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DAY 1

News AT A GLANCE



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CPHI & PMEC India 2025 kicks off, spotlighting pharma innovation and global collaboration

OUR BUREAU, MUMBAI

THE 18th edition of CPHI & PMEC India 2025, South Asia's largest pharmaceutical industry event got underway at the India Expo Mart, Greater Noida.

Branded as the "Heart of Pharma", the expo is being hosted by Informa Markets in India from November 25-27. The three-day expo is set to unite over 2,000 exhibitors and 50,000+ professionals

from 120+ countries, covering the entire pharmaceutical value chain—from APIs and formulations to packaging, machinery, and contract services.

Yogesh Mudras, Managing Director, Informa Markets in India, highlighted the sector's global stature in affordable generics and vaccines, contributing 1.72% to India's GDP. He noted the Union Budget 2025–26's Rs 5,268 crore allocation to the Department of Pharmaceuticals, a 29% rise, reinforcing India's ambition

to become a hub for pharma innovation.

With India's pharma market projected to reach USD 130 billion by 2030 and USD 450 billion by 2047, the 2025 edition will emphasize API self-reliance, sustainability, digitalization, and exports. Cutting-edge solutions in clean manufacturing, ESG compliance, and Pharma 4.0 will be showcased, alongside marquee events such as the Pharma Leaders Roundtable, Women in Pharma Roundtable, CPHI Pharma Awards, and Pharma Connect Congress.

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Redefining pharma: Innovation & manufacturing for next generation of affordable medicines



DR SANJAY AGRAWAL

In the realm of pharmaceuticals, where hope, health and heavy-duty regulatory complexity converge, we're witnessing one of the most profound yet quiet revolutions in modern medicine: redefining innovation and manufacturing to make next-generation medicines accessible and affordable. This transformation is more than a shift in process; it's a redefinition of how modern medicine is conceived, produced, and delivered.

Why is the shift urgent?

For decades, the pharmaceutical industry was built on a tried-and-true model: discover a novel compound, prove it in trials, scale bulk production, then distribute globally. That served us well but it's facing headwinds:

- Costs are skyrocketing. The average cost to bring a new drug to market often exceeds US\$2 billion.
- Access remains uneven. Too many regions, too many patients, especially in lower- and middle-income countries (LMICs) still can't afford vital treatments.
- Manufacturing and supply-chain fragility, characterized by reliance on specific geographic regions for Active Pharmaceutical Ingredients (APIs), raw materials, and finished goods, has created significant vulnerabilities.
- Patients' needs are evolving, including personalized therapies, rare disease

treatments, biosimilars, and value-based care, all of which ne-

cessitate new models.

Hence: we cannot just "discover

the next medicine" and manufac-

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ture it like we always have. We must rethink every link from lab bench to patient hand to deliver next-gen medicines affordably.

Innovation: From Generics & Volume to Value & Technology

Historically, many markets (India being a prominent example) achieved access primarily through generics and high-volume manufacturing. For instance, the Indian pharma industry is known for delivering affordable, quality generics worldwide. At the same time, policy initiatives are pushing the shift from generics toward R&D-driven innovation. For example, the PRIP (Promotion of Research and Innovation in Pharma & MedTech) scheme in India supports new chemical/biological entities, biosimilars, orphan drugs, etc.

Shifts at the Innovation Frontier

- AI, digital twins & advanced analytics are speeding drug discovery, optimizing formulations, and reducing early-phase cost/time burdens.
- Additive manufacturing / 3D printing and flexible manufacturing platforms are enabling personalized dosage forms and more agile production.
- Continuous biomanufacturing for biologics/complex therapies is entering mainstream, lowering cost and improving yield.

So, the story is no longer simply "make more of the same cheaper" but "make something more advanced, tailored, and cost-efficient".

Manufacturing: Innovation Meets Affordability

Manufacturing in pharma was once predominantly batch, centralized, and heavy capital-intensive. But the next wave is different:

- The Medicines Manufacturing Innovation Centre (UK) is a prime example: a collaboration between industry/academia/regulators to test and scale disruptive manufacturing technologies and make the supply chain more agile.
- Sustainability (waste reduction, energy efficiency) is now baked into manufacturing strategy. For instance, the UK's Sustainable Medicines Manufacturing Innovation Programme (SMMIP) is funding projects to reduce emis-

sions and waste in pharma production.

- Modular, flexible manufacturing systems (think mini-plants, on-demand production) are reducing the fixed-cost burden and enabling localisation closer to patients. Markets like India are especially poised to benefit from this transformation.
 - Digital tools - sensors, IoT, predictive maintenance, real-time release testing are boosting yield, reducing defects, and ultimately lowering cost of goods.
- The upshot: manufacturing becomes not just a scale-game but a smart game. Less waste. More agility. Lower cost. Improved access.

Affordability: Making Next-Gen Accessible

There's no point innovating if only a few can afford it. Affordability is the co-star in this story.

Here are the levers that are enabling next-gen medicines to be more affordable:

- **Biosimilars and complex generics:** By replicating high-value biologics at lower cost, many markets are bridging access gaps. In India, pharma firms have focused on biosimilars and generics to compress cost.
- **Local production of key inputs (APIs, intermediates):** Reducing import dependence, supply-chain risk, and cost-mark-ups.
- **Policy support:** As mentioned, schemes like PRIP (India) or SMMIP (UK) support innovation and manufacturing that deliver value, not just volume.
- **Designing for value from day-one:** When R&D and manufacturing design consider cost of goods, scalability and global access early on, the resulting medicine is more likely to reach broader populations.
- **Transparency and pricing models:** The industry is being nudged (and in some cases required) to align innovation with access. For instance, the report "From innovation to access" outlines how breakthrough medicines must still link to global health access.

The mantra becomes: innovate smart, manufacture lean, price responsibly.

Challenges & How We Must Respond

Of course, it's not all sunshine and generics. Some real-deal obstacles remain:

- **Regulatory complexity:** New manufacturing paradigms (continuous, modular, personalised) demand regulatory frameworks to evolve.
- **Up-front capital/investment risk:** Smart manufacturing systems are expensive initially; pay-off is longer-term.
- **Talent & culture:** The workforce must shift from traditional batch-production mindsets to digital, data-driven, agile thinking.

- **Supply-chain dependencies:** Raw materials sourcing, geopolitics, trade tensions still loom large.
- **Access vs innovation tension:** Incentivising blockbuster therapies while ensuring affordability and global access is a fine balance.

What can be essential responses are:

- **Collaborate across sectors:** Industry-academia-government must sync. New medicines need new manufacturing, and that demands partnerships.
- **Adopt a systems view:** Innovation is not just a new molecule, it's a new process, new facility, new economics.
- **Brand the mission of access:** The pharma story must evolve from "me-too drug" to "affordable,

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next-gen therapy for all. That resonates.

- **Embed affordability early:** From the first sketch in R&D to the final packaging, affordability must be a design parameter.
- **Connect with purpose:** You value traditions and the way things have always been done, but with forward vision. This journey mirrors that: honour the tried path of pharma-manufacturing, but infuse new tools, new values.

Real-world glimpses & future horizon

To make this concrete:

- In India, the pharma sector is evolving from being a generics-volume player to an innovation-driven hub, focusing on biosimilars, new chemical entities (NCEs), etc.
- In the UK, the Medicines Manufacturing Innovation Centre is actively enabling industry to adopt disruptive manufacturing processes in a GMP environment.
- Across the globe, AI-enabled manufacturing, digital twins and modular production are already tipping the cost curves.

If we zoom out: the future will see decentralised manufacturing hubs, personalised medicines, manufacturing lines that auto-optimize, and cost structures that permit access everywhere.

The takeaway

We're standing at a crossroads: on one side lies the old model, high cost, slow time-to-market, access limited to those who can pay. On the other side lies the new era, smart innovation, agile manufacturing, global affordability. It's not enough to declare that we'll change; we must redesign the entire chain: discovery, manufacturing, access.

So let me leave you with this poetic line: the medicines of tomorrow won't just be "new", they'll be right-for-all, designed with

heart, manufactured with efficiency, delivered with dignity. And you? You'll be part of the story that ensures they reach be-

yond the privileged few.

Let's reimagine medicine together: where innovation is not just breakthrough, but break-

through barriers to access.

(The author is a leading pharmaceutical consultant and inventor)



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