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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.

OPERON STRATEGIST

LATEST NEWS & UPDATES

Government Launches Incentive Scheme for Medical Device Manufacturers

NEW

Upcoming Events this Month

• Medicall Expo Chennai

Know More

TO KNOW MORE

CDSCO Manufacturing License for Medical Devices in India: Registration, SUGAM Portal, Documents, Process & Compliance Guide (2026)

Obtaining a CDSCO Manufacturing License is a mandatory requirement for manufacturing regulated medical devices in India under the Medical Devices Rules (MDR), 2017. The licensing process involves device classification, facility compliance, technical documentation, quality management system implementation, and approval through the CDSCO SUGAM Portal. Manufacturers must prepare documents such as the Device Master File (DMF) and Site Master File (SMF) while ensuring compliance with ISO 13485 and CDSCO requirements. Proper planning helps avoid regulatory delays and supports faster approvals.

READ MORE

How to Get an Import License for Medical Devices in India: A Complete Step-by-Step Guide

Importing medical devices into India requires obtaining a valid CDSCO Import License under the Medical Devices Rules (MDR), 2017. The process includes appointing an Indian Authorized Agent, obtaining Form MD-42, applying through Form MD-14, and receiving the Import License in Form MD-15. Importers must also comply with documentation, customs clearance, labeling, and post-market surveillance requirements. Proper device classification and complete regulatory submissions are essential for timely approvals.

READ MORE

TO KNOW MORE

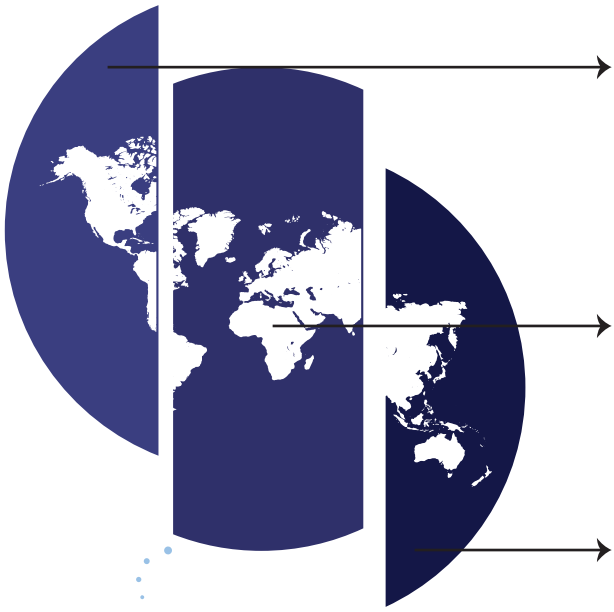
Cardiovascular Medical Devices: A Quick Guide to Manufacturing and Regulatory Compliance

Cardiovascular medical devices such as heart valves, coronary stents, pacemakers, and angioplasty balloon catheters are high-risk products that require stringent regulatory compliance and quality standards. Manufacturing these devices demands advanced engineering, comprehensive technical documentation, and adherence to global regulatory requirements. In India, manufacturers must comply with CDSCO regulations, implement ISO 13485 quality management systems, and complete appropriate product registration before commercialization. Accurate device classification and robust clinical evidence are critical for successful approvals.

READ MORE

Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

OUR SERVICES



- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **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

CONTACT US

For more details regarding licence process and regulatory services .

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