VOL.NO. 04 | ISSUE-05 | AUGUST-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

India swiftly emerging as global MedTech powerhouse; to grow at 12%

YEIDA Medical Device Park to Be Completed by January 2026, Centre Instructs

NEW

**Upcoming Events this Month**

- Medical Expo Ahmedabad 2025
- Africa Hospitals Expo 2025

Know More

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MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## India swiftly emerging as global MedTech powerhouse; to grow at 12%

India's MedTech sector is on a rapid growth trajectory, projected to reach USD 50 billion by 2030 with a 12% CAGR. Post-pandemic demand, strategic government policies like the PLI Scheme and Medical Device Parks, and the rise of MedTech hubs in cities like Pune and Hyderabad are driving this momentum. With growing exports and a skilled workforce, India is becoming a preferred destination for affordable, high-quality medical devices.

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## YEIDA Medical Device Park to Be Completed by January 2026, Centre Instructs

The ₹440 crore YEIDA Medical Device Park in Greater Noida is on fast track for completion by January 2026, as per central government directives. Spread across 350 acres, it has already allotted 89 plots to manufacturers of radiology devices, implants, IVD products, and more. With 6 Common Scientific Facilities and 13 specialized labs, the park is set to become a national hub for medical innovation and exports.
Need help setting up your unit in YEIDA Medical Device Park?

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MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## PLI Scheme Boosts Medical Device Manufacturing in India with 21 Projects and 54 Devices

India's PLI scheme has catalyzed domestic medical device manufacturing, with 21 approved projects producing 54 critical devices like MRI machines and heart valves. With Rs 1.76 lakh crore in investments and over 12 lakh jobs created, the scheme is reducing import reliance and boosting exports. The medical device sector is emerging as a key beneficiary alongside electronics and pharma.

Want to set up a medical device plant? Operon Strategist offers complete support for compliance, plant setup, and regulatory approvals.

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# TO KNOW MORE

## Medical Device Packaging Shelf-Life: Validation, Testing & Compliance

Proper packaging is essential to protect medical devices, maintain sterility, and meet global compliance. This blog explores shelf-life validation methods—including accelerated aging, real-time testing, and integrity/seal strength tests—as required by ISO 11607 and FDA regulations. Learn how to avoid packaging failures, ensure patient safety, and prepare documentation for audits.

Need help validating your packaging system? Operon Strategist offers end-to-end packaging compliance support.

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## SaMD Software Documentation: 7 Must-Haves for Premarket Submissions

Planning to launch a Software as a Medical Device (SaMD) in the U.S.? Your FDA premarket submission must include seven critical documents—Level of Concern (LoC) statement, software description, hazard analysis, SRS, V&V testing, traceability matrix, and revision history. These elements ensure safety, regulatory compliance, and approval readiness. Whether your device has minor or major risk potential, Operon Strategist helps you prepare accurate, audit-ready SaMD documentation tailored to FDA expectations.
Need expert help with SaMD documentation? Let's connect!

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# TO KNOW MORE

## Medical Device Labeling: A Complete Guide to Standards, Compliance, and Best Practices

Accurate and compliant labeling is essential for medical device safety and regulatory approval. In 2025, manufacturers must align labels with key standards like ISO 15223-1, ISO 20417, and region-specific regulations such as FDA 21 CFR Part 801 and EU MDR. From UDI and CE marking to IFUs and multilingual content, labeling must ensure clarity, durability, and traceability. Operon Strategist helps you design, review, and validate labels that meet global compliance—streamlining approvals and minimizing risk.

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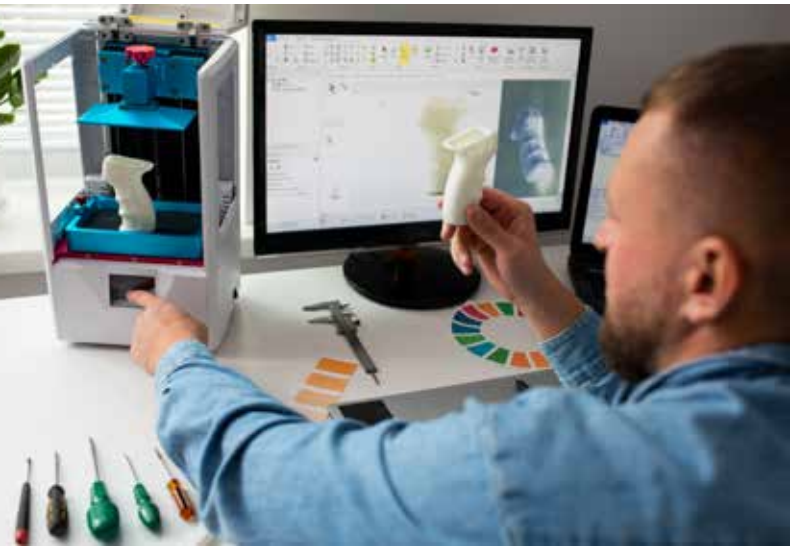

## 3D Printing in Implantable Devices: What's New in 2025 ?

In 2025, 3D printing is revolutionizing implantable medical devices with personalized, AI-driven designs and advanced biocompatible materials. From orthopedic and craniofacial implants to cardiovascular stents, this technology allows faster patient-specific solutions. Regulatory bodies like the FDA are updating guidance on design controls, material validation, and AI-assisted customization. As smart implants and bioresorbable materials gain traction, manufacturers must meet evolving standards and quality requirements. Operon Strategist offers end-to-end support for FDA submissions, QMS implementation, and 3D-printed implant development.

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## IOL Cast Molding Technology: A Breakthrough in IOL Manufacturing

IOL Cast Molding Technology is revolutionizing the production of intraocular lenses by offering precision, scalability, and superior quality. Unlike traditional methods, cast molding enables mass production of complex lens designs like toric and multifocal IOLs with consistent performance and minimal waste. As global demand for cataract solutions rises, this technology is becoming the go-to choice for manufacturers aiming for compliance with CDSCO, EU MDR, and FDA 510(k) regulations. Operon Strategist supports IOL manufacturers with turnkey plant setup, QMS implementation, regulatory filing, and full product lifecycle compliance.

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## FDA Guidance on AI-Enabled Medical Devices: Key Updates & Industry Impact in 2025


In 2025, the FDA introduced two major guidance documents to streamline the regulation of AI-enabled medical devices. The draft guidance outlines lifecycle management and marketing submission recommendations, while the final guidance on Predetermined Change Control Plans (PCCP) allows manufacturers to update machine learning algorithms post-market without repeated submissions. These updates emphasize transparency, performance validation, and risk assessment throughout the device lifecycle. Operon Strategist supports MedTech innovators with AI-focused regulatory strategy, PCCP drafting, and QMS integration to ensure fast, compliant FDA submissions.

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## Nanomaterials in Medical Devices: A Smart Guide to Biocompatibility

Nanotechnology is reshaping medical device innovation, but when using nanomaterials like silver nanoparticles or carbon nanotubes, biocompatibility becomes a critical concern. From particle size and surface chemistry to toxicity and degradation behavior, every factor can impact patient safety and regulatory approval. Global regulators, including CDSCO, US FDA, and EU MDR, demand thorough testing per ISO 10993 standards. At Operon Strategist, we help you plan biocompatibility assessments, compile technical documentation, and navigate global compliance — ensuring your nanotech-based medical device enters the market smoothly and safely.

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## New EU Rules on Medical Device Supply Disruptions Take Effect January 2025


Effective January 10, 2025, Regulation (EU) 2024/1860 will require medical device and IVD manufacturers to provide a mandatory six-month advance notice before discontinuing or interrupting product supply in the EU. This new rule aims to prevent device shortages and strengthen supply chain resilience by ensuring timely communication with authorities, healthcare providers, and distributors. Manufacturers must include clear reasons for the disruption, stock availability, and possible alternatives in their notifications. Operon Strategist can support your compliance by integrating these requirements into your QMS and helping you manage stakeholder communications efficiently.

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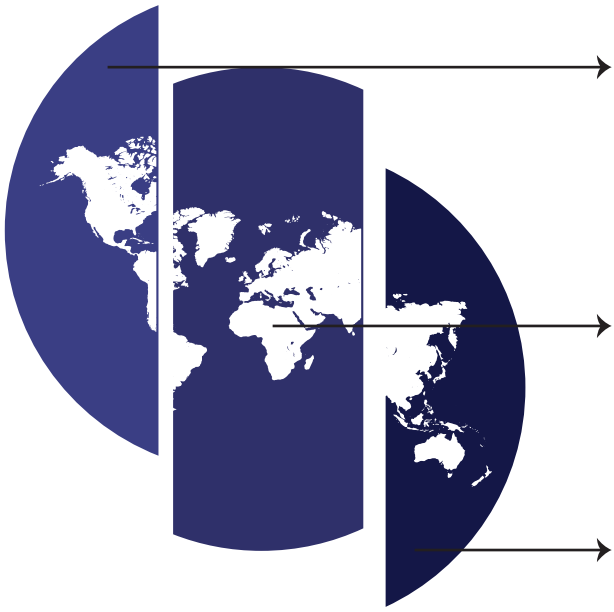
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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

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