

CDSCO becomes Affiliate Member of International Medical Device Regulators Forum

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IMDRF membership will strengthen CDSCO's medical device regulatory system



To achieve global alignment in its medical device regulatory system, enhance the competitiveness of the domestic industry, and boost transnational prominence, the Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, applied for Affiliate Membership in the International Medical Device Regulators Forum (IMDRF) in 2024.

After review of India's application for Affiliate membership and meeting discussions by the IMDRF Management Committee (MC) with the senior officers of CDSCO during the 26th Session of IMDRF held in September 2024 at Seattle, Washington, USA, the CDSCO has received approval from IMDRF as an Affiliate Member of the Forum.

The International Medical Device Regulators Forum (IMDRF), established in 2011, is a collaborative group of global medical device regulators dedicated to accelerating the harmonization and convergence of international medical device regulations. IMDRF members include national regulatory authorities from the United States, Australia, Canada, the European Union, Japan, the United Kingdom, Brazil, Russia, China, South Korea, Singapore, and the World Health Organization (WHO). Achieving Affiliate Membership in the IMDRF will provide significant opportunities for reliance and collaboration with regulatory authorities around the world.

The membership helps to harmonise regulatory requirements across the globe, which reduces the complexity for manufacturers and helps in safeguarding public health by promoting collaboration, harmonizing regulations, and promoting convergence. It also helps to support innovation and timely access to new medical devices.

As an affiliate member, India will participate in IMDRF Open Sessions to have information exchange on technical topics with other regulators, discussion on latest medical device regulatory strategies and trends, provide feedback on India's experience and perspectives, use IMDRF documents in part or in whole as the basis for India's regulatory framework for Medical Devices. This will strengthen the CDSCO's medical device regulatory system, helping meet emerging technical challenges that are increasingly diverse, to ensure protection of public health and safety, and continue to maintain the goal of

international recognition for its Medical Device regulation.

This membership will enable Indian medical device manufacturers to meet the regulatory requirements of IMDRF member countries, thereby strengthening the "Brand India" in the global market.