India’s Pharma Regulator Is Evolving from CAR-T Approvals to Cloud-Linked Labs: CDSCO

From CAR-T cell therapies to AI-led evaluations and cloud-linked labs, CDSCO outlines its tech-driven vision to power India’s transition from generic hub to innovation leader.

New Delhi:India’s pharmaceutical sector is undergoing a landmark transformation, shifting from its traditional image as a generics powerhouse to a globally competitive hub for new drug development and advanced therapies.

At the forefront of this evolution stands the Central Drugs Standard Control Organization (CDSCO), which is embracing cutting-edge technologies, regulatory harmonization, and data digitization to fuel innovation and patient safety, informed Dr. Annam Visala, Joint Drugs Controller (India), Central Drugs Standard Control Organisation.

Speaking at the second edition of ETPharma's PharmaTech Conclave on *Revised Schedule M – Can Use of Technology Help Indian Pharma MSMEs Match Global Quality Benchmarks?*

Dr. Annam said, "The country has taken a significant leap in the drug approval ecosystem, and we have moved beyond just generic or NDA approvals." She cited the example of how India's indigenous CAR-T cell therapy was developed in collaboration with IIT Bombay—which was recently approved by CDSCO—marking a milestone in advanced biologics and precision medicine.

"CDSCO has approved not only complex biologics and cell and gene therapies, but also handheld devices and software as medical devices. This reflects the coming of age of India's pharma and tech sectors," she added.

The regulator currently houses dedicated divisions for Investigational New Drugs (IND), New Drug Applications (NDA), Fixed-Dose Combinations (FDC), and biologics, encompassing everything from vaccines to recombinant products and gene therapies. In parallel, its efforts toward improving ease of doing business are seeing tangible progress—driven by its fully digitised drug submission platform *Sugam*, with version 2.0 already in planning stages.

The CDSCO is also aiming for next-level digitization. Having reached 99 percent digital processes, the regulator now plans to incorporate AI and metadata analytics, drawing inspiration from the USFDA's AI-led platforms.

"AI is now being used globally to assess submissions, and India is not far behind. We aim to use data analytics to reduce human trials where possible and to improve patient safety through predictive insights," Dr. Annam said. Adding to it, she said the next goal is shifting to parallel application reviews across CMC, clinical, and preclinical modules—starting with cell and gene therapy applications.

Digitization is also reshaping clinical trial monitoring in India. Electronic case record forms (eCRFs), digital patient diaries, and simulation tools are being deployed to reduce reliance on animal studies. “We’re moving toward the 3Rs—Replace, Reduce, Refine. Alternatives like organ-on-a-chip, cell-based assays, and validated in vitro systems are being encouraged,” she added.

Moreover, CDSCO’s nationwide lab network—including those at airports and major pharma hubs—is being linked via cloud platforms to provide real-time quality testing and analytics. This is expected to significantly speed up customs clearance and ensure consistent product quality.

To streamline regulatory workflows, the CDSCO is working on a unified national portal that integrates state and central regulatory authorities. Platforms like ONDLS (Online National Drug Licensing System) now enable faster processing of applications for blood banks and large-volume parenterals.

In addition, India will soon adopt module-based submissions similar to the USFDA, enabling simultaneous review of chemistry, clinical, and preclinical data—dramatically shortening review timelines.

For small and medium enterprises (MSMEs), digitization is poised to be a game-changer. CDSCO encourages pharma manufacturers to adopt electronic batch records, integrate shop-floor data loggers, and track product trends to identify quality deviations early.

Meanwhile, AI is finding increasing use in R&D—from screening formulations and preclinical development to adverse event detection. "We must integrate omics data, bioinformatics, and patient outcomes to close the loop from research to real-world use," the official emphasized.

Since the inception of the Drugs & Cosmetics Act in the 1940s, India has made long strides in self-sufficiency. Today, its regulatory landscape—backed by digitization, technology, and a growing culture of innovation—is being reshaped to align with global benchmarks like the USFDA and EMA.

"This transformation is not overnight. It's the result of collaborative efforts by regulators, pharma, tech innovators, and the medical fraternity. With smarter systems, global alignment, and a data-driven approach, India's regulatory ecosystem is poised to support next-gen drug development," Dr. Annam concluded.

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