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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

Union Budget 2025: Major Boost to Healthcare

Modi's US Visit: India Plans Tariff Cuts on Medical and Surgical Equipment to Strengthen Healthcare Trade

NEW

Upcoming Events this Month

· Medical Fair India 2025

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Union Budget 2025: Major Boost to Healthcare

The Union Budget 2025-26 allocates ₹99,858 crore to healthcare, a 10% increase from last year. Key initiatives include ₹9,406 crore for Ayushman Bharat PM-JAY and ₹4,200 crore for health infrastructure. The government plans 200 cancer centers and 10,000 new medical seats next year. With health expenditure rising to ₹6.1 lakh crore, accessibility and affordability are improving. Operon Strategist supports healthcare organizations with regulatory approvals and manufacturing setup, aligning with government initiatives for a stronger healthcare system.

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Modi's US Visit: India Plans Tariff Cuts on Medical and Surgical Equipment to Strengthen Healthcare Trade

India is set to reduce tariffs on medical and surgical equipment as part of PM Modi's visit to the US, aiming to boost healthcare trade and innovation. This move will lower costs for Indian healthcare providers, improve access to advanced medical technologies, and strengthen collaboration with US-based firms. The tariff cuts are expected to attract investment, enhance medical research, and support regulatory cooperation, contributing to India's growing medical device sector and healthcare infrastructure.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India Now Produces CT, MRI, and Dialysis Machines Under PLI Schemes

India has started manufacturing CT scanners, MRI machines, and dialysis equipment under the PLI scheme, reducing dependence on imports. With a 44% budget increase for manufacturing incentives, the initiative also supports high-value drug production. The National Medical Devices Policy fosters innovation and strengthens India's global market presence. Operon Strategist assists manufacturers with regulatory compliance and production optimization under the PLI scheme.

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UK Tech and Life Sciences Firms Expand in India

UK businesses in tech and life sciences are expanding into India's fast-growing market, securing major deals and strengthening UK-India trade ties. Companies like Radio Design, Microfresh, and Novocuris are driving innovation in healthcare, education, and manufacturing. Operon supports regulatory compliance, supply chain optimization, and market localization, ensuring smooth market entry. Read more!

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Custom-Made Medical Devices: Regulations, Classification, and Challenges

Custom-made medical devices provide personalized healthcare solutions, from prosthetics to orthopedic implants, tailored to individual patient needs. Unlike mass-produced devices, they follow unique regulatory pathways, varying across regions like the EU, USA, India, Egypt, and South Africa. Challenges include compliance documentation, safety validation, and timely production. Operon Strategist assists manufacturers in navigating regulatory complexities, ensuring compliance with global standards, and streamlining documentation, registration, and risk management processes for seamless market entry.

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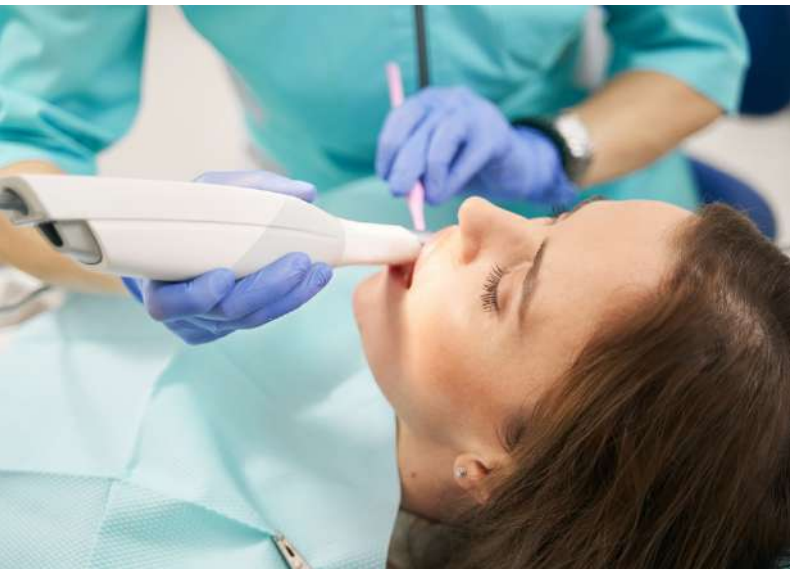

Dental Scanners Regulation Process: A Guide to Compliance

Bringing a dental scanner to market requires strict adherence to global regulatory standards, including FDA (USA), CE Marking (EU), and CDSCO (India). Compliance involves pre-market approvals, technical documentation, ISO 13485 QMS implementation, and ongoing post-market surveillance. Operon Strategist simplifies the process by assisting with regulatory submissions, risk management, and quality compliance, ensuring manufacturers achieve seamless market entry while maintaining safety and performance standards.

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FDA De Novo vs. US FDA 510(k): Choosing the Right Pathway for Your Medical Devices/IVDs

Choosing the right FDA regulatory pathway is crucial for medical device manufacturers. A 510(k) submission is used when a new device is substantially equivalent to an existing one, ensuring faster market entry. In contrast, the De Novo pathway applies to novel devices without a predicate, requiring a more detailed review but establishing a new regulatory classification. Operon Strategist helps manufacturers determine the right pathway, ensuring compliance and seamless market approval.

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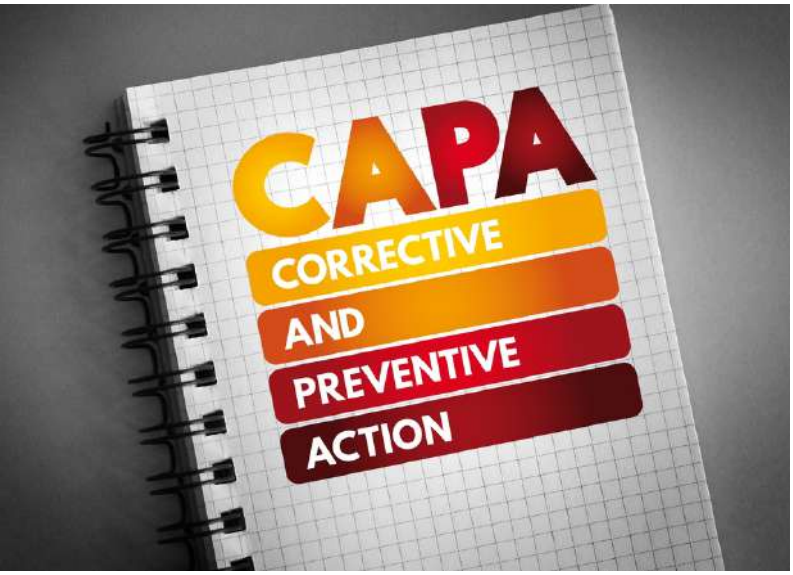

Correction vs Corrective Action vs Preventive Action: (CAPA) Differences and Best Practices

Correction, Corrective Action, and Preventive Action (CAPA) ensure quality and compliance in medical device manufacturing. Correction is an immediate fix, Corrective Action addresses root causes to prevent recurrence, and Preventive Action mitigates potential risks before issues arise. Effective CAPA implementation ensures compliance with ISO 13485, FDA 21 CFR Part 820, and EU MDR. Operon Strategist helps streamline CAPA processes for enhanced quality and efficiency.

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7 Expert Tips for Perfecting Your Technical File Medical Device Documentation

A well-structured Technical File is crucial for medical device compliance under MDR 2017/745. Poor documentation can lead to regulatory delays or market rejection. This guide covers essential files, traceability strategies, and best practices for keeping documentation up-to-date. Operon Strategist helps manufacturers create compliant, audit-ready Technical Documentation for smooth regulatory approval.

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4 Key Steps for a Smooth e-QMS Implementation

Implementing an electronic Quality Management System (e-QMS) helps medical device manufacturers enhance efficiency, ensure regulatory compliance, and improve quality control. A successful transition requires a dedicated team, careful planning, prioritization of critical documents, and continuous monitoring. Operon Strategist provides expert guidance to streamline e-QMS implementation, ensuring compliance and operational efficiency.

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Challenges and Solutions in Obtaining BIS Certification for Medical Devices

BIS certification is essential for medical device manufacturers entering the Indian market, ensuring compliance with safety and performance standards. However, navigating complex regulations, stringent testing, documentation hurdles, and high costs can be challenging. Non-compliance can lead to legal action, fines, and market exclusion. Operon Strategist simplifies the process by offering expert support in regulatory compliance, documentation, testing coordination, and cost optimization, ensuring a smooth and efficient certification journey. Learn more!

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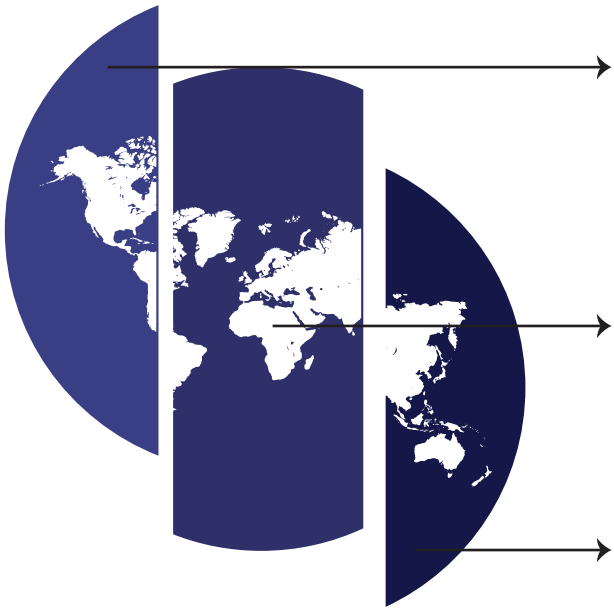
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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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