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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 Medical Device Alert:New Auto-Generated Workflow Requires Re-Submission

Clarifying USTR Claims on India's Medical Device Policy

NEW

Upcoming Events this Month

- India Med Expo 2025
- Global Conference on Pharma Industry and Medical Devices 2025

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

CDSCO Medical Device Alert: New Auto-Generated Workflow Requires Re-Submission

CDSCO has launched a new automated system for issuing Market Standing Certificates (MSC) and Non-Conviction Certificates (NCC), requiring all manufacturers and importers to re-submit applications from April 9, 2025. Previous submissions under the old system are now void. Operon Strategist helps companies navigate these regulatory changes with expert support, ensuring smooth and compliant submissions. Stay ahead — contact Operon Strategist today!

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Clarifying USTR Claims on India's Medical Device Policy

In its 2025 report, the USTR raised issues about India's tariffs, price controls, and refurbished device policies. However, India's Medical Device Policy 2023 focuses on boosting local manufacturing, ensuring patient safety, and making healthcare affordable. Efforts like PLI schemes, Medical Device Parks, and regulatory reforms are strengthening the ecosystem—not restricting trade. Operon Strategist supports companies navigating global regulations with expert solutions for faster, smoother compliance.

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TO KNOW MORE

Wearable Technology in Healthcare and All You Need to Know About Regulatory Compliance

From smartwatches to biosensor patches, wearable technology is transforming healthcare by delivering real-time health insights. But with innovation comes the need for strict regulatory compliance. This blog explores the critical regulations wearable medical devices must meet in the US (FDA), Europe (EU MDR), and India (CDSCO), and highlights the importance of ISO 13485 compliance. It also uncovers common challenges manufacturers face and how building a regulatory strategy early can save time and costs. Ready to launch your wearable device? Operon Strategist can help you every step of the way!

READ MORE

GSPR Checklist 2025: What's Changed and What Still Matters

With 2025 underway, medical device manufacturers must reassess their GSPR compliance strategies. New updates focus on cybersecurity controls, stronger clinical evidence requirements, environmental impact considerations, and stricter oversight of AI/ML devices. However, core areas like safety, biocompatibility, hygiene, and labeling remain critical. Operon Strategist offers expert support to help you navigate these evolving requirements and streamline your GSPR compliance.

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A Comprehensive Guide to HIPAA Compliance

HIPAA compliance is crucial for protecting patient health information and avoiding costly breaches. This guide explains who must comply, the key HIPAA rules to follow, and the essential steps to build a strong compliance program. From risk assessments to staff training and data security, staying compliant is vital for healthcare providers and their partners. Operon Strategist offers expert support to help you safeguard sensitive data and meet HIPAA requirements with confidence.

Need HIPAA compliance support? Contact Operon Strategist today!

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Custom-Made Medical Devices under EU MDR: A Complete Guide for Manufacturers

Manufacturers of custom-made medical devices must navigate specific EU MDR 2017/745 requirements to ensure compliance. While exempt from CE marking, these devices must meet strict safety, performance, and documentation standards, including technical file preparation, proper labeling, and post-market surveillance. Operon Strategist offers expert support to help manufacturers meet regulatory obligations, avoid common pitfalls, and successfully enter the EU market.

Need help with CMD compliance? Connect with Operon Strategist today!

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2025 Medical Device Trends: Innovations Shaping the Future of Healthcare

The medical device industry is evolving rapidly in 2025, with breakthrough trends like brain-computer interfaces (BCIs), medical robotics, clinical wearables, remote patient monitoring, AI automation, and 3D printing transforming healthcare. As technology reshapes care delivery, navigating complex regulatory pathways becomes essential. Operon Strategist provides end-to-end support to help innovators achieve compliance, accelerate approvals, and lead the future of healthcare.

Stay ahead of 2025's medtech trends—partner with Operon Strategist today!

Medical Device Trends

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Transdermal Patches: A Growing Drug-Device Combination Opportunity

Transdermal patches are revolutionizing drug delivery by offering a non-invasive, controlled method for treating chronic conditions like hypertension, pain, and hormonal imbalances. Classified as drug-device combination products, they present exciting opportunities—but also complex regulatory challenges. This blog explores key regulations (FDA, CE, CDSCO), manufacturing considerations like cleanroom setup and biocompatibility testing, and global market prospects.

Ready to launch your transdermal patch product? Operon Strategist offers end-to-end consulting support for regulatory approvals, QMS implementation, and global market entry.

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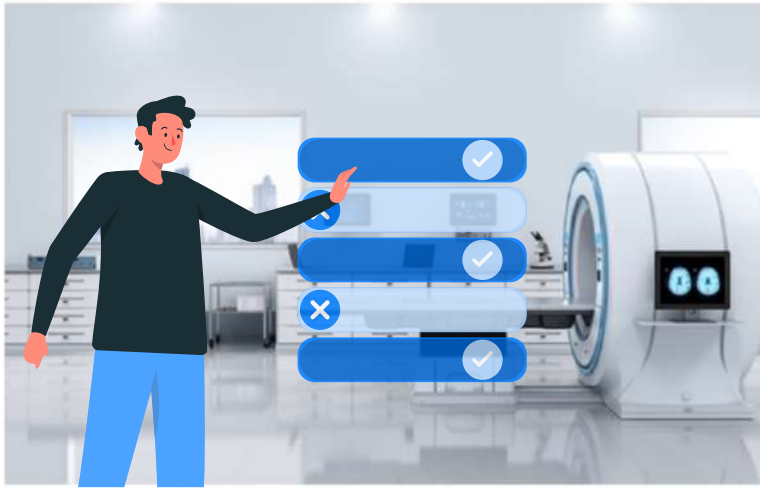
Top 10 Common Mistakes in Medical Device Regulatory Submissions

In the high-stakes world of medical device approvals, even small oversights can cause costly delays. This blog by Operon Strategist outlines the ten most common mistakes companies make during regulatory submissions — from poor risk management and misclassification to weak post-market surveillance and incomplete documentation. Learn practical strategies to stay compliant with global regulations like FDA, EU MDR, and ISO 13485. Whether you're launching a new product or expanding into international markets, this guide helps ensure your submission is right the first time.

Read more to streamline your path to approval and market success!



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Top 5 Businesses to Invest in 2025

2025 is shaping up as a prime year for smart investments, with sectors like sustainable packaging, telehealth, medical device manufacturing, AI-driven SaaS platforms, and renewable energy offering strong growth potential. Among these, medical device manufacturing stands out for its resilience and rising global demand. Operon Strategist supports entrepreneurs and manufacturers in this sector with complete turnkey solutions — from facility setup to regulatory approvals. Ready to turn your investment into a success story? Contact Operon Strategist today!

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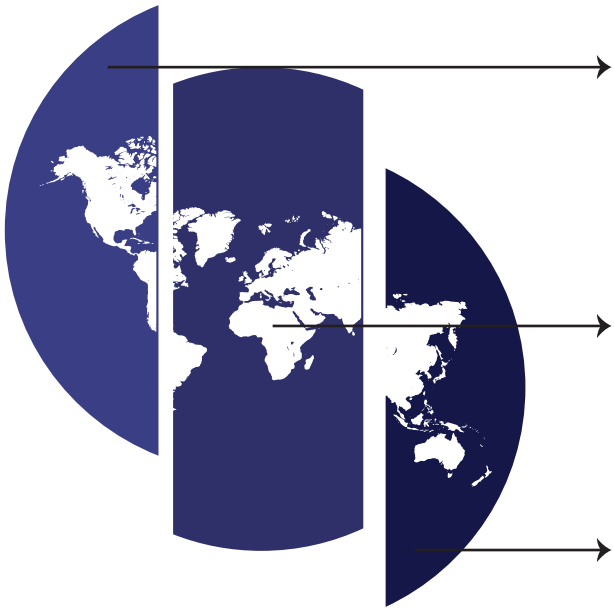
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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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