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CDSCO is piloting AI across regulatory processes to create data-driven regulatory system: DCGI

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Inaugural Global Drug Regulatory Conclave (GDRC) 2026, took place on 30 July in Delhi

The Global Drug Regulatory Conclave (GDRC) 2026, organised by Pharmexcil, focused on strengthening India's pharmaceutical regulatory ecosystem. India is building a future-ready drug regulatory framework to accelerate healthcare

innovation while maintaining the highest standards of patient safety, quality, and efficacy, Union Minister for Health and Family Welfare J.P. Nadda said in his virtual address at the inaugural Global Drug Regulatory Conclave (GDRC) 2026, on 30 July in Delhi.

Reinforcing this vision, Drugs Controller General of India (DCGI) Dr Rajeev Singh Raghuvanshi announced at the event that the Central Drugs Standard Control Organisation (CDSCO) will roll out the first phase of an end-to-end digital drug regulatory platform within the next 18 months, marking a significant step in modernising India's pharmaceutical regulatory ecosystem.

Highlighting the Government's ongoing regulatory reforms, Nadda said CDSCO is undergoing a comprehensive transformation driven by transparency, scientific rigour, efficiency, accountability, and digital governance. He added that digital regulatory platforms, risk-based oversight, strengthened inspection systems, and enhanced surveillance are creating a modern regulatory ecosystem that inspires greater global confidence. Calling for deeper international collaboration, he urged regulators to strengthen information sharing, regulatory science partnerships, collaborative inspections, and the convergence of scientific standards to improve global access to safe, effective, and affordable medicines.

In his opening remarks at the event, Dr Rajeev Singh Raghuvanshi outlined CDSCO's roadmap for regulatory transformation centered on digitalisation, innovation, quality assurance, and global regulatory convergence.

Dr Raghuvanshi said more than 99 percent of CDSCO's regulatory processes have already been digitised, significantly improving transparency and approval timelines. Building on this, CDSCO is piloting Artificial Intelligence (AI) across regulatory processes to create a faster, more agile, and data-driven regulatory system. He also announced that GMP and Certificate of Pharmaceutical Product (COPP) certificates will soon carry QR-code-based digital authentication, enabling overseas regulators to instantly verify their authenticity while reducing verification timelines.

Highlighting initiatives to strengthen quality and innovation, Dr Raghuvanshi said CDSCO has streamlined its export regulatory framework through a fully digitised export No Objection Certificate (NOC) system, introduced globally aligned regulatory reliance mechanisms, and accelerated approval pathways to enable faster patient access to innovative therapies. Around 25–30 percent of clinical trials are currently being considered for waiver for eligible innovative products. He further highlighted MedTech Mitra, which has already supported more than 800 startups in navigating regulatory pathways, and noted that similar facilitation mechanisms are planned for biologics and other emerging technologies.

Namit Joshi, Chairman, Pharmexcil, said, “India has earned its position as the pharmacy of the world, and the next step is to become a stronger regulatory partner. As global expectations on quality and compliance continue to evolve, GDRC will bring regulators and industry together to promote harmonised standards, clearer regulatory pathways, and faster access to quality, affordable medicines. It will also help translate policy into consistent compliance across the industry, strengthening confidence in Indian pharmaceuticals across global markets.”

The Global Drug Regulatory Conclave 2026, organised by the CDSCO in association with Pharmexcil, brought together global drug regulatory authorities, policymakers, researchers, industry leaders, and international organisations to deliberate on the future of pharmaceutical regulation.