

— REGUVEDA —

YOUR MONTHLY REGULATORY UPDATE

We provide turnkey services spanning from product design and development, manufacturing unit design up to achieving the regulatory approvals of national as well as international level.

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LATEST NEWS & UPDATES



India Waives Local Trials:
Exemption for
Investigational Medical
Devices with EU Clearance

FDA Medical Device User Fee: MDUFA
Rates for FY 2027 Announced

NEW

Upcoming Events this Month

- Medical Fair India – Mumbai 17-19 Sept 2026
- Medical Expo New Delhi 02-04 Oct 2026

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India Waives Local Trials for Investigational Devices with EU Clearance

India has expanded its clinical investigation exemption framework under the Medical Devices Rules, 2017, by recognizing approvals from the European Union alongside other trusted regulatory jurisdictions. Eligible devices must have been legally marketed in the recognized jurisdiction for at least two years and provide satisfactory safety, performance, and post-market surveillance data. The amendment could reduce the need for duplicate local clinical investigations and help EU-approved medical devices enter the Indian market more efficiently.



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FDA Medical Device User Fee: MDUFA Rates for FY 2027 Announced

The U.S. FDA has announced revised medical device user fees for Fiscal Year 2027 under the Medical Device User Fee Amendments (MDUFA V). The new rates will apply from October 1, 2026, through September 30, 2027, covering submissions such as 510(k)s, De Novo requests, PMAs, supplements, and annual establishment registrations. Small businesses that qualify under FDA requirements can benefit from substantially reduced fees, helping eligible manufacturers manage regulatory costs more effectively.



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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Medical Device Licensing Timelines in India Set to Shorten Under Proposed MDR 2026 Amendments

India has proposed amendments to the Medical Devices Rules, 2017, aimed at reducing manufacturing license approval timelines for medical devices. The proposed changes could reduce the timeline for Class B devices from 140 to 115 days and Class C and D devices from 105 to 90 days. The amendments also introduce defined review stages and a deficiency clock, providing greater transparency and predictability for manufacturers seeking CDSCO approvals while maintaining quality and regulatory oversight. These reforms are expected to support faster market entry and improve regulatory efficiency for domestic and international manufacturers. Manufacturers should begin preparing their QMS, technical documentation, and compliance requirements to benefit from the streamlined approval process once implemented.

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CDSCO Sanctions 1,500 New Posts and Announces Regulatory Reforms

The Indian government has sanctioned 1,500 new positions within CDSCO to strengthen scientific and technical capabilities in medical device regulation. The expansion includes specialists in engineering, software, AI, and medical devices, alongside a dedicated medical devices regulatory vertical. CDSCO is also advancing reforms such as EU recognition for clinical waivers, a proposed T-Licence exemption for R&D activities, and a structured framework for medical device software, supporting faster and more science-driven regulatory decision-making.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Panel Recommends Decentralisation of Medical Device Licensing to SLAs

A Parliamentary Standing Committee has recommended decentralising the licensing of Class A and Class B medical devices to State Licensing Authorities to strengthen India's regulatory and manufacturing ecosystem. The proposal aims to give states greater autonomy while relying on quality assessments from approved testing laboratories. The Committee also highlighted the need for stronger testing infrastructure, enforcement of licensed procurement requirements, and better regulatory oversight to support safe, compliant, and accessible medical devices across India.

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Medical Device Detailed Project Report: Step-By-Step Guide

A Detailed Project Report (DPR) provides a comprehensive roadmap for planning and establishing a medical device manufacturing project. It covers product definition, regulatory classification, market feasibility, site selection, manufacturing technology, facility layout, regulatory requirements, financial projections, risk assessment, and implementation timelines. The blog explains nine key steps for preparing a DPR and highlights how Operon Strategist can support manufacturers with feasibility studies, facility planning, regulatory strategy, financial modeling, and turnkey project execution.



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ISO 15378 Certification for Medical Device Packaging: 7 Key Steps



ISO 15378 certification provides a quality management framework for organizations manufacturing primary packaging materials for medicinal products, incorporating GMP principles into their quality systems. The blog explains seven major steps, including defining certification scope, conducting a gap assessment, establishing a QMS, implementing GMP controls, developing risk and traceability systems, conducting internal audits, and completing the certification audit. It also explains how ISO 15378 differs from ISO 13485 and ISO 11607 for medical device packaging applications.

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ISO 14155:2026 Explained: GCP Requirements for Medical Device Clinical Investigations

ISO 14155:2026 establishes an international Good Clinical Practice framework for medical device clinical investigations involving human participants. The standard focuses on participant safety, scientific validity, data integrity, risk-based trial management, and clearly defined responsibilities for sponsors, investigators, CROs, ethics committees, and regulatory authorities. The blog explains key documentation, including Clinical Investigation Plans, Investigator's Brochures, informed consent records, monitoring reports, safety reports, and final clinical investigation reports, while highlighting the standard's relevance to global regulatory submissions.



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SFDA Medical Device Establishment License (MDEL): Complete Compliance Guide

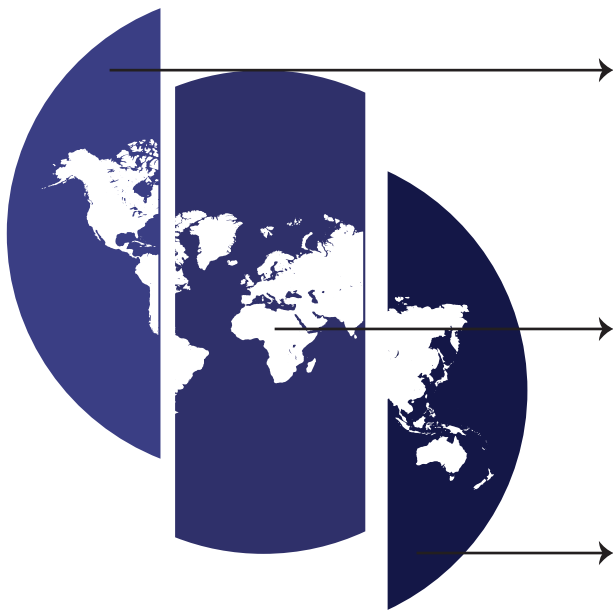
The SFDA Medical Device Establishment License (MDEL) is a mandatory establishment-level license for organizations involved in medical device activities in Saudi Arabia. The blog explains the difference between MDEL and Medical Device Marketing Authorization (MDMA), along with requirements for manufacturers, authorized representatives, importers, distributors, and warehouses. It covers commercial registration, GHAD registration, QMS requirements, traceability, technical personnel, storage controls, fees, validity periods, and post-approval compliance, helping businesses understand the steps needed for legal operation in the Saudi medical device market.

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OUR SERVICES



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 - Clean Room Guidance
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- **Regulatory Approvals:**
 - FDA 510(K)
 - CDSCO Registration
 - CE Marking
 - UKCA
 - SFDA
- **Medical Device Design Development Documentation:**
 - Drug Device Combination Product
 - USFDA 21 CFR 820.30 Design Control Requirements

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For more details regarding licence process and regulatory services .

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