without a skilled, healthy workforce, even advanced facilities risk downtime, recalls, or failures that ripple through healthcare systems worldwide.

MSDS AND CHEMICAL EXPOSURE RISKS IN PHARMA PLANTS

Despite the critical nature of their role, pharmaceutical workers face significant occupational hazards. Repetitive tasks such as capping, labeling, pipetting, manual material handling, and packaging, often performed in cleanrooms under time pressure contribute to high rates of musculoskeletal disorders (MSDs). Studies on pharmaceutical workers report MSD prevalence ranging from approximately 63% to over 83%, with common

complaints in the lower back, neck, shoulders, wrists/hands, and lower extremities. Symptoms include aches, pain, cramps, and moderate severity that still allows work but leads to discomfort, reduced productivity, and potential long-term disability.

Broader manufacturing data underscores the scale: In the U.S. private sector, MSDs accounted for about 30% of days-away-from-work (DAFW) cases in recent years, with manufacturing among the top contributors alongside retail and healthcare. Median DAFW for MSD cases hovers around 12 days, imposing substantial costs through lost productivity, medical expenses, and workers' compensation. Factors exacerbating risks include prolonged standing, awkward postures, high repetition, and extended shifts (e.g., over 8 hours), which elevate ergonomic strain in pharma's high-volume lines.

Chemical exposure presents another major threat. Workers handle Active Pharmaceutical Ingredients (APIs), many of which are potent compounds capable of causing adverse effects at very low concentrations via inhalation, skin contact, or accidental ingestion. Risks include respiratory irritation, dermatitis, systemic toxicity, and long-term effects from potent or highly potent substances. While full-shift exposures often stay below limits with proper controls, short-term peaks during tasks like powder scooping or equipment cleaning can spike dust or vapor levels. Industry-wide, chemical-related injuries, though declining as a percentage of total cases, still result in thousands of incidents annually, with potential for acute poisonings or chronic conditions. Dermatitis from repeated PPE use or cleaning agents is also common.

These issues threaten not only worker health but also supply chain stability: injured or ill workers lead to absenteeism, training burdens, reduced output, and higher error rates that could compromise product quality.

ERGONOMICS AND REPETITIVE MOTION: PROTECTING THE HANDS THAT MANUFACTURE HEALTH

Pharmaceutical manufacturing is, at its core, a hands-on industry. Despite increasing automation in upstream synthesis, the downstream operations blister packing, manual capping, label application, tablet counting, ampoule inspection, and secondary packaging remain heavily reliant on human dexterity performed at pace, under pressure, and at scale. A packaging operator on a 12-hour shift may perform the same wrist flexion-extension movement upwards of 8,000–12,000 times. This is the epidemiological breeding ground for Repetitive Strain Injuries (RSI), carpal tunnel syndrome, rotator cuff tendinopathy, and lower back dysfunction collectively categorised as Musculoskeletal Disorders (MSDs).

Workstation adjustment is equally non-negotiable. The principle of neutral posture maintaining the spine in its natural lordotic and kyphotic curves, keeping elbows at approximately 90 degrees during manual tasks, and ensuring that the work surface height is positioned to eliminate shoulder elevation, is the foundation of MSD prevention. In cleanroom environments, this is complicated by the need for gowning, restricted footwear, and the absence of conventional ergonomic furniture. The following checklist addresses this challenge directly.

CHEMICAL EXPOSURE & POTENT COMPOUND SAFETY: ENGINEERING OUT THE INVISIBLE RISK

Active Pharmaceutical Ingredients (APIs) are, by molecular design, biologically active at microgram quantities. This pharmacological potency, the very property that makes them therapeutic, also makes occupational exposure a critical risk. Workers in API synthesis, granulation, blending, and sterile filling operations may be exposed to potent compounds that carry Occupational Exposure Limits (OELs) measured in nanograms per cubic metre of air. A single shift's inadequate containment can result in acute toxicity, hormonal disruption, reproductive harm, or long-term carcinogenesis.

The industry standard framework for managing this risk is the Hierarchy of Controls, a structured, prioritised approach to hazard management that moves from the most effective permanent solutions to the least effective temporary measures. Dr. Venkataraman emphasises that in high-potency API environments, the hierarchy is not a philosophical guide but a legal and engineering mandate.

HEPA filtration High-Efficiency Particulate Air filtration is the cornerstone of engineering control for potent compounds. Facility design must ensure that OEB 4/5 handling areas operate under negative pressure relative to adjacent spaces, with HEPA-filtered exhaust. HVAC systems must be validated for HEPA filter integrity (using DOP/PAO challenge testing) on a minimum biannual basis, or following any facility modification. Potent compound containment failures must trigger immediate area evacuation, biological monitoring of exposed workers, and root cause investigation under a documented CAPA (Corrective and Preventive Action) framework.

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● THOUGHT CENTRAL ●

AI-AUGMENTED CLINICAL TRIALS & DRUG DEVELOPMENT EVOLUTION IN INDIA

Jennifer Li, SVP & Head of Sales - APAC, Medidata

Jennifer Li, SVP & Head of APAC Sales, Medidata, engaged in a conversation with Thiruamuthan, Assistant Editor at India Pharma Outlook, discusses how AI is transforming clinical trials in India by accelerating patient recruitment, enhancing data analysis, and enabling predictive decision-making. She highlights leveraging genetic diversity, real-world data, evolving regulations, and ecosystem collaborations to drive inclusive, efficient, and scalable drug development.

Jennifer Li, a life sciences business leader, brings over 18 years of experience across clinical research and analytics. She specializes in business strategy, sales leadership, data analytics, and statistical modeling, with strong expertise in driving growth, market expansion, and commercial excellence.

Jennifer Li,
SVP & Head of Sales - APAC

AI IS ENHANCING CLINICAL TRIAL EFFICIENCY, PARTICULARLY IN DATA ANALYSIS AND PATIENT RECRUITMENT. HOW HAS AI TECHNOLOGY IMPACTED THESE AREAS IN INDIA, AND WHERE IS IT MOST EFFECTIVE?

AI's most significant impact is in improving patient recruitment and participation, which is driven by its ability to efficiently handle large volumes of complex information.

As AI excels at processing massive amounts of data in seconds, a task that would take humans years, this capability can be leveraged to increase and improve patient recruitment through the three key pillars.

Advanced Screening and Targeting: AI mines complex sources like Real-World Data (RWD) and electronic health records (EHR) to identify qualified participants and detect patterns that manual analysis would miss. This capability enables more targeted outreach and significantly shortens recruitment timelines.

Predictive Site Performance: The technology also uses this complex information to predict which research sites are most likely to recruit effectively.

Handling Complexity: The efficient management of high levels of complexity is essential, particularly in areas like clinical trial imaging, where over 50 percent of trials and 95 percent of oncology trials rely on it.

At Medidata, we believe that embedding AI across the clinical trial lifecycle is key to driving meaningful transformation in drug development, having delivered tangible results, such as reducing study startup time by up to 75 percent and study build time by as much as 80 percent.

INDIA'S GENETIC DIVERSITY IMPACTS PERSONALIZED MEDICINE. HOW IS AI LEVERAGING THIS DIVERSITY TO OPTIMIZE PATIENT RECRUITMENT AND OUTCOMES IN CLINICAL TRIALS ACROSS THE COUNTRY?

India's genetic diversity creates a real opportunity for clinical research, however, it remains underutilized. With its diverse and treatment-naïve population, AI can change this to not just enable more inclusive trials but also increase the country's trial capacity and positioning as a global clinical trial hub.

For example, AI can mine RWD across diverse geographic regions, including tier-2 and tier-3 cities where large patient populations exist but trial participation has been traditionally low. In doing so, it can identify qualified participants from a previously untapped pool whose genetic and demographic profiles match trial requirements to create a more

representative patient cohort. Not only does this accelerate recruitment, but it also generates outcomes data that reflects India's actual patient population.

INDIA'S EVOLVING REGULATORY ENVIRONMENT FOR AI IN HEALTHCARE PRESENTS CHALLENGES. WHAT REGULATORY HURDLES DOES AI-DRIVEN DRUG DEVELOPMENT FACE IN INDIA, AND HOW ARE THEY BEING ADDRESSED?

An emerging challenge as clinical trials become more technology-enabled and AI-driven is aligning innovations within existing frameworks designed for traditional trials. However, India's regulatory environment is evolving and moving in the right direction to address these hurdles.

Earlier this year, the Union Ministry of Health and Family Welfare announced key amendments to the New Drugs and Clinical Trials Rules. The reforms aim to streamline approvals, reduce regulatory timelines, and establish clearer pathways for technology-enabled trials to accelerate clinical research and drug development in the country.

While streamlined approvals can fast-track access to new therapies, patient consent and data privacy remain critical. The way forward lies in regulators, sponsors, and technology providers co-creating intuitive, accessible systems that protect patient rights while upholding ethical standards and enabling innovation.

> **Leveraging real-world data and India's genetic diversity, AI enables more inclusive trials while identifying untapped patient populations and improving recruitment accuracy and outcomes**

AI ALGORITHMS ARE RESHAPING CLINICAL TRIAL EFFICIENCY. WHAT TRENDS IN PREDICTIVE ANALYTICS OR MACHINE LEARNING ARE MOST TRANSFORMING TRIAL DESIGNS AND REDUCING TIMELINES IN INDIA?

The first key transformation is patient recruitment and trial startup timelines. Machine learning algorithms analyze vast datasets to predict which patient populations are most likely to meet trial criteria and remain engaged, while simultaneously forecasting which research sites will perform best based on historical performance. By identifying high-potential patient groups and predicting site-level recruitment success, resource allocation can be enhanced, and recruitment and trial startup timelines can be reduced.

Beyond recruitment, AI is revolutionizing real-time risk detection and decision-making. Machine learning continuously monitors incoming trial data to flag inconsistencies, protocol deviations, and safety signals in real time. Additionally, it also analyzes historical data to anticipate treatment efficacy, dropout risks, and adverse events, enabling researchers to make proactive, risk-averse decisions.

We are also seeing the rise of digital twins and adaptive trial design. AI can create virtual patient models by integrating diverse data sources, allowing researchers to simulate disease progression and predict how different patient populations might respond to therapies. This enables teams to test and iterate study designs before implementing them in real-world settings.

PHARMACEUTICAL COMPANIES IN INDIA ARE COLLABORATING WITH STARTUPS TO HARNESS AI INNOVATIONS. HOW ARE THESE COLLABORATIONS STRUCTURED, AND WHAT IMPACT DO THEY HAVE ON DRUG DEVELOPMENT PROCESSES?

The pharmaceutical industry is increasingly recognizing that accelerating drug development requires ecosystem collaboration, with startups, tech innovators, research institutions, regulators, and healthcare providers. Rather than siloed approaches, companies are building partnerships across the entire value chain. This collaborative ecosystem approach can compress timelines and reduce costs through shared infrastructure and data.

LOOKING AHEAD, HOW DO YOU FORESEE THE ROLE OF AI EVOLVING IN CLINICAL TRIALS OVER THE NEXT 5-10 YEARS, ESPECIALLY IN TERMS OF SCALABILITY AND INNOVATION?

Over the next 5-10 years, I foresee AI becoming part of the infrastructure for clinical research, much like electronic data capture did a decade ago. To see real transformation, this will be coupled with partnerships that bridge pharma, technology, and patient advocacy around interoperability and data sharing.

The biggest opportunity lies in connecting clinical, real-world, and patient-reported data in ways that are usable and secure. This will happen through the continued adoption of interoperability standards that create common language across systems, as well as disruption through emerging technologies like agent-to-agent communication that enable seamless data exchange.

When pharma teams up with platforms that can crack interoperability, we'll see faster drug development, more precise insights, and a seamless experience for patients. The companies and platforms that lead these partnerships, prioritizing data sharing and integration, will define the next era of clinical research. **PO**

TRIDENT LIFELINE

Building an Institution of Trust in Pharmaceutical Manufacturing

By Priya S

The pharmaceutical finished dosage contract manufacturing industry has become a cornerstone of modern healthcare, enabling pharmaceutical companies to bring quality medicines to market with greater speed, efficiency, and regulatory confidence. As global demand for affordable healthcare continues to rise, contract manufacturers are no longer viewed simply as production partners; they are expected to deliver robust quality systems, technological capabilities, regulatory compliance, and supply chain resilience. India's emergence as one of the world's leading pharmaceutical manufacturing hubs has further accelerated this transformation, with Indian manufacturers playing an increasingly significant role in supplying medicines across regulated and emerging markets alike.

Within this evolving landscape, Trident Lifeline has steadily built a reputation as a trusted pharmaceutical formulation manufacturer driven by quality, capability, and sustainable growth. From manufacturing a diversified portfolio of formulations to serving customers in over 46 countries, the company's evolution reflects a carefully planned strategy rather than rapid expansion alone. Behind this journey lies a leadership philosophy that views finance not merely as a function of reporting numbers but as a catalyst for organizational growth. As Executive Director & Chief Financial Officer, Ashish Bafna has played an instrumental role in supporting Trident Lifeline's transformation into a publicly listed pharmaceutical company while helping build a business founded on governance, financial discipline, regulatory excellence, and long-term stakeholder value.

COVER STORY


India Pharma Outlook TOP
PHARMACEUTICAL FINISHED DOSAGE CONTRACT MANUFACTURER FOR THE YEAR - 2026
Trident Lifeline envisions to build a globally respected pharmaceutical institution recognized for quality, innovation, governance, and responsible growth
ASHISH BAFNA,
EXECUTIVE DIRECTOR & CHIEF FINANCIAL OFFICER

Finance Beyond Numbers

For Ashish Bafna, finance has always extended beyond accounting, reporting, or balance sheets. A Chartered Accountant who qualified in 1999, he has spent over 27 years building expertise across financial planning, corporate governance, strategic business management, and organizational development. Throughout his professional journey, he has consistently believed that sustainable businesses are created through disciplined decision-making, ethical leadership, and carefully planned growth.

His association with Trident Lifeline began during one of the company's most defining phases. As a consultant involved in its fundraising and IPO journey, he had the opportunity to closely observe the organization's leadership, strategic direction, and long-term aspirations. What impressed him most was the management's vision of building an institution rather than merely creating a high-value business.

That conviction ultimately inspired him to join Trident Lifeline as Chief Financial Officer before assuming the additional responsibility of Executive Director. He recognized an organization with a diversified product portfolio, a strong commitment to quality, growing international presence, dedicated manufacturing capabilities, resilient supply chain systems, and an expanding research ecosystem. More importantly, he saw a company prepared to invest patiently in building long-term credibility rather than pursuing short-term gains.

This philosophy continues to define his leadership today. Financial stewardship, in his view, is not limited to safeguarding resources but involves enabling sustainable expansion, strengthening governance, supporting innovation, and ensuring that every strategic decision contributes to lasting value for customers, investors, employees, and society.

Investing in Sustainable Growth

The pharmaceutical manufacturing industry is experiencing significant transformation. Higher regulatory expectations, digital manufacturing technologies, specialty formulations, automation, and increasingly complex global supply chains are redefining how pharmaceutical companies select their manufacturing partners.

Ashish Bafna believes these industry shifts present opportunities for organizations that are willing to invest consistently in capability building.

Under his financial leadership, Trident Lifeline has adopted a measured expansion strategy that balances ambitious growth with disciplined capital allocation. Rather than pursuing expansion for its own sake, every investment has been aligned with strengthening manufacturing infrastructure, technological capabilities, and long-term competitiveness.

The results are evident. Over the past four years, the company has recorded annual revenue growth exceeding 50 percent while significantly expanding its global footprint to more than 46 countries. During the same period, Trident Lifeline has established three modern manufacturing facilities, strengthening its transition from a contract manufacturing and loan licence business into a fully integrated pharmaceutical formulation manufacturer.

"The company's manufacturing capabilities now extend across tablets, capsules, dry syrups, liquid formulations, ointments, nutraceuticals, cosmetics, and medical devices, allowing it to serve both contract manufacturing clients and customers seeking comprehensive pharmaceutical solutions under one roof", shares Ashish Bafna.

The Trident Lifeline Advantage

- Comprehensive Finished Dosage Expertise
- Global Reach, Local Regulatory Excellence
- Quality Embedded in Every Process
- nnovation Powered by Strategic Research
- Built for Sustainable, Scalable Growth

The growth story, however, is far from complete. With approximately 50,000 square metres of industrial land already secured and regulatory approvals in place, Trident Lifeline has outlined an ambitious five-year roadmap to establish five additional manufacturing facilities. These investments are intended not only to increase production capacity but also to position the company for sustained global expansion in an increasingly competitive pharmaceutical landscape.

Building Trust Through Quality and Governance

In pharmaceuticals, growth can never come at the expense of quality. Regardless of market opportunities or production volumes, patient safety remains the industry's ultimate responsibility.

Ashish Bafna firmly believes, "Quality and compliance cannot be confined to individual departments; they must become part of an organization's culture. At Trident Lifeline, this philosophy is reflected in systems that integrate quality across every stage of manufacturing rather than treating compliance as a regulatory obligation alone."

The company maintains rigorous quality management practices supported by Good Manufacturing Practices (GMP), continuous employee training, structured skill development, regular process reviews, and performance monitoring. Employees across all levels are encouraged to take ownership of quality, reinforcing accountability throughout the organization.

Equally important is the company's dedicated regulatory affairs team, which continuously evaluates evolving regulatory requirements across international markets. Before entering any new geography, regulatory expectations are thoroughly assessed to ensure manufacturing processes align with country-specific standards from the outset.

Technology has become another important pillar of Trident Lifeline's governance framework. Investments in advanced manufacturing equipment, automation, AI-enabled systems, and CFR-compliant machinery have strengthened product consistency, documentation integrity, traceability, and operational efficiency. These investments not only enhance manufacturing performance but also reinforce customer confidence in the company's ability to consistently deliver safe, reliable, and compliant pharmaceutical products.

For Ashish Bafna, governance and quality are inseparable. Strong financial systems support operational excellence, while operational excellence ultimately strengthens long-term business sustainability.

An Institution with a Larger Purpose

Every organization encounters moments that test its resilience. For Trident Lifeline, changing market dynamics, supply chain disruptions, evolving regulatory frameworks, and global geopolitical uncertainties have all presented significant challenges in recent years. Rather than responding with short-term measures, the company has chosen to remain focused on transparency, operational continuity, and sustainable decision-making. These experiences have reinforced Ashish Bafna's belief that resilient organizations are built through empowered teams, ethical leadership, and robust systems capable of adapting to uncertainty.

One milestone that particularly reflects Trident Lifeline's long-term outlook is its strategic collaboration with NIPER Ahmedabad, one of India's premier pharmaceutical research institutions. The partnership has resulted in the company becoming the first organization in the institute's history to enter into a technology transfer agreement. Through this collaboration, Trident Lifeline has acquired technology for the treatment of a rare skin cancer while also supporting patient access through its corporate social responsibility initiatives.

Looking ahead, the company's ambitions extend beyond manufacturing expansion. The vision is to build a globally respected pharmaceutical institution recognized for quality, innovation, governance, and responsible growth. Every investment in infrastructure, technology, research, and people is intended to strengthen that objective.

For Ashish Bafna, the true measure of success is not defined solely by revenue growth or manufacturing capacity. It lies in building an organization that creates enduring value for every stakeholder - customers, employees, shareholders, suppliers, regulators, and ultimately the patients who depend on its products. It is this philosophy of institution-building, supported by financial prudence and long-term thinking, that continues to shape Trident Lifeline's journey and positions the company for sustained success in the global pharmaceutical manufacturing industry. PO

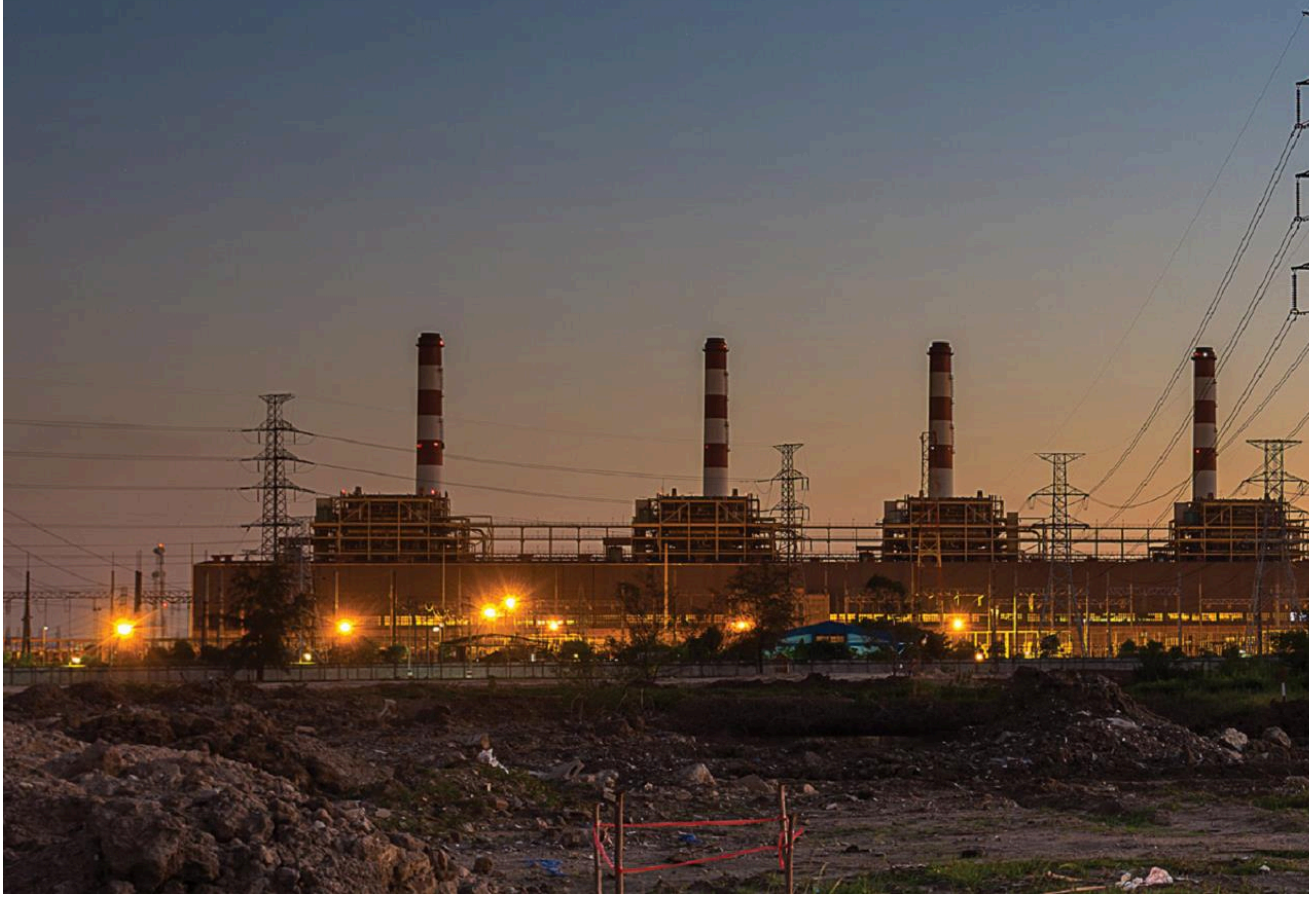
India Pharma Outlook's Manufacturers & Product Solutions - 2026: The edition has been prepared after being closely scrutinized by a distinguished panel of judges including CXOs, analysts, and our editorial board. We recognize their valuable contribution to the ever expanding and competitive market and their ability to sustain themselves and emerge as top contestants through their reliable products.

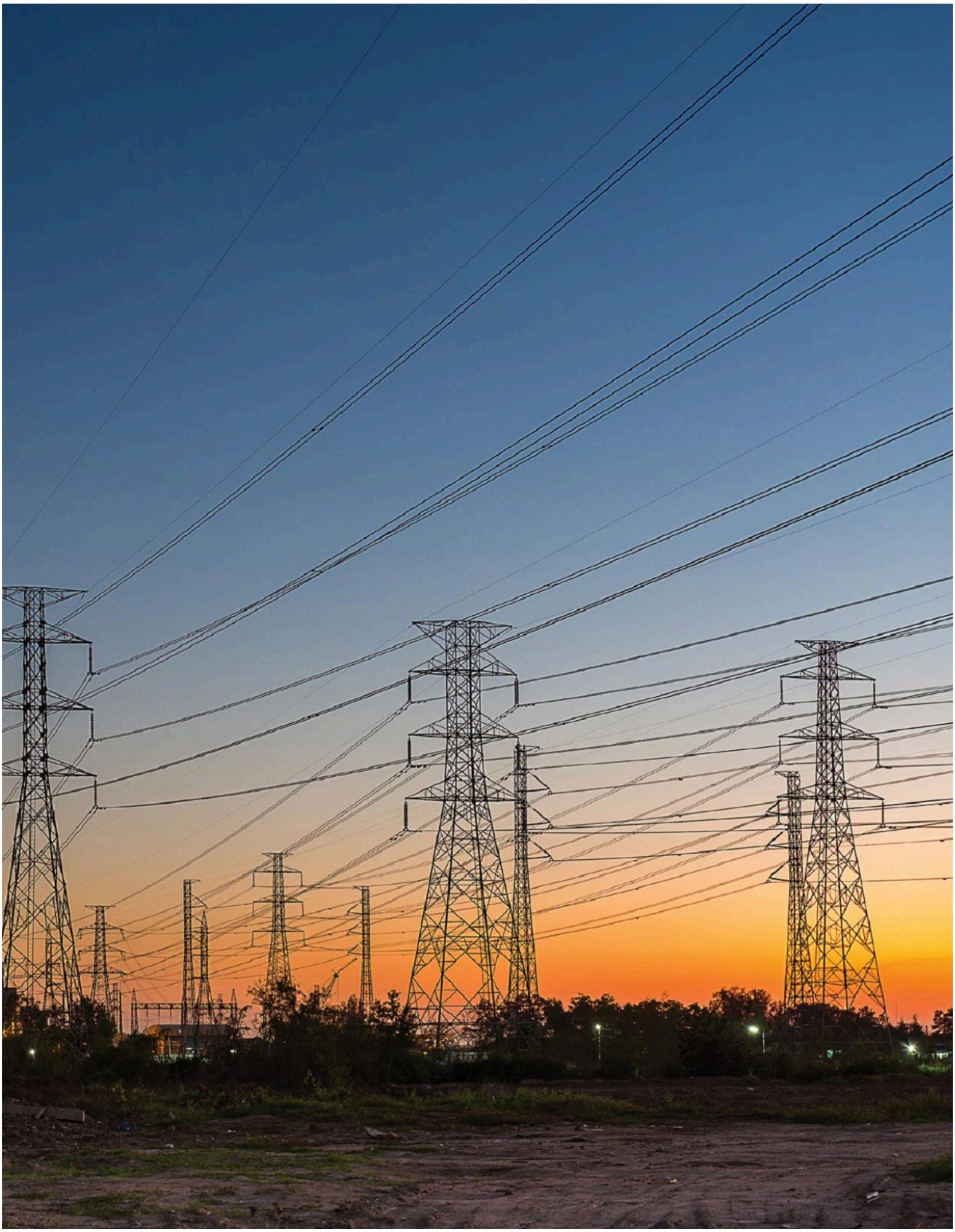
"ARRIDE Healthcare continues to support healthcare camps and medicine distribution initiatives through NGOs, reflecting its broader commitment to improving healthcare accessibility" - ARRIDE HEALTHCARE

"Borosil Scientific's role extends beyond supplying pharmaceutical containers to support customers throughout their manufacturing and regulatory journey" - BOROSIL SCIENTIFIC

"Trident Lifeline envisions to build a globally respected pharmaceutical institution recognized for quality, innovation, governance, and responsible growth" - TRIDENT LIFELINE

Let's delve more into these prominent players and know how they are spearheading the industry today.





ARRIDE HEALTHCARE

PIONEERING SPECIALTY ORTHOPEDIC SOLUTIONS WITH QUALITY AT THE CORE

India's orthopedic healthcare market is witnessing sustained growth, driven by an aging population, rising incidences of osteoporosis and arthritis, sports-related injuries, and increasingly sedentary lifestyles that contribute to musculoskeletal disorders. Alongside these demographic and lifestyle shifts, healthcare professionals are placing greater emphasis on preventive bone health, nutritional supplementation, rehabilitation, and evidence-based pain management. Operating within this dynamic landscape, ARRIDE Healthcare has steadily built a reputation as a specialty pharmaceutical company focused on orthopedic and women's healthcare solutions. Established in 2010, the company has combined quality-focused manufacturing partnerships, ethical business practices, and strong engagement with healthcare professionals to create a growing portfolio of affordable, clinically relevant products. Rather than competing solely on scale, ARRIDE Healthcare has differentiated itself through consistency, scientific engagement, and a long-term commitment to delivering dependable healthcare solutions that support both physicians and patients.


Anurag Pokhra
Director

Building a Specialty Pharmaceutical Company on Strong Foundations

The foundation of ARRIDE Healthcare is closely linked to the professional journey of its founder, whose academic background in science and management, coupled with more than seven years of experience at Unichem Pharmaceuticals, shaped the company's vision. Exposure to pharmaceutical sales, marketing, customer engagement, and physician interactions provided valuable insight into the evolving needs of India's healthcare ecosystem and highlighted the importance of delivering accessible, quality medicines supported by ethical practices.

Established on 6 July 2010, ARRIDE Healthcare began with a focused product portfolio and a clear objective of becoming a trusted pharmaceutical partner for healthcare professionals. Over the years, the company has expanded its offerings to more than 45 products across Orthopedics and Gynecology, supported by a dedicated team comprising medical representatives and an expanding network of distributors and stockists. This measured yet consistent growth reflects a business strategy centered on sustainable expansion rather than rapid diversification.

"The company's vision extends beyond commercial success. ARRIDE Healthcare aims to improve patient outcomes by delivering reliable pharmaceutical solutions while creating long-term value for doctors, channel partners, and patients through quality, affordability, and professional integrity", says Anurag Pokhra, Director.

A Comprehensive Portfolio Supporting Musculoskeletal Health

As orthopedic care increasingly shifts toward holistic management that integrates prevention, treatment, rehabilitation, and nutritional support, ARRIDE Healthcare has expanded its portfolio to address multiple stages of patient care.

Its orthopedic product range includes calcium supplements, Vitamin D3 formulations, nutraceuticals, anti-inflammatory medicines, muscle support therapies, and pain management solutions designed to support bone health and faster recovery. Flagship brands such as Waftcal-MAX, Waftcal-CC, GRFCAL-D3, Vontafil, Esob-D, Qustagab-MNT, and Qustagab-NT cater to various musculoskeletal health requirements, while pain management offerings including Coxjet-90, Coxjet-MR, Dicqua-SP, and Dicqua Gel address inflammation and pain relief.

The company has also strengthened its nutraceutical portfolio with formulations such as Qusta Joint, Qustaroz-3, Qustagem, Qustagem-L, and Qustagem-Q10, supporting

long-term joint health and recovery. Complementing its orthopedic business, ARRIDE Healthcare has established a Women's Healthcare division offering products for hormone therapy, fertility support, and gynecological care, enabling the company to diversify within specialty pharmaceutical segments while maintaining clinical relevance.

By continuously evaluating therapeutic trends and healthcare professionals' feedback, ARRIDE Healthcare seeks to ensure that its portfolio remains aligned with evolving patient needs and contemporary treatment practices.

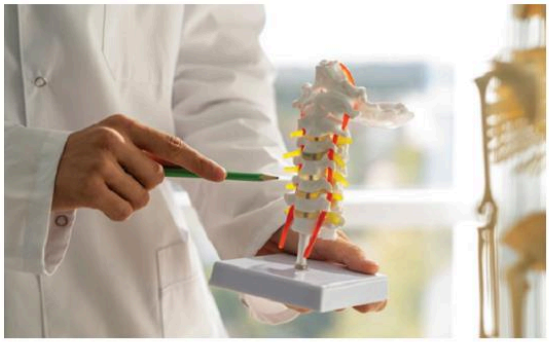
Quality, Scientific Engagement, and Ethical Growth

One of ARRIDE Healthcare's defining strengths lies in its unwavering focus on product quality and professional credibility. Rather than investing in proprietary manufacturing facilities, the company collaborates with WHO-GMP and ISO-certified manufacturing partners that adhere to stringent quality assurance protocols. Laboratory-certified raw materials, comprehensive quality control processes, and stability studies collectively ensure that products meet established standards for safety, consistency, and efficacy.

> ARRIDE HEALTHCARE CONTINUES TO SUPPORT HEALTHCARE CAMPS AND MEDICINE DISTRIBUTION INITIATIVES THROUGH NGOS, REFLECTING ITS BROADER COMMITMENT TO IMPROVING HEALTHCARE ACCESSIBILITY

"Beyond manufacturing excellence, ARRIDE Healthcare places considerable emphasis on scientific engagement. Through Continuous Medical Education (CME) programs and regular interactions with healthcare professionals, the company promotes clinical awareness while gaining valuable insights into changing therapeutic requirements. This collaborative approach supports evidence-based product development and strengthens relationships with physicians who increasingly seek dependable pharmaceutical partners capable of delivering both quality products and clinical value", mentions Anurag Pokhra.

Ethical marketing practices, reliable product availability, and responsive customer support have further reinforced ARRIDE Healthcare's credibility within its operating markets, enabling it to cultivate long-standing partnerships built on trust rather than transactional engagement.



Scaling with Innovation and a Long-Term Vision

Competing against significantly larger pharmaceutical companies has been one of ARRIDE Healthcare's most notable challenges. Instead of pursuing aggressive expansion, the company has focused on strengthening customer relationships, selecting dependable manufacturing partners, and building a committed field force capable of delivering consistent service. This disciplined strategy has enabled ARRIDE Healthcare to achieve approximately 25 percent annual growth while recording an annual turnover of around ₹2.4 crore, demonstrating that sustained progress can be driven by quality, credibility, and customer confidence.

Looking ahead, the company plans to strengthen its presence across Orthopedics, Pain & Inflammation, Hormone Therapy, and Infertility Management while expanding its product portfolio and geographical reach. A significant strategic initiative is the development of a nationwide digital pharma franchise platform aimed at strengthening distribution across India. Alongside business expansion, ARRIDE Healthcare continues to support healthcare camps and medicine distribution initiatives through NGOs, reflecting its broader commitment to improving healthcare accessibility.

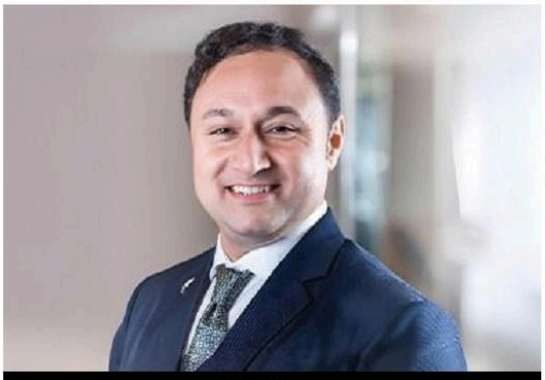
As India's specialty pharmaceutical sector continues to evolve, ARRIDE Healthcare is positioning itself as a trusted partner that combines quality manufacturing, ethical leadership, scientific collaboration, and patient-centric innovation to contribute meaningfully to the future of orthopedic healthcare. PO

THE STRATEGIC ROLE OF REGIONAL CORRIDORS IN FUTURE-READY MEDTECH

Dr Rajiv Chhibber, Joint Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)

In an insightful discussion on "Building a Strong MedTech Ecosystem" with Thiruamuthan, Assistant Editor at India Pharma Outlook, Dr. Rajiv Chhibber, Joint Forum Coordinator, Association of Indian Medical Device Industry (AiMeD), shares his perspectives on strengthening India's position as a globally competitive MedTech hub. Drawing on his extensive experience across policy forums, government engagements, and industry platforms, he highlights the importance of balancing immediate industry needs with broader national priorities. His exposure to leading MedTech hubs in Singapore, Boston, and Germany has further reinforced the value of collaborative, innovation-driven ecosystems in driving sustainable growth.

In an increasingly dynamic geopolitical and technology-driven landscape, Dr. Chhibber believes that adaptability, stakeholder alignment, and evidence-based policymaking are critical to navigating complexity and delivering long-term value for both industry and society.



Dr Rajiv Chhibber,
Joint Forum Coordinator

GIVEN THE GROWING IMPORTANCE OF REGIONAL CORRIDORS IN MEDTECH DEVELOPMENT, HOW ARE THEY RESHAPING MANUFACTURING, INNOVATION, AND SUPPLY CHAIN ECOSYSTEMS?

Regional MedTech corridors are redefining the global healthcare manufacturing landscape by shifting the industry from a concentrated production model to a more distributed, resilient, and innovation-driven ecosystem. Countries are increasingly developing specialized corridors that integrate manufacturing, R&D, logistics, testing infrastructure, and academia within a coordinated framework.

Globally, there are several successful examples that offer valuable lessons. The Minnesota MedTech corridor in the United States, which is closely associated with companies such as Medtronic, demonstrates how strong collaboration between academia, advanced manufacturing, and the clinical ecosystem can create sustained innovation leadership.

Similarly, during a visit to Germany, I had the opportunity to learn more about the Tuttlingen cluster, often referred to as the world capital of surgical instruments. It showcases how a highly specialized SME-driven ecosystem can establish global leadership in niche segments such as surgical devices and instruments.

India also has emerging examples of such regional specialization. The Surat belt, for instance, has evolved into an important hub for cardiovascular device manufacturing, highlighting the potential of focused industrial ecosystems within the country.

Another notable example is Singapore, where Biopolis and the Tuas Medical Devices Park demonstrate how integrated infrastructure, regulatory efficiency, and export-oriented manufacturing can create a highly competitive MedTech ecosystem.

Overall, these regional corridors are reshaping the industry by bringing together manufacturing capabilities, innovation ecosystems, supply chain networks, research institutions, and regulatory support within a single framework. This integrated approach not only strengthens manufacturing competitiveness but also accelerates innovation, improves supply chain resilience, and enables regions to build leadership positions in specific MedTech segments.

AMID INCREASING DEMAND FOR LOCALIZED HEALTHCARE SOLUTIONS, WHAT ROLE DO REGIONAL CORRIDORS PLAY IN IMPROVING ACCESSIBILITY AND RESPONSIVENESS IN MEDTECH DELIVERY?

The whole concept of regional corridors is basically propelled in the right direction, as it was expected with the availability, accessibility, and affordability.

So, I would say that regional corridors would improve accessibility by enabling healthcare technologies to be designed, manufactured, and distributed closer to the end-user market. In a diverse country such as India, healthcare needs vary significantly across regions. In this regard, making localized innovation and manufacturing increasingly important.

> **India's future MedTech leadership will depend on building specialized regional ecosystems that combine talent, regulatory efficiency, logistics, and advanced manufacturing capabilities**

So, I think, if we look at China, from a global point of view, the Shenzhen Medical Electronics Corridor in China illustrates how dense manufacturing ecosystems can rapidly respond to market demand through agile supply chains, component integration, etc.

In terms of India, we can leverage similar corridor-based models to develop regional-specific healthcare capabilities. For instance, if we take South India, it has emerged as a very strong electronics and imaging device corridor, but that's because of the engineering ecosystem present there. It has improved not only accessibility but also the responsiveness of academia towards MedTech delivery.

On the other hand, looking at the northern corridors, the focus is more on consumables. Further, if you go to the northwest areas, it's more on implants, diagnostics, and rehabilitation technologies.

Ultimately, the industrial corridors are confined largely to the infrastructure available there. Furthermore, these corridors will also improve responsiveness. A clear example is in the past, during COVID emergencies, when it reduced dependency on distant supply chains. India has demonstrated its ability to rapidly scale domestic manufacturing of diagnostics, PPEs, ventilator components and oxygen-related devices.

I would state this as when industry and government collaborated closely with academia, I think we had the best solutions available.

AS MEDTECH COMPANIES EXPAND BEYOND TRADITIONAL HUBS, HOW ARE EMERGING CORRIDORS INFLUENCING INVESTMENT PATTERNS AND INFRASTRUCTURE DEVELOPMENT?

The emerging corridors are significantly altering investment flows. Earlier, what was happening is the investment was confined to one or two regions.

However, now the necessary measures are taken, which is definitely altering the investment flows by encouraging companies to establish manufacturing and R&D bases closer to the strategic trade routes.

This enables companies to have an advantage of having skilled labor pools. Hence, I think that is a pattern which is now becoming more and more predominant globally.

In essence, India is also now revitalizing its entire pattern. Countries such as Ireland and Costa Rica have built successful Med-Tech ecosystems through strong regulations, skilled talent, workforce development, and business-friendly policies. Currently, India is striving to strengthen its own MedTech ecosystem and can learn from these models to become a globally competitive manufacturing and export hub.

The country has shifted towards a more state-centric model. The opportunity lies between combining scale and strategic geography. Certainly, India has been doing this through agreements such as EFTA trade agreement between European Union, UK, Gulf, and Oman trade agreements.

As a matter of fact, India can position itself as a trusted manufacturing and distribution base connecting Europe, Middle East, Africa, and Indo-Pacific markets. It is true that these corridors play a crucial role.

Despite India's progress in developing industrial infrastructure and policy support, companies have not yet fully leveraged initiatives such as PM Gati Shakti. This is significant because MedTech manufacturing depends heavily on integrated infrastructure, including multimodal

logistics, cold-chain networks, cleanroom facilities, and reliable transport connectivity. As emerging industrial corridors become better connected to ports, airports, freight corridors, and digital logistics systems, they are likely to attract greater domestic and foreign investment.

WHEN ASSESSING THE COMPETITIVENESS OF REGIONAL CORRIDORS, WHAT FACTORS SUCH AS TALENT AVAILABILITY, REGULATORY SUPPORT, OR LOGISTICS, MATTER MOST FOR SUSTAINABLE GROWTH?

Three critical pillars stand out for the success of India's MedTech corridors: skilled talent, regulatory efficiency, and logistics integration. India possesses a strong foundation of engineering and pharmaceutical talent, but the next phase of growth will require deeper investments in biomedical engineering, regulatory sciences, quality systems, and translational research. These capabilities are essential for ensuring regulatory predictability and enabling faster approval pathways, both of which are critical for investor confidence. Indiapharma outlook.

Regulatory efficiency is critical for the success of MedTech corridors. In India, healthcare is largely a state subject, which can sometimes result in variations in regulatory implementation. Medical devices are categorized into classes A, B, C, and D, with lower-risk devices generally regulated at the state level and higher-risk devices overseen by central authorities. Given this regulatory landscape, coordination across stakeholders becomes crucial. The most successful MedTech corridors globally demonstrate that competitiveness is driven not by isolated incentives alone, but by the depth and integration of the overall ecosystem.

Logistics has also emerged as a key differentiator. Strategic policies can play a transformative role by reducing logistics costs and integrating manufacturing zones with ports, railways, airports, and industrial corridors. Recent geopolitical disruptions and supply-chain challenges have reinforced the importance of building domestic capabilities and reducing dependence on external trade routes.

The long-term sustainability of MedTech corridors depends not only on production capacity but also on the efficient movement of products across domestic and international markets. Global examples demonstrate this clearly. Germany's industrial corridors have benefited from decades of specialized technical training and workforce development. Singapore has leveraged highly coordinated regulatory systems and advanced infrastructure, while the Boston–Cambridge innovation corridor in the United States has shown how universities, hospitals, startups, and venture capital can come together to create a thriving innovation ecosystem.

India has the potential to replicate these successes by building an ecosystem that effectively integrates talent, regulatory efficiency, and logistics, thereby supporting both sustainable growth and global competitiveness.

IN AN ENVIRONMENT WHERE GLOBAL SUPPLY CHAIN DISRUPTIONS HAVE EXPOSED VULNERABILITIES, HOW ARE REGIONAL CORRIDORS STRENGTHENING RESILIENCE AND CONTINUITY IN MEDTECH OPERATIONS?

Recent disruptions, including the COVID-19 pandemic, geopolitical tensions in West Asia, and recurring global shipping bottlenecks, have reinforced the importance of diversified and regionally distributed manufacturing ecosystems. As a result, many countries are increasingly adopting China+1 and friend-shoring strategies, supported by free trade agreements that facilitate the seamless movement of goods and services across partner nations.

Countries such as Vietnam, Mexico, Costa Rica, and several Eastern European economies have benefited significantly from this shift by positioning themselves as reliable alternatives within global supply chains. Their success has been driven not only by manufacturing capabilities but also by efforts to improve the ease of doing business and attract long-term investment.

For the MedTech sector, resilience requires the development of localized supplier ecosystems across critical segments such as electronics, polymers, metals, sterilization technologies, packaging, and precision engineering. Regional manufacturing corridors can further strengthen supply-chain continuity by reducing overdependence on a single geography and enabling faster responses during periods of disruption.

India's experience during the pandemic demonstrated that domestic manufacturing capabilities can be scaled rapidly when policy and industry work in alignment. Initiatives such as the Production Linked Incentive (PLI) scheme have accelerated investments in high-value manufacturing. Looking ahead, specialized corridors focused on implants, diagnostics, critical-care devices, and digital health technologies, supported by Global Capability Centers (GCCs), could significantly enhance India's healthcare resilience while strengthening its export potential.

From a border perspective, resilience should be viewed not merely as a crisis-management strategy, but

as the foundation for long-term healthcare sovereignty supported by globally competitive manufacturing capabilities.

WHILE POLICY FRAMEWORKS CONTINUE TO EVOLVE, HOW EFFECTIVE ARE CURRENT INCENTIVES AND REGULATORY MECHANISMS IN SUPPORTING CORRIDOR-LED MEDTECH GROWTH?

After COVID, India has introduced several policy initiatives that have strengthened the momentum for corridor-led MedTech growth. Key among these are the Production Linked Incentive (PLI) scheme and the establishment of dedicated medical device parks in Uttar Pradesh, Madhya Pradesh, and Tamil Nadu. In addition, emerging MedTech clusters across regions such as Rajkot, Odisha, Himachal Pradesh, and the Northeast are helping to expand the country's manufacturing footprint.

Infrastructure initiatives, including PM Gati Shakti and other connectivity-focused programs, are further supporting the development of integrated MedTech corridors. Together, these measures have helped attract manufacturing investments and enhance confidence in India's MedTech ecosystem. Indiapharma outlook

India is also witnessing growing international interest. Industry bodies are increasingly engaging with global stakeholders, embassies, and trade delegations to explore collaborations in research and development, commercialization, testing infrastructure, standards harmonization, component manufacturing, and export growth.

At the same time, trade agreements such as EFTA and TEPA, along with ongoing engagements with the European Union and the United Kingdom, are creating more opportunities to integrate Indian manufacturing corridors deeply into global value chains.

From an industry perspective, the long-term objective should be to build a globally benchmarked MedTech ecosystem where Indian manufacturers compete not only on affordability, but also on innovation, quality, reliability, and technological capability.

THE PRINCIPLES THAT CONTINUE TO SHAPE RAJIV'S LEADERSHIP JOURNEY

For him, leadership is anchored in a simple yet powerful belief: sustainable progress in healthcare is built on collaboration, credibility, and long-term institution building. These principles have consistently guided his approach to leadership, policy engagement, and strategic decision-making across the MedTech ecosystem.

KEY PILLARS THAT DEFINE HIS LEADERSHIP PHILOSOPHY INCLUDE:

- Collaboration as the foundation of progress: Meaningful advancements in healthcare can only be achieved when government, industry, academia, and healthcare stakeholders work together toward shared objectives.
- Credibility and trust-driven leadership: Building trust through responsible actions, ethical practices, and evidence-based decision-making remains central to creating long-term industry impact.
- Institution building over short-term gains: Sustainable success comes from strengthening ecosystems and institutions that can continue driving innovation and healthcare access for years to come. PO

BOROSIL SCIENTIFIC

REDEFINING PRECISION BEHIND PHARMACEUTICAL PACKAGING

Today, every injectable drug relies on a packaging system that preserves sterility, maintains chemical compatibility, withstands demanding manufacturing processes, and performs consistently throughout its shelf life. As pharmaceutical companies develop increasingly complex biologics, vaccines, and specialty injectables, the expectations placed on glass ampoules and vials have expanded well beyond containment. Today, primary packaging has become a critical quality component that directly influences manufacturing efficiency, regulatory compliance, and product integrity.

This evolving landscape has shifted the industry's focus toward manufacturers capable of delivering precision, consistency, and pharmaceutical-grade quality at scale. Borosil Scientific has established itself in this space through its expertise in manufacturing primary pharmaceutical packaging solutions using Type I Neutral Borosilicate Glass. By combining advanced manufacturing technologies with stringent quality systems and regulatory readiness, the company supports pharmaceutical manufacturers with packaging solutions engineered to perform reliably across every stage of the drug manufacturing lifecycle.

Vials & Ampoules Manufacturing Facility, Nashik

Precision in Every Form

For pharmaceutical packaging, consistency is measured in microns rather than millimetres. Even the smallest dimensional variation can disrupt filling operations, compromise sealing performance, or affect product stability. Borosil Scientific addresses these challenges through fully automated, high-speed forming lines designed to produce ampoules and vials with exceptional dimensional accuracy and repeatability.

"The manufacturing process is reinforced by precision-controlled annealing, which systematically removes residual thermal and mechanical stresses from the glass. This improves the structural strength of each component, enabling it to withstand demanding pharmaceutical processes such as washing, sterilization, depyrogenation, filling, and transportation without compromising performance", speaks Bhoomi Kotwani, Director.

Quality control is equally integral to production. Every vial and ampoule passes through European-made most precised inspection systems equipped with high-resolution cameras that perform continuous, real-time cosmetic and dimensional inspection. Critical parameters including wall thickness, overall dimensions, mouth diameter, crimp diameter, and potential defects such as micro-cracks or airlines are automatically evaluated, ensuring only compliant products move forward.

The company's expertise also extends to precision-engineered One Point Cut (OPC) ampoules. Manufactured within tightly controlled tolerances, these systems enable clean and reliable opening while minimizing the possibility of glass particle generation during use.

Designed for Modern Therapeutics

Borosil Scientific manufactures an extensive portfolio of pharmaceutical ampoules and vials exclusively using Type I Neutral Borosilicate Glass in both clear and amber variants. Every product is designed to comply with internationally recognized pharmacopoeial standards including USP, EP, BP, and JP, supporting pharmaceutical companies operating across regulated global markets.

Its ampoule range spans from 1 ml to 50 ml and is available in multiple ISO and DIN configurations, along

with customized designs tailored to specific customer requirements. Additional options such as colour break rings, multi-colour identification bands, score lines, and One Point Cut systems provide greater flexibility for pharmaceutical manufacturers. For pH-sensitive formulations, ammonium sulphate treatment further enhances glass compatibility with sensitive drug products.

"The company's vial portfolio ranges from 1 ml to 100 ml and is engineered for liquid injectables, infusion products, and lyophilized formulations. Optional blowback profiles improve rubber stopper retention, helping maintain container closure integrity during high-speed filling operations. Every design reflects an understanding that pharmaceutical packaging must integrate seamlessly with increasingly sophisticated production environments rather than function as a standalone component", highlights Bhoomi Kotwani.

Quality Built Into the Process

Borosil Scientific's manufacturing philosophy extends beyond meeting specifications to embedding quality into every stage of production. Its cGMP-compliant manufacturing facility has been designed with unidirectional movement of personnel and materials to minimise contamination risks while maintaining efficient production flow.

BOROSIL SCIENTIFIC'S ROLE EXTENDS BEYOND SUPPLYING PHARMACEUTICAL CONTAINERS TO SUPPORT CUSTOMERS THROUGHOUT THEIR MANUFACTURING AND REGULATORY JOURNEY

Critical inspection, handling, testing, and packaging operations are carried out inside validated ISO Class 8 cleanrooms. These controlled environments are supported by advanced HVAC systems that regulate temperature, humidity, pressure differentials, and particulate levels, while periodic validation ensures continued compliance with ISO 14644-1 requirements.

The company's Quality Management System is certified to ISO 15378, reflecting its alignment with pharmaceutical packaging requirements. Stringent Acceptable Quality Levels are maintained for cosmetic and functional defects, with inspection criteria aligned to internationally accepted PDA defect classification guidelines. Supporting this framework is a comprehensive laboratory equipped to perform physical and chemical evaluations, including hydrolytic resistance, glass surface testing, glass etching studies as per USP <660>, composition analysis, and break-force testing.

Every manufacturing batch is supported by complete traceability through Batch Manufacturing Records, while structured Change Control, Failure Mode and Effects Analysis (FMEA), deviation management, and Corrective and Preventive Action (CAPA) systems reinforce a culture of continuous quality improvement.

Beyond Manufacturing

Borosil Scientific's role extends beyond supplying pharmaceutical containers to support customers throughout their manufacturing and regulatory journey. To maintain the effectiveness of automated inspection systems, quality teams conduct routine challenge testing using calibrated defect masters, validating inspection performance across every production shift.

Its regulatory capabilities further strengthen this partnership. Drug Master Files are registered with the US FDA, Health Canada, and China's National Medical Products Administration, while Letters of Access are provided to support customers' regulatory submissions. Comprehensive technical documentation, including extractables and delamination studies, validation protocols, and technical data packages, enables pharmaceutical companies to accelerate product registrations while meeting evolving global compliance requirements. Through advanced manufacturing, rigorous quality systems, regulatory expertise, and engineering-led precision, Borosil Scientific continues to strengthen its position as a trusted manufacturer of pharmaceutical primary packaging that enables safe, reliable, and efficient drug delivery across global healthcare markets. PO

ANALYSIS

INDIAN CDMO 2.0 GUIDE: RISK-SHARING AND HYBRID MODELS

The pharmaceutical outsourcing landscape is undergoing its most consequential structural transformation in decades, and Indian CDMO players are leading the charge.

As global drug innovators race to compress timelines and de-risk capital-intensive pipelines, the Indian CDMO 2.0 framework has emerged as the industry's answer: a new generation of contractual architectures built on aligned incentives, shared financial exposure, and the hybrid model that blends traditional manufacturing muscle with agile, innovation-grade capabilities.

This is no longer a market defined by cost arbitrage alone. Indian CDMO represents a fundamental re-engineering of how risk, reward, and responsibility are distributed between pharma innovators and their manufacturing partners.

According to Expert Market Research, the Indian contract development and manufacturing organization (CDMO) market was valued at USD 25.51 billion in 2025 and is projected to reach USD 71.14 billion by 2035, growing at a CAGR of 10.80 percent. A 2025 Boston Consulting Group report further underscored the momentum: some India CDMO players witnessed a 50 percent year-on-year surge in requests for proposals in 2024 alone, driven by global pharma companies aggressively diversifying away from single-source dependencies. The era of passive service has ended. Indian CDMO and the hybrid model are now the architecture of choice for sophisticated pharma-CDMO partnerships.

SHIFTING FROM PAY-FOR-EFFORT TO PAY-FOR-PERFORMANCE

Traditional pharmaceutical manufacturing relied on rigid cost-plus or time-and-materials pricing—structures that insulated the service provider from clinical and commercial risk entirely. If a batch failed, if a regulatory submission stalled, or if yields fell below expectation, the client bore the financial fallout. The CDMO operated as a fee-collecting vendor, not a strategic partner.

The CDMO 2.0 era dismantles this asymmetry. The introduction of pay-for-performance (P4P) metrics forces service providers to have genuine skin in the game. Under this model, Indian contract development and manufacturing organizations share the financial rewards of successful drug development while absorbing a portion of the losses during clinical or manufacturing failures. This structural realignment makes CDMO incentives coextensive with client outcomes.

The shift is quantifiable. Industry analysis from Persistence Market Research projects the Indian CDMO market growing from USD 23.3 billion in 2026 to USD 55.5 billion by 2033 at a 13.2 percent CAGR. Much of this premium valuation is attributed to new contract structures that embed performance accountability directly into pricing architecture and not just low-cost manufacturing.

Rajendra Kumar Sahu (CEO) & Jordi Robinson (CCO), Navin Molecular said, "India remains economically advantageous in comparison with its competitors ... The bigger and more established Indian CDMOs have made huge advances and investments over the past decades, and their facilities would rival the infrastructure and quality seen in the west. As well as excellent facilities, India boasts a large, educated workforce."

MILESTONE-BASED PAYMENT STRUCTURES

To ease the capital burden on emerging biotech and pharma innovators, modern contract development and manufacturing organizations accept lower upfront development fees. In exchange, contracts embed back-ended, high-yield payouts tied directly to specific milestones:

- **Regulatory Approvals:** Success fees triggered upon IND, NDA, or EMA product clearances. A typical structure might front-load only 40–50 percent of the contracted development fee, with the balance released upon successful regulatory submission. For EMA-targeted programs, these success gates are particularly high-yield given the complexity of European dossier requirements.
- **Commercial Launches:** Escalating bonus tiers tied to first-commercial-batch readiness. CDMOs that demonstrate the ability to transition from Phase III supply to commercial-scale manufacturing without production interruption unlock premium payout structures.

- **Technological Feats:** Bonuses unlocked when matching specific yield targets, stability profiles, or API purity thresholds. For complex biologics programs, hitting a bioreactor titer milestone can trigger a carried interest-style payout that retroactively rewards the CDMO's early-stage investment in process optimization.

"The old transactional model commoditized Indian manufacturing talent. What we are building now is an ecosystem where our scientific depth is priced into the outcome, not just the invoice." — Dr. Satyanarayana Chava, CEO, Laurus Labs.

THE FINANCIAL LOGIC OF PAY-FOR-PERFORMANCE

Pay-for-performance structures do more than redistribute risk—they fundamentally reframe how return on invested capital (ROIC) is calculated for CDMO operators. Under traditional models, ROIC is a straightforward function of asset utilization and margin on services rendered. Under P4P, the CDMO's ROIC incorporates a deferred revenue component: the probability-weighted value of milestone payments tied to drug development outcomes. RiskManagement

This has meaningful implications for total shareholder return (TSR) among publicly listed Indian CDMOs. Laurus Labs, for instance, reported a 33 percent year-on-year revenue increase to INR 3,223 crore in H1 FY26, driven in part by multiple late-phase and commercial-scale deliveries—milestone events that triggered back-ended payment realizations. The stock rallied 82 percent in calendar year 2025, illustrating how the market prices milestone-rich revenue pipelines at significant premiums over pure-service revenue.

Carried interest mechanics (borrowed conceptually from private equity) are beginning to appear in certain long-duration CDMO partnerships. In these structures, the CDMO receives a profit participation in the commercial revenues of drugs it helped develop, in exchange for accepting below-market development fees during the pre-commercial phase. While still nascent in the Indian context, early adopters in the biologics space are deploying this model selectively for oncology and rare disease programs.

CAPITAL OPTIMIZATION STRATEGIES: SHARED INVESTMENT & KPI-LINKED COMPENSATION

Building dedicated biological or small-molecule infra-structure requires immense upfront capital expenditure. A single GMP-compliant bioreactor suite can cost upwards of INR 150–250 crore to establish. Under legacy CDMO models, this burden fell entirely on the service provider, who then sought to recoup it through pricing premiums—a mechanism that created structural tension between cost competitiveness and infrastructure adequacy.

The Indian CDMO 2.0 framework resolves this bottleneck through Co-Investment Models that replace CapEx concentration with shared ownership of strategic infrastructure assets.

THE CO-INVESTMENT FRAMEWORK

Under co-investment arrangements, pharma clients directly fund specialized infrastructure—advanced bioreactors, fill-finish lines, continuous flow chemistry setups, or high-potency API (HPAPI) containment suites—within the CDMO's facility. This capital injection delivers three discrete advantages:

- **Dedicated Capacity:** Guaranteed cleanroom access and equipment priority, effectively insulating the client from market capacity crunches—particularly relevant in post-BIOSECURE Act reorientation, where demand for Indian CDMO capacity has surged dramatically.
- **Preferred Pricing:** Substantially lower per-unit commercial manufacturing costs over time, as the CDMO's margin requirement decreases once CapEx has been client-funded.
- **Production Credits:** Amortization of the initial capital investment returned as billing discounts on future production batches, improving the client's return on invested capital over the duration of the partnership.

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● VIVID OUTLOOK ●

TRANSFORMING API & PHARMA MANUFACTURING WITH NEXT-GEN EHS TECHNOLOGIES

Dr Kuber Jagdale, *President - API Business Unit, Emcure Pharmaceutical Business Formation*

Dr. Kuber Jagdale, a seasoned business transformation leader, brings 35+ years of experience driving organizational performance, with expertise in API and Pharma manufacturing, operational excellence, EHS, cGMP, supply chain management, strategic planning, and business development.

In an interview with Thiruamuthan, Assistant Editor at India Pharma Outlook, Dr Kuber Jagdale, President - API Business Unit, Emcure Pharmaceuticals Limited, discusses how Indian API and pharma are shifting to data-driven, proactive EHS strategies using AI, IoT, and automation to improve compliance, safety, and operational efficiency. He also highlights key challenges and innovations shaping future-ready and sustainable EHS practices.

Dr Kuber Jagdale,
President - API Business Unit

AS INDIA'S PHARMA INDUSTRY FACES EVOLVING REGULATIONS, HOW ARE MANUFACTURERS USING NEXT-GEN EHS TECHNOLOGIES TO IMPROVE COMPLIANCE, REDUCE RISKS, AND ENHANCE OPERATIONAL EFFICIENCY IN PRODUCTION?

The Indian pharma industry today is heading in a direction from a reactive to a proactive mode and trying to implement the data-driven approach, address the EHS-related compliance requirements. Besides this, this journey has been already started by many top companies. The Ministry of Corporate Affairs requires that some of this information should be published in their annual reports.

As this journey has started, most of the top companies have already progressed well in automating these requirements through SAP-EHS module, which captures all the data and provides a dashboard and gives timely alerts for monitoring, etc. There are some other compliance tools available to meet EHS compliance requirements, which are also being used by some companies.

HOW NEXT-GEN EHS TECHNOLOGIES ARE HELPING INDIAN PHARMACEUTICAL MANUFACTURERS REDUCE THEIR ENVIRONMENTAL IMPACT WHILE MAINTAINING HIGH PRODUCTION QUALITY AND ENSURING COMPLIANCE WITH SUSTAINABILITY AND SAFETY STANDARDS?

The next-gen technologies are helping very well, and the reason is because now companies have started adopting and monitoring them. Unless measurements and monitoring are in place, improvements cannot be effectively pursued further. When companies adopt these systems, all the data required for environment related EHS compliance gets monitored. This in turn encourages stakeholders to focus on reducing impacts in areas such as carbon neutrality, waste management, energy and water conservation, waste generation etc. Once monitoring is in place, organizations start identifying ways to reduce these metrics further. Many companies have started setting annual targets, typically around 2 to 5 percent reduction.

HOW ARE AI AND IOT TECHNOLOGIES TRANSFORMING RISK ASSESSMENT PROCESSES IN INDIAN PHARMACEUTICAL PLANTS, PARTICULARLY IN PREDICTIVE ANALYTICS AND REAL-TIME MONITORING OF HEALTH AND SAFETY PROTOCOLS?

For companies to use AI- or IoT-based tools, what is important is having data in data lake for whatever they are doing; otherwise, AI is not going to help if there is no basic data in place.

So, what companies are trying to do first is create a data management system to capture live data from production, quality control, engineering, etc. There are various systems being installed to capture this data. Once that is done as a basic requirement, AI- or IoT-based tools can be installed so that they can further analyze the data, provide analytics, and create

dashboards for management to take decisions. The use of AI or IoT has started, but it is still at an early stage of implementation, as companies first must address data management systems and establish data lakes before adopting AI- or IoT-based solutions.

IN WHAT WAYS IS INTEGRATING REAL-TIME DATA AND AI-DRIVEN ANALYTICS INTO EHS SYSTEMS HELPING INDIAN PHARMA MANUFACTURERS REDUCE RISKS WHILE IMPROVING COMPLIANCE, EFFICIENCY, AND OPERATIONAL WORKFLOWS?

Currently, in most companies, especially the top companies have already installed automation systems for production, quality control, and engineering. For production, there is an MES system for quality control, there is a LIMS system; and for warehouse and material management, there is an SAP/ bar code system. All these systems are already being used by many pharma companies and are at a fairly mature stage.

Now, the focus is on how to make use of these systems when all the data is available at common place. Companies have started building analytics to create dashboards. Once all the systems are integrated into a single platform, AI tools can be introduced to generate predictive insights, which can help organizations improve their overall EHS compliance.

WHAT CHALLENGES ARE INDIAN PHARMACEUTICAL MANUFACTURERS FACING IN ADOPTING NEXT-GEN EHS TECHNOLOGIES, SUCH AS COST, INFRASTRUCTURE, AND SKILLS GAPS, AND HOW ARE THEY OVERCOMING THESE OBSTACLES?

There are certain challenges companies face in integrating these technologies. To clearly further, one is adaptability. Implementing such systems in existing operational plants takes time because it requires several modifications to the plant and systems. It can be implemented immediately on day one if a new plant is being designed or constructed.

The second challenge is timelines. Due to the above complexities, the timelines tend to be longer. Timelines also depend on the ability of companies to invest, as implementing this technology in existing plants requires additional capex. Another challenge is the need for skilled personnel. Implementing automation, analytics, or AI-based systems requires people who understand these technologies and have the necessary education and skills.

These are the key challenges most organizations are facing, and it is a matter of time as most companies are moving in this direction for future EHS compliance.

> **Integrated systems like MES, LIMS, and SAP are enabling pharma firms to centralize data, paving the way for advanced analytics and predictive EHS insights**

LOOKING AHEAD, HOW DO YOU SEE AI AND MACHINE LEARNING SHAPING FUTURE EHS COMPLIANCE STRATEGIES AND SAFETY STANDARDS IN INDIA'S PHARMACEUTICAL MANUFACTURING SECTOR, ESPECIALLY WITH REGULATORY CHANGES?

When companies move from a reactive to a proactive mode, it is going to improve overall EHS standards as well as compliance and regulatory requirements. To achieve this, they need to first create a data management system and a data lake, and then implement AI and data analytics, which will provide dashboards at various levels as required.

Some next-generation technologies are also being adopted; smart EHS wearables are now available that can capture live data on the shop floor, send it to a data lake, and provide predictive insights. Additionally, remote drones are being used for large or high-rise buildings to capture data. Such technologies are becoming more common, and new innovations continue to evolve as this journey progresses. PO

AFTERWORD

BRIDGING COLLABORATION GAPS TO BOOST INDIA'S PHARMA DISCOVERY

Dr Sadhna Joglekar, *Senior VP & Head - Global Drug Development India, Novartis*

Dr. Sadhna Joglekar, Senior VP & Head of Global Drug Development India at Novartis, with over 25 years of experience in pharma and biotech, emphasizes that India's R&D ecosystem must strengthen early-phase trials, foster academia startup pharma collaboration, and ensure sustained funding to fully realize its biotech innovation potential, as highlighted at Scale-Up Health 2025, organized by Eight Roads Ventures.

India's biotech and pharmaceutical R&D journey began much earlier than many believe, with its foundations laid in the 1990s and early 2000s. Indian companies, inspired by global multinationals such as Pfizer, Merck, and Novartis, invested heavily in infrastructure and talent. However, three critical differences stood out compared to today: the startup ecosystem was almost non-existent, the CDMO space was immature, and innovation was largely adapted from the West.

CLINICAL DEVELOPMENT VS. DISCOVERY

India's R&D can broadly be split into two tracks: clinical development and discovery. Clinical development, particularly late-phase studies, is relatively mature today. India has built strong capabilities with experienced investigators, trained regulators, and robust CRO support. Yet, the early phase first-in-human and proof-of-concept trials remain a weak spot. On this note, training can be given to the people, but without experiential learning, maturity never develops. There is a need for more Phase 1 centers and mentorship from experienced clinicians.

On the discovery front, the story is different. Startups are emerging in areas like immunology, oncology, dermatology, diabetes, and antimicrobials. But academia remains the weak link. Outside a few pockets like IISc, IITs, and BITS, most universities lack incentives for translational research. Scientists don't always understand drug development, and clinicians don't always engage with basic science. That gap means we rarely see spin-offs from universities.

WHY ACADEMIA STARTUP PHARMA COLLABORATION MATTERS

Globally, academia plays a pivotal role in translational research, often leading to startup spin-offs. In India, this connection is largely missing. A scientist is rewarded for publishing papers, not for building a therapy. Notably, C-CAMP and select incubators at IISc and IITs but highlights the lack of scale. For India's discovery ecosystem to mature, she believes there must be a strong feeder system where academia seeds ideas, startups build prototypes, and pharma scales them.

> **We need policies that give confidence to investors and founders that they won't be left stranded mid-journey**

Pharma companies have evolved from building everything in-house to tapping into CDMOs and external advisors, while regulators have become more supportive through initiatives like DBT and BIRAC funding programs. But compared to countries like China, the scale is still modest.

THE BIG IDEA FOR INDIA'S INNOVATION ECOSYSTEM

Looking ahead, one critical enabler is deep funding pools. Without sustained capital, early ideas struggle to survive. Collaboration between the government, private investors, and global venture capital is essential to commit to Indian biotech in a long-term, systematic manner.

For India to unlock its biotech decade, academia, start-ups, and pharma must work in close synergy. Without this collaboration, India's discovery ecosystem risks remaining fragmented and unable to reach its full potential. PO

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