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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

CDSCO to Reject Non-Responsive SUGAM Applications After 30 Days

UK MHRA Proposes Indefinite Acceptance of CE-Marked Devices

NEW

Upcoming Events this Month

• World Conference on Pharma Industry and Medical Devices 2026

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

CDSCO to Reject Non-Responsive SUGAM Applications After 30 Days

India's drug and device regulator, Central Drugs Standard Control Organization (CDSCO), has announced that long-pending applications on the SUGAM portal will be rejected if applicants fail to respond to queries within 30 days. This move aims to clear regulatory backlogs, improve efficiency, and ensure faster decision-making. Manufacturers must monitor portal communications closely and submit timely responses to avoid automatic rejection and delays in product approvals.

We assist manufacturers with end-to-end SUGAM query management, documentation correction, and timely regulatory submissions to prevent application lapses.

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UK MHRA Proposes Indefinite Acceptance of CE-Marked Devices

The Medicines and Healthcare products Regulatory Agency (MHRA) has proposed indefinite acceptance of CE-marked medical devices in the UK, extending regulatory flexibility post-Brexit. This proposal aims to maintain supply continuity, reduce compliance burden, and support manufacturers already certified under EU MDR. The move provides stability for global manufacturers supplying both EU and UK markets.

We guide companies in aligning CE and UK compliance strategies to ensure uninterrupted market access and regulatory readiness.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India's Medical Devices Market to Reach $50.1 Billion by 2030

India's medical devices market is projected to grow to $50.1 billion by 2030, driven by rising healthcare demand, government initiatives, and increased domestic manufacturing. Expansion in diagnostics, implants, and consumables is strengthening India's global MedTech position. Policy reforms and infrastructure development are accelerating investment and innovation across the sector.

We support manufacturers with facility setup, regulatory approvals, and quality system implementation to capitalize on India's growing MedTech opportunities.

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Industry Opposes Import of Refurbished Medical Equipment

Indian medical device manufacturers have raised concerns over the import of refurbished medical equipment, citing quality, safety, and market fairness issues. Industry leaders argue that unrestricted imports may impact domestic manufacturing growth and compromise patient safety standards. The debate highlights the need for balanced policies that protect local innovation while ensuring technology access.

We help manufacturers strengthen compliance frameworks and competitiveness in evolving regulatory and trade environments.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India–EU FTA to Strengthen Pharma and MedTech Trade

The proposed India–EU Free Trade Agreement (FTA) is expected to enhance pharmaceutical and medical device exports by reducing tariffs and improving regulatory cooperation. With strong EU demand for healthcare products, Indian manufacturers could gain wider market access and integration into global supply chains. The agreement may significantly boost MSME participation and export growth.

We assist companies in preparing regulatory documentation, CE compliance strategies, and export readiness to leverage FTA-driven opportunities.

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Uttar Pradesh Plans US FDA-Level Testing Infrastructure

The Government of Uttar Pradesh is planning to establish medical device testing infrastructure aligned with standards comparable to the U.S. Food and Drug Administration (FDA). The initiative aims to enhance domestic testing capabilities, reduce reliance on foreign labs, and strengthen product quality validation. This development supports India's vision of becoming a global medical device manufacturing hub.

We support manufacturers with testing compliance strategies, validation documentation, and regulatory alignment for global approvals.

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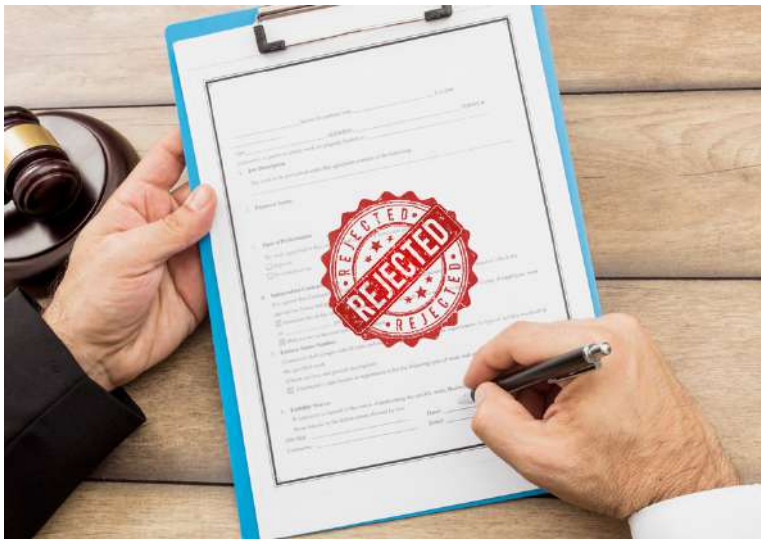
TO KNOW MORE

Manufacturing Facilities: The Real Reason Medical Device Approvals Get Delayed or Rejected



Setting up a medical device manufacturing facility requires careful planning of cleanroom design, HVAC systems, regulatory zoning, and ISO 13485-compliant quality systems. Proper layout design ensures workflow efficiency, contamination control, and regulatory approval readiness. Infrastructure decisions significantly impact long-term scalability and compliance success.

We provide turnkey support from feasibility assessment to facility validation and regulatory approval.

READ MORE

Catheter Manufacturing Machinery: Equipment, Processes, Applications, and Regulatory Readiness

Catheter manufacturing involves precision extrusion, tip forming, assembly, bonding, and sterilization processes. Selecting the right machinery and automation systems is essential for ensuring product consistency and regulatory compliance. Material compatibility and process validation are critical to achieving high-quality outcomes.

We guide manufacturers in equipment selection, process validation, and regulatory documentation for catheter production facilities.

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Pacemaker Manufacturing Process: From Design to Assembly

Pacemaker manufacturing demands advanced electronics integration, hermetic sealing, battery assembly, and stringent quality testing. Compliance with global regulatory standards and robust risk management systems is essential due to the life-sustaining nature of the device. Precision engineering and traceability define successful pacemaker production.

We support manufacturers with design controls, validation protocols, and global regulatory submission strategies.

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How Design Changes Impact Regulatory Approvals Mid-Project

Mid-project design changes in medical devices can significantly affect regulatory approvals, timelines, and compliance requirements. Modifications may require updated risk analysis, verification, validation, and fresh regulatory submissions depending on classification and market. Proper change management systems are essential to prevent costly delays.

We help manufacturers implement structured design control and change management processes aligned with global regulatory standards.

READ MORE

Catheter Materials: Choosing the Right Components

Material selection plays a crucial role in catheter performance, biocompatibility, and regulatory acceptance. Common materials include silicone, polyurethane, and PTFE, each offering specific flexibility, durability, and chemical resistance properties. Material validation and supplier qualification are essential for consistent manufacturing quality.

We assist manufacturers in material evaluation, biocompatibility documentation, and regulatory compliance for global market approvals.

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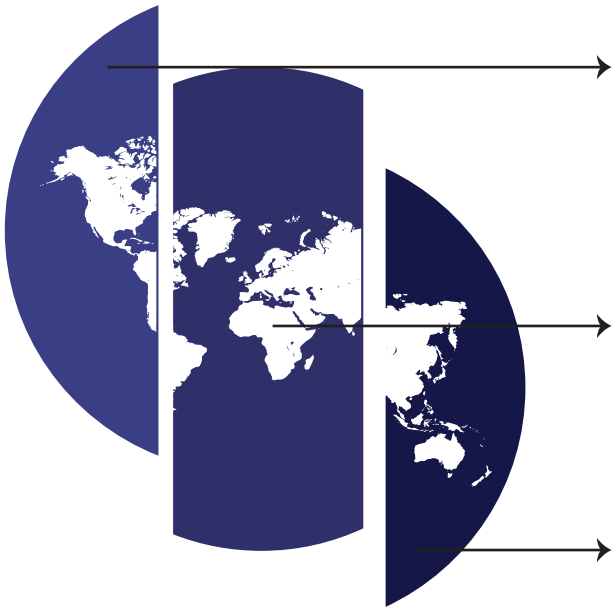
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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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