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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.

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LATEST NEWS & UPDATES

India Begins Manufacturing 44 Advanced Medical Devices, Including MRI Machines and Linear Accelerators

NEW

Upcoming Events this Month

· Asia Pacific Implant Society Conference 2025

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OPERON STRATEGIST

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India Begins Manufacturing 44 Advanced Medical Devices, Including MRI Machines and Linear Accelerators

India has begun manufacturing 44 advanced medical devices, including MRI machines, Linear Accelerators, and CT scanners, under the PLI scheme for medical device manufacturing. With a financial outlay of ₹3,420 crore, the initiative has already commissioned 19 greenfield projects, achieving ₹8,039.63 crore in cumulative sales and ₹3,844.01 crore in exports. Gujarat has emerged as a key player, hosting four greenfield projects.

Stay ahead with expert regulatory and manufacturing support, including ISO 13485, CE marking, and FDA approvals. Contact us today!

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Parliamentary Committee Urges Reforms in Testing and Regulation of Radiation-Emitting Medical Devices

A parliamentary committee has highlighted critical gaps in India's ability to test and regulate radiation-emitting medical devices, such as X-ray machines and MRI scanners. The report emphasizes the need to upgrade the National Testing House (NTH) with advanced infrastructure, expand geographical coverage, and invest in staff training. Key recommendations include establishing more testing centers nationwide and fostering collaborations with research institutions. Ensure compliance with expert guidance from Operon Strategist. Contact us today!

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Centre Amends MDR Notification, Includes Surgical, Medical Gloves; Designates 27 MDTOs

The Indian government has updated the Medical Devices Rules (MDR), officially classifying surgical and medical examination gloves as medical devices. The amendment also designates 27 Medical Device Testing Officers (MDTOs) across six laboratories, including CDTLs in Chennai, Kolkata, and Mumbai, to enhance regulatory oversight.

This change aims to improve quality control and compliance for gloves and other healthcare products, reinforcing safety standards in the medical device sector. Navigate regulatory changes with Operon Strategist. Contact us for expert guidance!

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India Advances Self-Reliance in MedTech: 19 Greenfield Projects Operationalized under PLI Scheme

India's PLI Scheme for medical devices has operationalized 19 greenfield projects, driving domestic production of high-value equipment like MRI machines, CT scanners, and linear accelerators. With a financial outlay of ₹3,420 crores and ₹1,057.47 crores in realized investments, the scheme has achieved cumulative sales of ₹8,039.63 crores, including ₹3,844.01 crores in exports.

This initiative, alongside PLI schemes for bulk drugs and pharmaceuticals, reflects India's commitment to reducing import reliance, fostering innovation, and creating a self-reliant MedTech ecosystem.

Explore opportunities in India's MedTech growth! Contact Operon Strategist today!

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India’s MedTech Industry Transforming into a Global Hub with Exports Surging to $3.8 Billion

India's MedTech industry is transforming into a global hub, with $3.8 billion in exports (2023-24) and a projected market size of $50 billion by 2030. Growth is driven by rising demand, healthcare initiatives like PM-JAY, and government support through the National Medical Device Policy and PLI schemes.
Leading segments include electronic equipment, disposables, and in-vitro diagnostics, bolstered by innovations in AI, digital health, and affordability. With a focus on manufacturing excellence and localization, India is set to expand its global market share. Explore opportunities in India’s MedTech market today!

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Delays in Clearing Imports Disrupt Medical Device Manufacturing in India

Prolonged import clearance delays for essential components are disrupting medical device production in India, affecting high-risk Class C and D devices like X-ray and C-Arm machines. Despite MD-9 certifications, manufacturers face additional MD-14 license demands, causing production delays of over three months and threatening the Make in India initiative.
Manufacturers urge streamlined processes, allowing imports under MD-9 certifications, clear policy guidelines, and improved customs coordination to mitigate these challenges. While the government emphasizes quality assurance, a balanced approach is needed to support timely manufacturing. Need help navigating regulatory challenges? Contact Operon Strategist today!

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Medical Device Import to Russia: Boosting Bilateral Trade Between India and Russia

Russia is seeking medical device imports from India, including ultrasound scanners and artificial body parts, to boost its healthcare sector. This presents a key opportunity for Indian exporters to reduce the trade deficit and strengthen economic ties. Operon Strategist aids this process by ensuring regulatory compliance and helping Indian manufacturers meet Russian import standards, facilitating smoother trade between the two countries.

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Top 5 Mistakes to Avoid During ISO 13485 Audits

Preparing for ISO 13485 audits is critical for ensuring compliance and avoiding costly delays. This blog highlights five common mistakes manufacturers make, including neglecting process risks, overlooking MDR requirements, and skipping root-cause analysis in CAPA. It provides actionable tips to address these pitfalls, such as aligning risk management practices with MDR Annex I and defining measurable criteria for trend reporting.

Streamline your compliance journey with expert guidance in QMS audits, risk management, and regulatory alignment. Contact us to ensure audit success!

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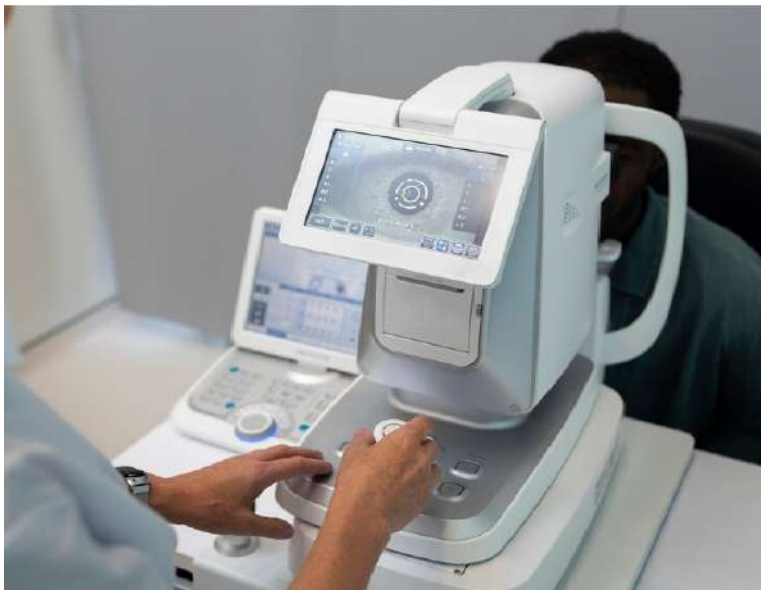
Scheme for Strengthening Medical Device Industry (SMDI): Unlocking India's Healthcare Potential



India's medical device sector is on a growth trajectory, powered by the Scheme for Strengthening Medical Device Industry (SMDI). This initiative aims to build a robust manufacturing ecosystem through financial assistance, infrastructure development, skill enhancement, and research support. Key highlights include incentives for common facilities, skill-building programs, and research funding to reduce import dependence and boost global competitiveness.
Leverage our expertise in regulatory compliance, manufacturing plant setup, and quality management to navigate this evolving landscape. Contact us today to accelerate your medical device business!

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Understanding the PRRC under EU MDR and IVDR

The EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) introduce the role of the Person Responsible for Regulatory Compliance (PRRC), crucial for ensuring regulatory adherence. This blog outlines the key responsibilities and qualifications required for a PRRC, including oversight of technical documentation, post-market surveillance, reporting obligations, and device conformity. It highlights the importance of the role in maintaining compliance across manufacturers and authorized representatives.
Get expert guidance on navigating EU MDR and IVDR requirements, including PRRC responsibilities, regulatory approvals, and compliance strategies for your medical devices. Contact Operon Strategist today for tailored solutions!

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Mastering PSUR Compliance: A Guide to Post-Market Surveillance for Medical Devices

The Periodic Safety Update Report (PSUR) is a crucial component of post-market surveillance under the EU Medical Device Regulation (MDR). This report ensures that devices remain safe and effective throughout their lifecycle by summarizing surveillance activities, corrective actions, and safety assessments. Manufacturers of Class IIa, IIb, and III devices are required to prepare and update PSURs regularly.

Key Compliance Tips:

- Clear data representation for each device.
- Unified PSUR schedules based on the leading device.
- Consistent review processes across devices within the same group.

Navigating PSUR requirements can be complex, but Operon Strategist offers expert guidance, helping manufacturers stay compliant and manage risk effectively.

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Medical Device Equivalence: A Key to Regulatory Success

In the blog Medical Device Equivalence: A Key to Regulatory Success, Operon Strategist explores the importance of equivalence in medical device regulation. Equivalence allows manufacturers to demonstrate that their device is comparable to an existing one in terms of safety, performance, and functionality, streamlining the approval process. However, strict adherence to regulatory guidelines is essential. The blog outlines the three pillars of equivalence—technical, biological, and clinical alignment—and highlights key requirements and challenges. Operon Strategist offers expert support in navigating these complexities, ensuring manufacturers meet regulatory requirements and achieve successful device approval.

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5 Key Insights for Effective Medical Device Market Research

In the blog 5 Key Insights for Effective Medical Device Market Research, Operon Strategist highlights essential tips for successful market research in the medical device industry. These include understanding the needs of all device users, targeting the right audience for specific research questions, using alternative methods for hospital-based research, ensuring healthcare professionals can identify devices correctly, and mapping the patient journey for better insights. Operon Strategist offers expert guidance in creating comprehensive research strategies to help manufacturers optimize their market research efforts and ensure a successful product launch.

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9 Effective Approaches to Navigate Challenges in the EU Medical Device Market Beyond 2025

In the blog 9 Effective Approaches to Navigate Challenges in the EU Medical Device Market Beyond 2025, Operon Strategist outlines key strategies to address challenges in the European medical device market. These include enhancing predictability and transparency in approvals, introducing conditional certification, promoting innovation-friendly pathways, and addressing notified body constraints. The blog also emphasizes harmonizing regulatory practices, supporting low-risk device manufacturers, embracing digital transformation, and advocating for legislative revisions. Operon Strategist provides expert guidance to help manufacturers navigate EU MDR and IVDR compliance, ensuring efficient market access and successful product launches.

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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.

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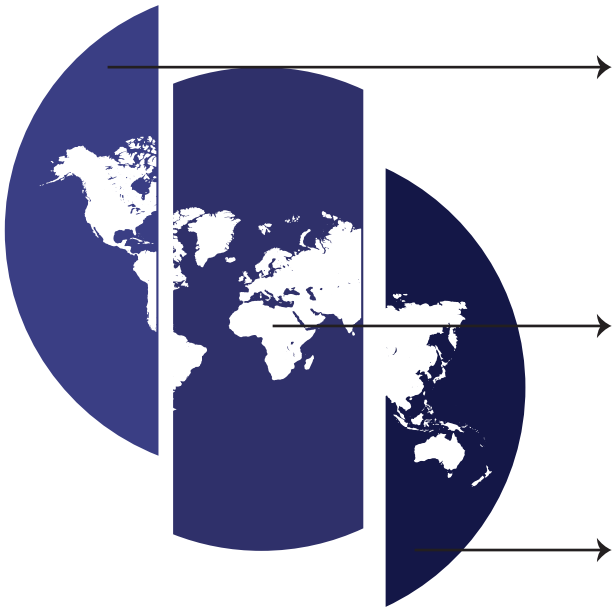

- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **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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