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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

CDSCO Directs MedTech Manufacturers to Revise MRPs After GST Cut

ICMR & CDSCO Release 39 Standard IVD Evaluation Protocols

NEW

Upcoming Events this Month

- Global Health Exhibition 2025

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

CDSCO Directs MedTech Manufacturers to Revise MRPs After GST Cut

The Central Drugs Standard Control Organisation (CDSCO) has instructed manufacturers and importers of Class C & D medical devices to revise Maximum Retail Prices (MRPs) in line with the reduced GST rate of 5% (from 12%). Companies have three months to update labels with revised prices, while state drug controllers have been asked to fast-track approvals.

Operon Strategist helps manufacturers manage labeling, compliance, and regulatory transitions smoothly during GST and pricing revisions.

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ICMR & CDSCO Release 39 Standard IVD Evaluation Protocols

The Indian Council of Medical Research (ICMR) and CDSCO have launched a compendium of 39 standardized protocols for evaluating In-Vitro Diagnostics (IVDs). These protocols cover diseases like TB, Malaria, Dengue, Zika, Typhoid, and Respiratory Viruses, setting uniform standards for performance, reliability, and validation.

Operon Strategist guides IVD manufacturers in compliance, documentation, and regulatory strategy to align with these protocols for faster approvals and market access.

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TO KNOW MORE

Top 5 Barriers to Global Market Entry for Medical Devices

Expanding into international markets offers massive growth opportunities for medical device manufacturers, but challenges like complex regulations, high entry costs, supply chain hurdles, cultural differences, and IP risks often stand in the way. This blog outlines practical strategies to overcome these barriers—ranging from ISO 13485-compliant QMS and smart budgeting to building strong distribution networks and securing IP rights.

Read how Operon Strategist can help medical device companies navigate global compliance and enter new markets with confidence.

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Post-Market Surveillance for SaMD under EU MDR

For Software as a Medical Device (SaMD), Post-Market Surveillance (PMS) is not just a regulatory requirement—it ensures safety, performance, and market access in Europe. Manufacturers must implement PMS plans, submit reports (PMSR/PSUR), conduct post-market clinical follow-up, and strengthen vigilance against cybersecurity risks. Best practices include automated monitoring, strong risk management, and cross-functional teamwork.

Discover how Operon Strategist helps SaMD companies streamline PMS and achieve smooth EU MDR compliance.

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IVD Technology Transfer in India: Ensuring Quality & Compliance

Technology transfer for In Vitro Diagnostic (IVD) products is vital for scaling production while maintaining safety, quality, and compliance. It involves structured planning, robust QA/QC systems, detailed documentation, and adherence to CDSCO and ISO 13485 standards. Key success factors include process validation, traceability, and effective training.

Learn how Operon Strategist supports IVD manufacturers in India with end-to-end technology transfer, compliance, and market readiness.

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Unclassified Medical Devices from 510(k): What Manufacturers Should Know

Some devices don't fit neatly into FDA's Class I, II, or III categories—these are Unclassified Medical Devices. While still requiring 510(k) clearance, they pose unique challenges such as unclear predicates, extended review times, and possible reclassification. Manufacturers must carefully plan submissions to avoid delays and compliance risks.

Learn how Operon Strategist helps companies navigate 510(k) submissions for unclassified devices and achieve faster FDA clearance.

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Linking Design Qualification (DQ) with ISO 14971 Risk Management

In medical devices, Design Qualification (DQ) ensures designs meet user needs, while ISO 14971 manages safety risks across the product lifecycle. Linking both creates a robust framework for compliance, safety, and efficiency. Benefits include stronger audit readiness, fewer design flaws, and smoother global approvals.

Read how Operon Strategist guides manufacturers in integrating DQ with risk management for safer, compliant devices.

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FDA Humanitarian Device Exemption (HDE): A Pathway for Rare Conditions

The FDA's Humanitarian Device Exemption (HDE) allows medical devices for rare diseases (affecting fewer than 8,000 patients annually in the U.S.) to reach the market without proving full effectiveness. Instead, manufacturers must demonstrate safety and probable patient benefit. While the pathway offers faster approvals and lower costs, challenges include profit restrictions, small patient pools, and strict eligibility.

Explore how Operon Strategist helps manufacturers navigate the HDE process for faster patient access and compliance.

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A Guide to Training Management for Medical Devices

Effective training management is vital for ensuring regulatory compliance, product quality, and patient safety in the medical device industry. Global regulators like FDA, CDSCO, and ISO 13485 mandate documented employee training and competency proof. A robust system includes training needs analysis, structured plans, record-keeping, evaluation, and continuous updates.

Operon Strategist assists medical device companies in India and globally with training system design, digital implementation, and audit readiness.

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3D Printing Intraocular Lenses: Opportunities, Challenges, and Future Innovations

3D printing is revolutionizing intraocular lens (IOL) manufacturing, offering patient-specific customization, advanced optical designs, faster prototyping, and sustainable production. This innovation enhances surgical outcomes and accelerates product development for ophthalmic device companies.

Operon Strategist supports manufacturers in technology transfer, regulatory compliance, material testing, and global market readiness for 3D printed IOLs.

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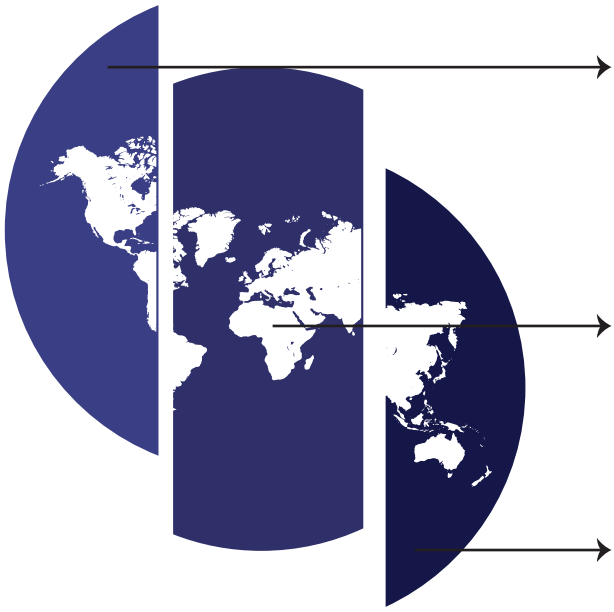
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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

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