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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

India to Launch INR 1,000 Crore MedTech Investment Fund to Strengthen Healthcare Innovation

CDSCO Introduces 90-Day Rule for Application Rejection on SUGAM Portal

NEW

Upcoming Events this Month

- Japan Medtec

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India to Launch INR 1,000 Crore MedTech Investment Fund to Strengthen Healthcare Innovation

India's medical technology sector is set to receive a major boost with the launch of a dedicated INR 1,000 crore investment fund to support innovation and manufacturing in healthcare. The initiative aims to strengthen the domestic MedTech ecosystem, reduce reliance on imports, and accelerate indigenous technology development under the Make in India vision.

We support medical device companies with regulatory approvals, manufacturing setup, and end-to-end consulting to help them scale and succeed in the evolving MedTech landscape.

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CDSCO Introduces 90-Day Rule for Application Rejection on SUGAM Portal

India's Central Drugs Standard Control Organisation (CDSCO) has announced that applications will be rejected if applicants fail to respond to regulatory queries within 90 days. This move aims to clear long-pending submissions and improve efficiency in the approval process for drugs, medical devices, and IVDs. Manufacturers must ensure timely responses and accurate documentation to avoid rejection risks.

We assist with end-to-end CDSCO registration, SUGAM portal management, and pre-filing consultation to ensure smooth and timely regulatory approvals.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Centre to Establish Three Medical Device Parks in MP, UP, and Tamil Nadu

The Government of India is strengthening domestic medical device manufacturing by establishing dedicated medical device parks across states like Madhya Pradesh, Uttar Pradesh, and Tamil Nadu. These parks will provide shared infrastructure such as testing labs, sterilization facilities, and R&D centers to reduce costs and improve competitiveness. The initiative aims to reduce import dependency and position India as a global MedTech manufacturing hub.

We support manufacturers with facility setup, regulatory compliance, and end-to-end consulting to successfully establish and scale operations in these medical device parks

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TO KNOW MORE

DPR for Medical Device Manufacturing: The First Step Toward a Compliant & Scalable Facility

A Detailed Project Report (DPR) is a critical foundation for successful medical device manufacturing, providing a complete roadmap covering technical feasibility, regulatory strategy, infrastructure planning, and financial viability. It ensures that projects are aligned with GMP, ISO standards, and market demand, reducing risks and enabling smooth execution from concept to commercialization.

We provide expert DPR services, including feasibility analysis, regulatory planning, and financial modeling to help manufacturers build compliant and scalable facilities.

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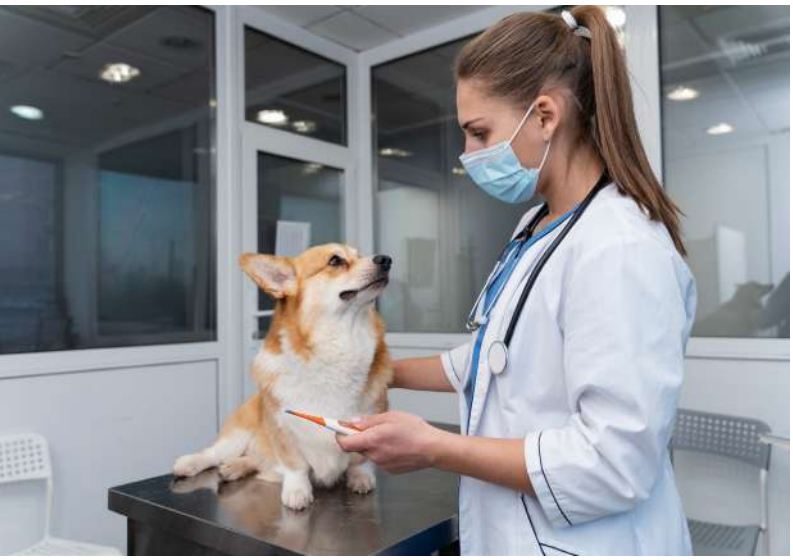

Challenges Facing Veterinary Medical Device Manufacturers

The veterinary medical device industry is growing rapidly due to rising pet ownership and increasing demand for animal healthcare. However, manufacturers face challenges such as complex regulatory requirements, lack of global standardization, high R&D costs, and market access barriers. Overcoming these obstacles is essential for successful product development and commercialization in this evolving sector.

We support manufacturers with regulatory strategy, compliance documentation, and market entry planning to help them navigate challenges and achieve sustainable growth.

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CDSCO License for Blood Bag Manufacturing: Regulatory Process Explained

Blood bags are critical Class C medical devices, and obtaining a CDSCO license is mandatory for manufacturing in India. The process involves strict compliance with Medical Device Rules (MDR) 2017, ISO 13485 standards, technical documentation (DMF & PMF), and facility audits. Proper planning, quality systems, and validated manufacturing processes are essential for timely approval and safe production.

We provide end-to-end support including CDSCO registration, documentation preparation, facility setup, and compliance to ensure smooth and successful licensing.

READ MORE

How to Start ECG Machine Manufacturing: Complete Regulatory & Setup Guide (2026)

ECG machine manufacturing is a growing opportunity driven by rising cardiac health needs and demand for advanced diagnostic devices. However, entering this market requires careful planning, including product design, regulatory approvals, quality management systems, and compliant manufacturing setup. Following a structured approach ensures smooth approvals and successful market entry.

We provide end-to-end support, including regulatory strategy, QMS implementation, technical documentation, and manufacturing setup to help you successfully launch ECG devices in global market

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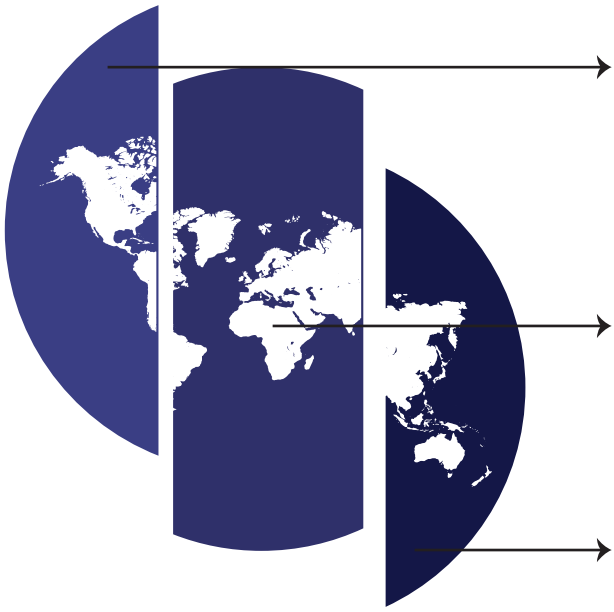
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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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