VOL.NO. 04 | ISSUE-04 | JULY-2025

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
Transforming Thoughts In To Reality

LATEST NEWS & UPDATES

CDSCO Relaxes Loan License Rule for Medical Device Sterilization

UP Government Launches Scheme to Boost Medical Device Manufacturing in Greater Noida

NEW

Upcoming Events this Month

- India Health 2025
- Medicall Chennai 2025

Know More

REGUVEDA
YOUR MONTHLY REGULATORY UPDATE

VOL.NO.04 | ISSUE-04 | JULY-2025

MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

CDSCO Relaxes Loan License Rule for Medical Device Sterilization

CDSCO has relaxed the requirement for medical device manufacturers to obtain a loan license when outsourcing sterilisation to third-party facilities. Now, companies can proceed with sterilisation through licensed external facilities via a mutual agreement—no loan license needed. This update streamlines operations and reduces the regulatory burden for manufacturers.

Need help drafting CDSCO-compliant sterilisation agreements?
Partner with Operon Strategist for expert regulatory support!

READ MORE

UP Government Launches Scheme to Boost Medical Device Manufacturing in Greater Noida

The Uttar Pradesh government, through YEIDA, has launched a plot allocation scheme for medical device manufacturers in Sector-28, Greater Noida. With 21 industrial plots on offer, this initiative supports the development of India's largest Medical Device Park. The scheme targets high-potential segments like IVDs, implants, electronic devices, and cardio-respiratory equipment. Applications are open until July 7.

Operon Strategist provides end-to-end support for manufacturers, including regulatory approvals, plant setup, and QMS implementation.

READ MORE

MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

CDSCO Updates List of Laboratories for Performance Evaluation of IVD Medical Devices in India

CDSCO has updated its list of approved laboratories for performance evaluation of in vitro diagnostic (IVD) medical devices, streamlining regulatory approval under India's Medical Device Rules, 2017. The update includes disease-specific lab authorizations across categories like HIV, HBV, Dengue, TB, and COVID-19, with a special focus on SARS-CoV-2 RT-PCR testing.

Operon Strategist assists IVD manufacturers with regulatory pathways, documentation, and coordination with approved labs to ensure fast and compliant market entry.

READ MORE

The 5 Key Elements of an Effective CAPA System

An effective Corrective and Preventive Action (CAPA) system is vital for maintaining compliance and quality in medical device manufacturing. This blog by Operon Strategist outlines the 5 key elements of a robust CAPA system—issue identification, pre-investigation planning, root cause analysis, CAPA action implementation, and effectiveness review. Learn how to overcome common pitfalls and enhance your QMS with expert guidance.

Need help building a CAPA system that ensures compliance and quality?
Contact the Operon Strategist today!

READ MORE

TO KNOW MORE

How Cleanrooms Play a Major Role in Manufacturing Sterile Medical Devices

In this insightful blog, Operon Strategist explains why cleanrooms are essential for the safe and compliant manufacturing of sterile medical devices. Learn about cleanroom classifications (ISO 14644-1), contamination control, regulatory compliance (FDA, EU MDR, ISO 13485), and the importance of ongoing validation and environmental monitoring.

The blog also outlines how Operon Strategist supports manufacturers with cleanroom design, validation, and turnkey regulatory solutions tailored to global standards.

Read the full blog to ensure your cleanroom is audit-ready and patient-safe.

READ MORE

The Future of Medical Device Labeling: Global Trends and Innovations

In this forward-looking blog, Operon Strategist explores how medical device labeling is evolving into a powerful tool for compliance, safety, and innovation. Key trends include e-labeling, UDI & RFID tracking, AI-powered personalization, and regulatory harmonization across India, the EU, and the US.

Discover how smart packaging, sustainable materials, and automated systems shape the future of labeling and why early adoption is crucial for market success.

Read the full blog to stay ahead in global labeling compliance and innovation.

READ MORE

TO KNOW MORE

Process Validation in Medical Device Manufacturing: New Expectations and Compliance (2025 Guide)

As global regulations tighten, Operon Strategist explains the evolving 2025 expectations for process validation in medical device manufacturing. The blog outlines the full validation lifecycle—from Process Design to Continuous Process Verification (CPV)—and emphasizes compliance with FDA QSR, EU MDR, ISO 13485:2025, and regional bodies like the Egyptian Drug Authority (EDA).

Discover how to tackle validation challenges, implement data-driven monitoring, and maintain audit readiness.

Read the full blog to align your manufacturing processes with the latest global standards.

READ MORE

How to Get Legacy Devices to IVDR Compliance

This informative blog from Operon Strategist walks manufacturers through the critical steps needed to transition legacy IVD devices from IVDD to IVDR (EU 2017/746) compliance. With stricter technical documentation, PMS, and vigilance requirements, early action is essential.

Key steps include engaging a Notified Body early, appointing a PRRC, updating risk and performance data, and evaluating any design changes that could affect legacy status.

Read the full blog to ensure uninterrupted EU market access for your IVD devices.

READ MORE

TO KNOW MORE

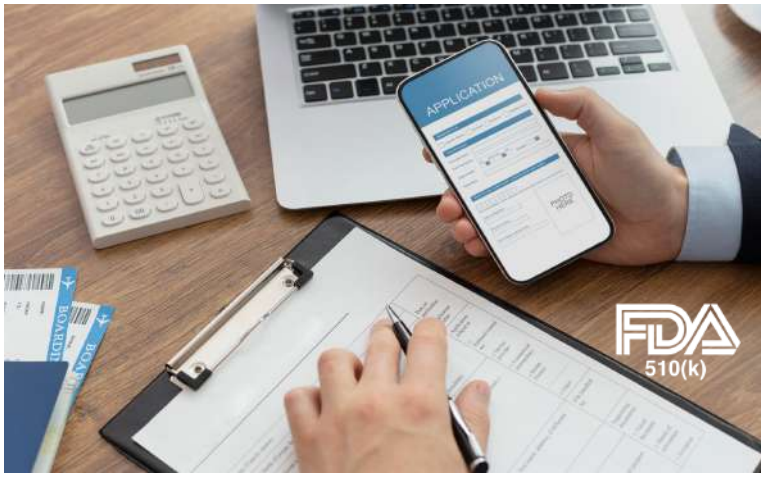
When to Submit a USFDA 510(k): Timing Your FDA Application Strategically

This blog by Operon Strategist explains the importance of strategic timing when filing a US FDA 510(k) application for moderate-risk (Class II) medical devices. Learn when a 510(k) is required, how to choose the right predicate device, and the differences between Traditional, Special, and Abbreviated 510(k) submissions.

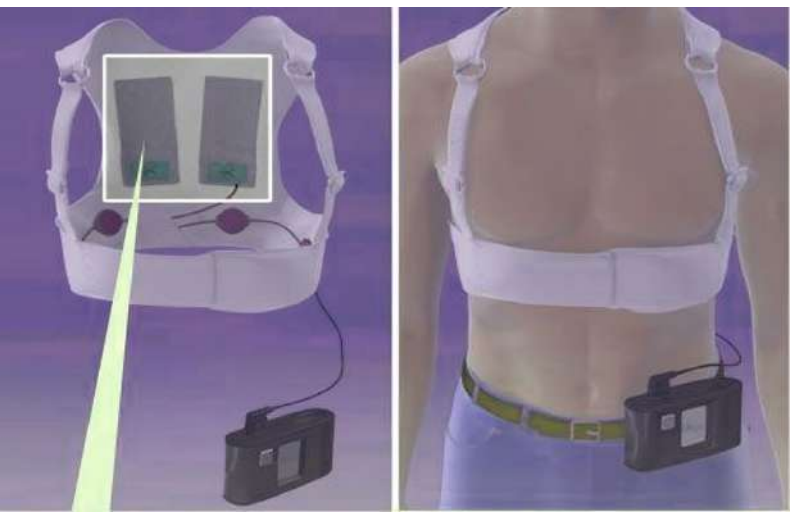
It also includes key insights on submission timelines, when a new 510(k) or Letter to File is needed, and how to reduce risks of rejection or delay.

Read the full blog to ensure your FDA submission is accurate, timely, and approval ready.

READ MORE



Wearable Defibrillators Manufacturing Process and Regulatory Requirements



In this latest blog, Operon Strategist explores the complete manufacturing process and regulatory requirements for wearable defibrillators, a life-saving solution for patients at risk of sudden cardiac arrest. Learn about key components, cleanroom assembly, QMS implementation (ISO 13485), and how to navigate CDSCO approval in India, FDA PMA, and EU MDR CE Marking.

Whether you're launching a new device or expanding to global markets, this guide outlines everything from design to post-market surveillance.

Read the full blog and set your wearable defibrillator project on the right regulatory path.

READ MORE

TO KNOW MORE

UCMPMD Guidelines: How to File Self-Declaration & Marketing Expenditure Disclosure

In this blog, Operon Strategist breaks down the UCMPMD Guidelines (Uniform Code for Medical Devices Marketing Practices)—a voluntary code that promotes ethical and transparent marketing in India's medical device sector. It explains how companies must file an annual self-declaration and disclose their marketing expenditures, including event sponsorships and product samples. The article also guides manufacturers on where and how to submit reports, who is responsible, and why compliance is crucial for maintaining credibility.

Stay ahead with transparency—read the full blog to ensure your company remains ethically compliant.

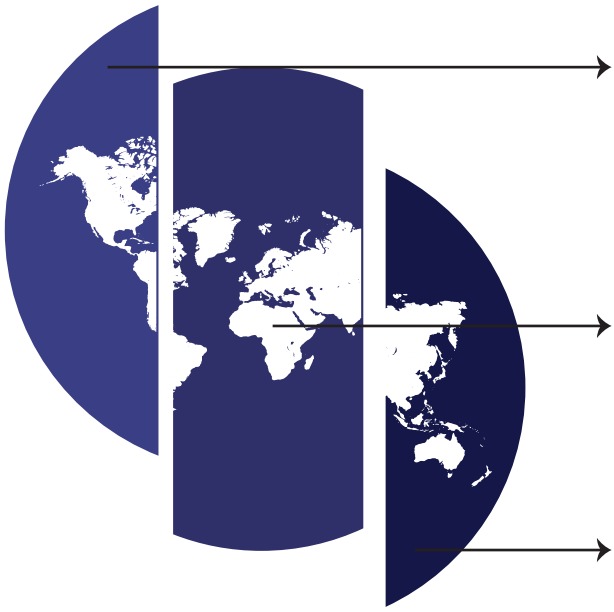
READ MORE

REGUVEDA

A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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 .

enquiry@operonstrategist.com

+91-9370283428

Office No.14, 4th Floor, MSR capital,
Morwadi, Pimpri, Pune 411 018