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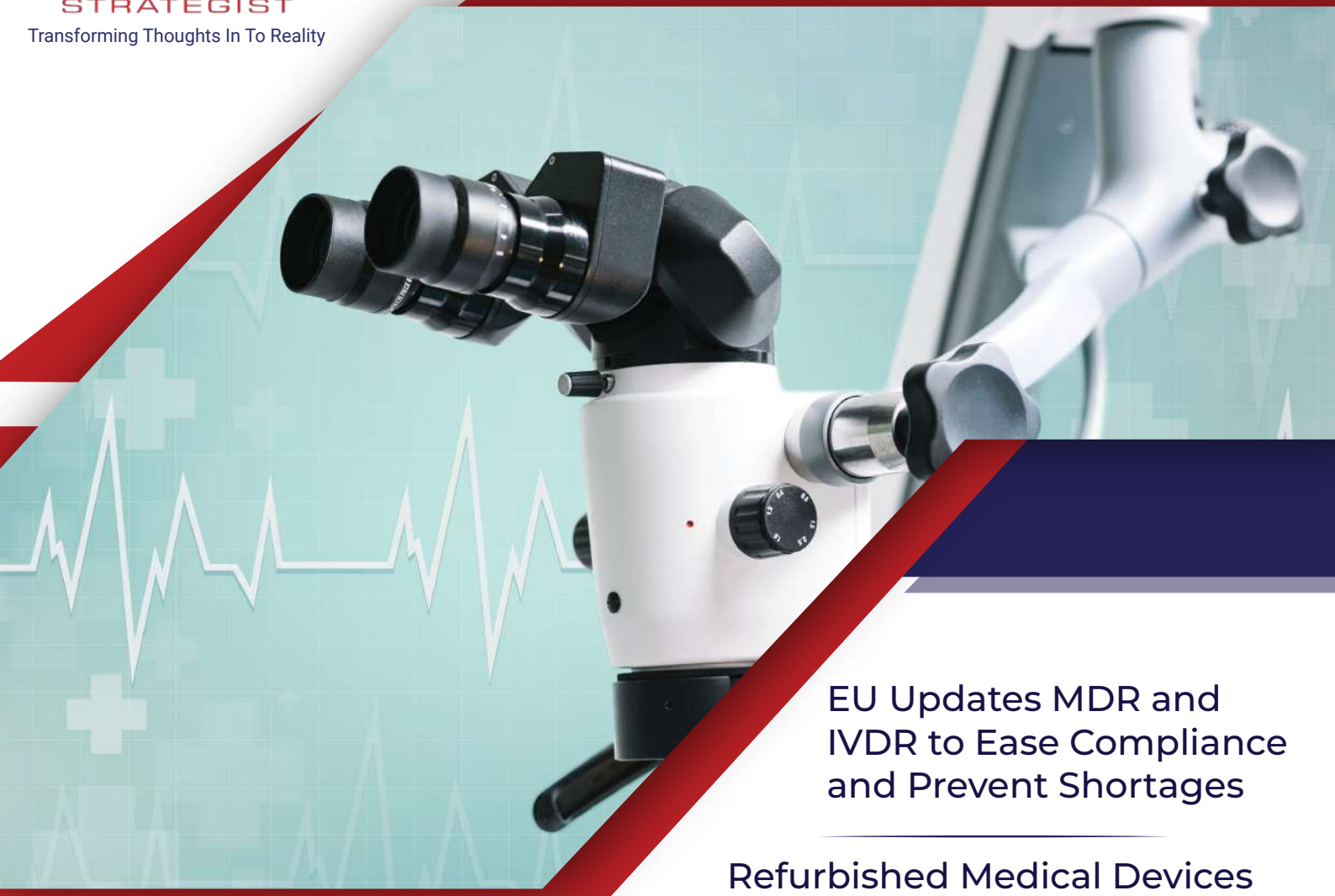
# REGUVEDA

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



EU Updates MDR and IVDR to Ease Compliance and Prevent Shortages

Refurbished Medical Devices in India

NEW

**Upcoming Events this Month**

- Global Conference on Pharma Industry and Medical Devices 2026 (GCPIMD)

Know More

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MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## EU Updates MDR and IVDR to Ease Compliance and Prevent Shortages

The European Union has introduced key updates to MDR and IVDR to reduce regulatory burden and avoid medical device shortages. The changes include extended transition timelines, phased EUDAMED implementation, and mandatory supply disruption notifications to ensure patient access and market stability. These updates aim to balance patient safety with realistic compliance timelines for manufacturers. Early awareness and proactive planning are critical to avoid market disruptions and regulatory non-compliance.


We guide manufacturers in understanding these regulatory changes, aligning technical files, and ensuring uninterrupted EU market access.

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## Refurbished Medical Devices in India

India's refurbished medical device market faces regulatory uncertainty due to conflicting environmental and CDSCO policies. While import permissions were initially allowed under e-waste rules, later clarifications restricted approvals, creating challenges for manufacturers, importers, and healthcare providers. This regulatory ambiguity impacts affordability and access to healthcare technology. Stakeholders must closely monitor policy updates to remain compliant and operational.

We provide expert consultation for navigating regulatory compliance, import approvals, and documentation for refurbished devices in India.

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## QMSR Compliance: What FDA Investigators Will Look for in 2026

As FDA transitions to the Quality Management System Regulation (QMSR), inspections will focus on integrated, risk-based quality systems aligned with ISO 13485. Key areas include CAPA effectiveness, complaint handling, risk management, and real-world product performance. The shift moves inspections away from procedural checklists toward system effectiveness. Companies that delay preparation may face inspection delays or enforcement actions.


We help companies prepare for QMSR compliance by reviewing QMS processes, CAPA systems, and risk management frameworks to meet FDA expectations.

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## Medical Device Documentation Gaps that Trigger Regulatory Audits

Documentation gaps remain a major cause of audit observations across global regulations. Common deficiencies include weak design controls, incomplete risk management files, poor traceability, and inadequate supplier documentation, highlighting the need for audit-ready technical files. Even minor documentation inconsistencies can escalate into major audit findings. Maintaining documentation throughout the product lifecycle is essential for regulatory success.

We assist in auditing, strengthening, and gap-filling technical documentation to ensure compliance and audit readiness.

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## How to Transfer a CE Certificate to a New Notified Body

Transferring a CE certificate requires early planning, complete technical documentation, and strong ISO 13485 compliance. The process involves coordination with both old and new Notified Bodies to ensure uninterrupted EU market access. Delayed planning can result in certification gaps and product withdrawal from the EU market. A structured transition strategy reduces regulatory and commercial risk.

We guide clients through CE certificate transfers, manage Notified Body coordination, and ensure seamless continuity in regulatory approvals.

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## MDSAP Audit Checklist: How to Prepare for a Successful Audit


The MDSAP audit framework enables access to multiple global markets through a single audit. Successful preparation depends on robust QMS processes, internal audits, supplier control, complaint management, CAPA, and regulatory documentation readiness. Poor preparation often leads to major nonconformities across multiple jurisdictions. A well-executed audit strategy can significantly reduce compliance costs and timelines.

We provide end-to-end support in MDSAP audit preparation, including checklists, gap analysis, and process optimization for global compliance.

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## Top 10 Medical Device Trends in 2026

The medical device industry in 2026 will be driven by AI-powered devices, digital health, remote monitoring, smart implants, robotics, cybersecurity, 3D printing, IoMT connectivity, and sustainable product innovation shaping the future of healthcare. These trends are accelerating regulatory complexity alongside technological advancement. Manufacturers must align innovation strategies with evolving global regulations.

We advise manufacturers on adopting emerging technologies while ensuring regulatory compliance and market readiness.

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## Sustainable Medical Device Manufacturing: Regulatory and Compliance Perspective

Sustainability is becoming a regulatory priority, with manufacturers expected to integrate environmental considerations into risk management, material selection, packaging validation, and lifecycle documentation to meet evolving compliance expectations. Regulatory bodies increasingly scrutinize environmental impact alongside product safety. Sustainable practices now influence both compliance outcomes and brand reputation.

We support sustainable manufacturing initiatives with regulatory guidance, compliance strategies, and lifecycle documentation assistance.

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## Medical Software Validation and Verification: A Complete Guide to ISO 13485 Requirements

Medical device software must be rigorously validated and verified to comply with ISO 13485. Proper software lifecycle management ensures safety, performance, data integrity, and regulatory acceptance in an increasingly digital healthcare ecosystem. Inadequate software validation is a common cause of regulatory findings. Structured validation processes are essential for long-term product success.

We assist in software validation planning, verification protocols, and ISO 13485 compliance for medical software and digital health devices.

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## CDSCO Medical Device Consultants in India


Navigating India's CDSCO regulatory framework requires expert guidance for device registration, import and manufacturing licenses, and post-market compliance. Professional regulatory consulting helps manufacturers accelerate approvals and maintain long-term compliance. Regulatory expectations in India continue to evolve with expanding device classifications. Early engagement with experts minimizes approval delays and compliance risks.

We provide complete CDSCO regulatory support, including registration, licensing, documentation, and post-market compliance guidance for medical device manufacturers in India.

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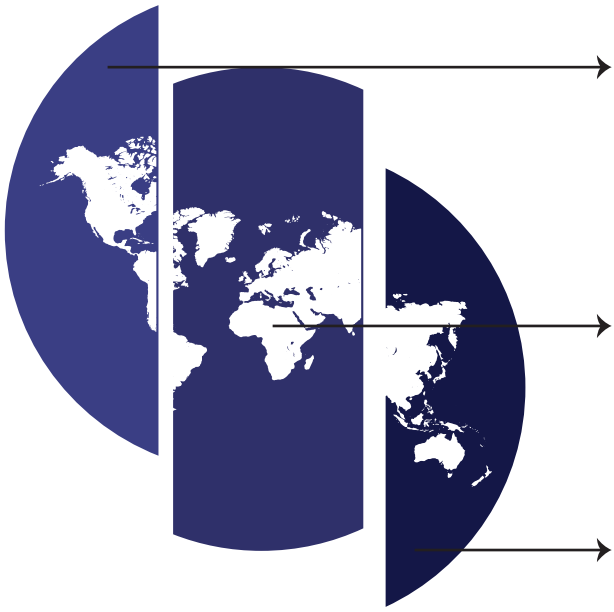
# REGUVEDA

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 .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