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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's First Indigenous MRI Machine Ready to Reshape Healthcare

PLI Scheme Boosts Domestic Manufacturing, Jobs, and Exports

NEW

Upcoming Events this Month

- Medicall Hyderabad 2025
- Medical Expo Guwahati 2025

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India's First Indigenous MRI Machine Ready to Reshape Healthcare

India has developed its first 1.5 Tesla MRI machine, set to be installed at AIIMS Delhi by October. This breakthrough will reduce healthcare costs and dependence on imported devices. Led by MeitY and implemented by SAMEER, the project supports India's vision of self-reliance in medical technology.

Operon Strategist helps manufacturers navigate regulatory approvals like CE Marking, FDA 510(k), and CDSCO, ensuring a smooth market entry for innovative medical devices.

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PLI Scheme Boosts Domestic Manufacturing, Jobs, and Exports

India's Production-Linked Incentive (PLI) scheme is shaping the future of manufacturing by driving investments, creating jobs, and strengthening exports. With ₹1.61 lakh crore invested and over 11.5 lakh jobs generated, the initiative is helping India become a global hub for advanced industries like medical devices, electronics, and telecom.

For medical device manufacturers, this is a game-changer! Operon Strategist is here to help you navigate the PLI scheme, secure regulatory approvals (CE Marking, FDA 510(k), CDSCO), and maximize incentives to scale your business.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Australia Introduces New Procedures for Recalls (PRAC) in Post-Market Surveillance Medical Devices

Australia's Therapeutic Goods Administration (TGA) has introduced the PRAC (Procedures for Recalls, Product Alerts, and Product Corrections) to simplify and speed up medical device recalls and post-market surveillance. Replacing the older, complex system, PRAC streamlines recall categories, reduces response times, and provides clearer guidelines for manufacturers. With a faster 5-step process, improved risk classification, and better communication, the new approach ensures swift action on safety concerns while keeping compliance transparent. These updates make it easier for manufacturers to navigate recalls, protect patients, and maintain regulatory standards

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Indian Medical Device Industry Faces Challenges Amid US Reciprocal Tariffs

The Indian medical device industry is facing a tough challenge as the U.S. introduces new tariffs, making it more expensive to export medical devices. This could impact manufacturers' profits and competitiveness in the U.S. market. To overcome this, companies might look at expanding to new markets like Europe and Southeast Asia or partnering with U.S. firms to reduce costs. While these tariffs bring short-term difficulties, smart strategies and trade discussions could help Indian manufacturers stay strong.

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PRRC Under EU MDR & IVDR: Everything You Need to Know

If you're a medical device manufacturer or an authorized representative in the EU, you're required to have a Person Responsible for Regulatory Compliance (PRRC) under EU MDR (2017/745) and IVDR (2017/746). This role is essential to ensure your products meet all regulatory requirements.

- Who can be a PRRC? Someone with a relevant degree or at least 4 years of experience in regulatory affairs or quality management.
- What do they do? They oversee technical documentation, post-market surveillance, and compliance reporting to keep your devices market-ready.
- Can small companies outsource this role? Yes! Micro and small manufacturers can hire an external PRRC under certain conditions.

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FDA Breakthrough Device Designation: Accelerating Medical Innovation

Getting innovative medical devices approved can be a long and complex process. But with the FDA Breakthrough Device Designation, manufacturers can fast-track approvals and bring cutting-edge treatments to patients sooner. This program offers priority review, ongoing FDA guidance, and a smoother regulatory journey—making a real difference in healthcare.

If your device addresses a serious condition, offers a significant improvement over existing treatments, and introduces groundbreaking technology, it could qualify for this designation.

At Operon Strategist, we help manufacturers navigate the regulatory process with expert guidance, compliance support, and seamless submissions.

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eQMS Medical Device Migration: Essential Steps to Avoid Chaos

Switching to a new eQMS for medical devices can improve efficiency and compliance, but if not handled properly, it can lead to data issues and workflow disruptions.
In this blog, we break down the essential steps for a hassle-free transition—from assessing your current system and cleaning up data to validation and employee training. With Operon Strategist by your side, you can ensure a smooth, fully compliant migration that keeps your quality processes running seamlessly.
Thinking about upgrading your eQMS? Let's make it easy—connect with us today!

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Understanding the Impact of MDCG 2019-6 Rev. 5 on EU Medical Device Manufacturers

The latest update to MDCG 2019-6 (Rev. 5) brings more structure to pre-submission interactions with Notified Bodies. But industry experts warn that the lack of early clinical strategy discussions could lead to delays, unexpected data requests, and higher compliance costs.
To stay ahead, manufacturers should strengthen clinical evidence, refine technical documentation, and seek expert guidance. Need help navigating EU MDR compliance? Operon Strategist is here to support you. Let's connect!

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Effective Risk Assessment Medical Device Management: Handling Reasonably Foreseeable Misuse

Managing reasonably foreseeable misuse is a crucial aspect of medical device risk assessment under ISO 14971:2019. Beyond simple use errors, it involves anticipating how users might unintentionally or intentionally misuse a device—impacting safety and compliance. This blog explores common misuse scenarios, risk assessment strategies, and best practices to mitigate potential hazards.

Need expert guidance? Operon Strategist provides tailored risk management solutions, including Risk Management Plans (RMPs), Hazard Traceability Matrices, and compliance consultation to help manufacturers meet regulatory requirements. Connect with us today!

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Breaking Down ISO 13485: What Every MedTech Professional Should Know ?

ISO 13485 is the global standard for medical device quality management systems, ensuring regulatory compliance, product safety, and market access. Whether you're a manufacturer, supplier, or distributor, understanding and implementing ISO 13485 is essential. This blog covers who needs ISO 13485, key benefits, certification steps, and common challenges in compliance.

Need expert guidance? Operon Strategist provides end-to-end support for ISO 13485 certification, helping businesses streamline their QMS and achieve compliance efficiently. Get in touch today!

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Clinical Study vs. Clinical Evaluation: What's the Difference in Medical Device Regulation?

Understanding the difference between Clinical Studies and Clinical Evaluations is crucial for medical device market approval. A Clinical Study involves new trials on human participants to assess a device's safety and performance, often required for innovative products. In contrast, a Clinical Evaluation analyzes existing data from literature, market use, or post-market surveillance to demonstrate compliance, making it essential for CE marking under EU MDR 2017/745.

Need help navigating regulatory requirements? Contact Operon Strategist for expert guidance on Clinical Evaluation Reports and compliance strategies!

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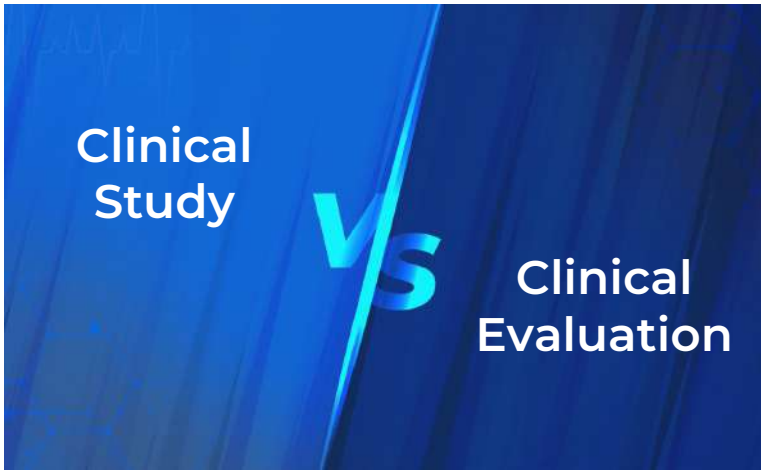

How Regulatory Compliance Automation Simplifies Medical Device Processes

Regulatory compliance automation transforms the medical device industry by streamlining workflows, reducing errors, and cutting compliance costs. By leveraging advanced tools, companies can enhance efficiency, improve data management, and ensure seamless adherence to evolving regulations like MDR, IVDR, and ISO 13485. Successful automation requires selecting the right tools, training teams, and maintaining human oversight to maximize benefits.

Want to optimize your regulatory processes? Contact Operon Strategist for expert guidance and take your compliance to the next level!

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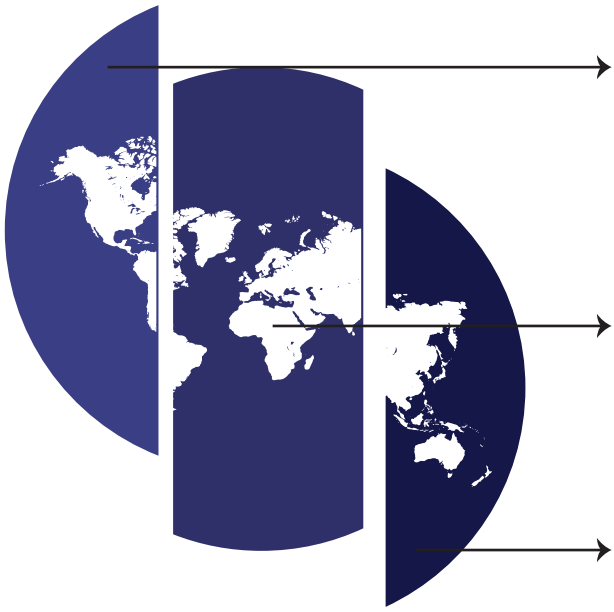
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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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