DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology
Government of India

बाइरैक
बायोटेक्नोलॉजी इंडस्ट्री रिसर्च असिस्टेंस काउंसिल
birac
Ignite Innovate Incubate

CDSCO
Central Drugs Standard Control Organization
Ministry of Health, Government of India

World Health Organization
India

LSSSDC

cliniminds
Institute of Health Sciences Training & Management
AN ISO 9001:2015 Certified Academy

National Regulatory Professionals Development Program 2026

10th - 14th March, 2026 | IIT Delhi

Building India's Future-Ready Regulatory Workforce

A National Capacity-Building Initiative for Biopharma & Medical Devices

Register

Building India's Future-Ready Regulatory Leaders in Biopharma and Medical Devices

India's life sciences ecosystem is undergoing a rapid transformation driven by innovation, global regulatory convergence, advanced therapies, and medical devices. This **National Regulatory Professionals Development Program** is a first-of-its-kind, industry-led masterclass series designed to strengthen regulatory, quality, and safety capabilities across the product lifecycle. This initiative directly supports India's vision of regulatory excellence, global competitiveness, and skilled workforce development in biopharma and medical device, two of the country's fastest-growing strategic sectors.

The program integrates policy, practice, and real-world execution, delivered by current & former regulators, senior industry leaders, and global compliance experts. All participants will receive a national certificate of participation recognizing advanced regulatory capability development.

Program Structure

A 5-day national program, delivered through two focused masterclasses:

Masterclass 1

Biopharma Regulatory Excellence (2 Days)

- Indian and global biopharma regulatory landscape
- Drug development pathway and CTD/eCTD dossiers
- Regulatory strategy, intelligence, and change management
- Pharmacovigilance principles and safety regulations
- Pharmaceutical QMS, GMP, GLP, and GCP essentials
- Data integrity, ALCOA+, GDP, and documentation practices

Masterclass 2

Medical Devices Regulatory & Quality Systems (2 Days)

- Indian medical device regulatory framework
- Quality systems framework, ISO 13485
- Technical documentation & Materiovigilance
- Risk management principles and ISO 14971
- General safety and performance requirements
- Clinical evidence, ISO 14155-aligned clinical investigations

👉 **Both programs includes one day industrial visit**

👉 **Participants may enroll in one masterclass or attend the complete program**

Who Should Attend ?

Ideal for start-up founders, regulatory, quality, clinical, and medical affairs professionals across biopharma and medical devices. Also suited to industry leaders, scientists, managers, policy-facing professionals, and academicians engaged in healthcare innovation.

Faculty & Leadership

Program led by current and former CDSCO leaders, senior industry regulatory heads, and global GxP, PV, and medical device experts with hands on experience across Indian, FDA, EMA and MHRA regulatory framework.

Limited seats | National - level participation | High - impact learning

Registrations Open

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