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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
Transforming Thoughts In To Reality

LATEST NEWS & UPDATES

India–EU FTA to Boost Pharma and MedTech Exports

Uttar Pradesh Plans US FDA-Level Medical Device Testing Infrastructure

NEW

Upcoming Events this Month

- Odisha Medical Devices Expo 2026

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India–EU FTA to Boost Pharma and MedTech Exports

The proposed India–EU Free Trade Agreement is expected to significantly strengthen India's pharmaceutical and medical device exports by reducing tariffs and improving regulatory cooperation. The EU imports over $572 billion worth of pharma and MedTech products annually, offering a massive growth opportunity for Indian manufacturers. Lower duties and smoother market access will help Indian MSMEs expand exports, integrate into global supply chains, and increase healthcare manufacturing competitiveness.

We support manufacturers in aligning regulatory documentation, quality systems, and EU market entry strategies to maximize FTA export opportunities.

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Uttar Pradesh Plans US FDA-Level Medical Device Testing Infrastructure

Uttar Pradesh is planning advanced medical device testing facilities aligned with global regulatory standards, including US FDA expectations. This initiative aims to strengthen domestic manufacturing quality, reduce dependence on foreign testing labs, and support exports of Indian medical devices. The move will also help local manufacturers meet global compliance requirements faster and more cost-effectively.

We help manufacturers prepare for global regulatory testing, validation planning, and FDA-compliant documentation.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Department of Pharmaceuticals Invites Proposals for Common

The Department of Pharmaceuticals (DoP) is inviting proposals to establish shared infrastructure such as testing labs, sterilization facilities, and R&D centers for medical device clusters. The initiative aims to reduce capital investment burden on individual manufacturers, improve quality standards, and accelerate India's MedTech ecosystem growth.

We guide companies in leveraging government schemes, cluster participation, and compliance readiness for infrastructure-based manufacturing expansion.

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CDSCO Advances Regulation of AI-Based Cancer Diagnostic Software

India's CDSCO is strengthening regulatory oversight for AI-driven cancer diagnostic software to ensure patient safety and performance reliability. The move reflects global regulatory trends where AI medical software must meet strict validation, clinical performance, and cybersecurity requirements before approval.

We help digital health and AI device manufacturers navigate CDSCO registration, clinical validation, and software lifecycle compliance.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Government Sub-Schemes Supporting Pharma and MedTech Manufacturing

India offers multiple sub-schemes under national manufacturing initiatives to support pharma and medical device sectors. These include funding for infrastructure, R&D, skill development, and export promotion. These schemes are designed to boost domestic manufacturing capacity and global competitiveness.

We help companies identify applicable schemes and prepare documentation for approvals and incentives.

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When Manufacturing Facility Issues Cause Medical Device Rejection

Manufacturing facility deficiencies are a major reason for regulatory rejection globally. Common issues include poor cleanroom control, weak validation processes, incomplete documentation, and inadequate quality management systems. Regulators increasingly focus on facility design, process validation, and lifecycle quality assurance.

We help manufacturers perform facility gap assessments, validation planning, and audit readiness for global approvals.

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Disposable Syringe Manufacturing Plant – Process and Compliance Overview

Setting up a disposable syringe manufacturing plant requires robust process control, cleanroom infrastructure, automation, and compliance with global standards such as ISO 13485 and regulatory requirements like FDA and CE. High-volume production combined with strict sterility and validation requirements makes compliance planning critical from the design stage.

We provide end-to-end consulting from plant design and equipment selection to regulatory approval and documentation.

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EU MDR Common Pitfalls Manufacturers Must Avoid

Many manufacturers face delays in EU MDR certification due to incomplete technical documentation, weak clinical evaluation, poor risk management integration, and lack of post-market surveillance planning. MDR requires lifecycle-based compliance rather than document-based compliance, increasing regulatory complexity. Manufacturers often underestimate the level of clinical evidence required, especially for legacy devices transitioning from MDD to MDR. Inadequate alignment between risk management, clinical evaluation, and PMS data is another common cause of Notified Body nonconformities. Early gap assessments and structured compliance planning are critical to avoid certification delays or market withdrawal.

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Regulatory Difference Between SiMD and SaMD

Software in Medical Device (SiMD) refers to embedded software controlling or supporting a physical medical device, while Software as a Medical Device (SaMD) functions independently as a medical product. Both require full regulatory lifecycle compliance, including risk management, validation, and post-market surveillance. However, regulatory classification, clinical evidence expectations, and cybersecurity requirements vary significantly between SiMD and SaMD. SaMD products typically face higher scrutiny for software lifecycle processes, algorithm validation, and real-world performance monitoring. Misclassification can lead to approval delays, rework, or regulatory rejection.

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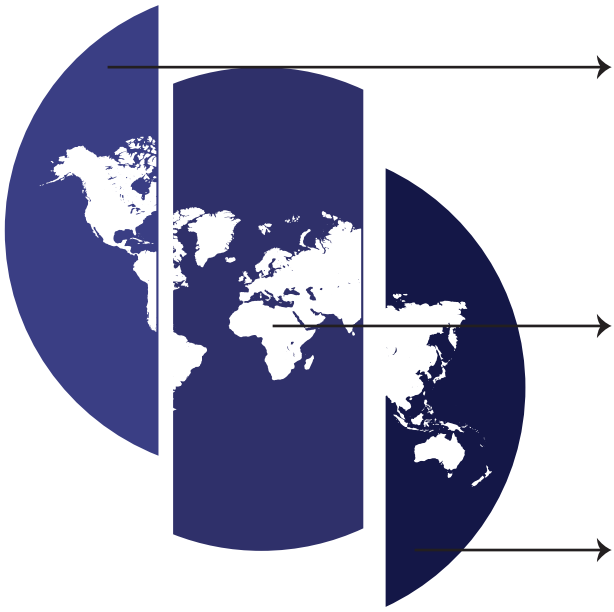
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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

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