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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

Illegal Pathology Laboratories in Gujarat: A Growing Concern

Centre to Roll Out ₹1 Lakh Crore R and D Fund for Private Sector

NEW

Upcoming Events this Month

- India Med Expo (Hyderabad)
- Medical Expo (Lucknow)

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Illegal Pathology Laboratories in Gujarat: A Growing Concern

In Gujarat, around 10,000 pathology laboratories are allegedly operating illegally, often run by unqualified individuals instead of MD Pathologists as mandated by law. Despite a 2017 Supreme Court ruling that only MD Pathologists can sign lab reports, violations persist, especially in rural areas, posing significant health risks due to inaccurate diagnoses. Malpractices, such as using virtual signatures or displaying false credentials, are rampant. Efforts by the Gujarat Association of Pathologists and Microbiologists to address the issue have seen little response from authorities. The Lokayukta has sought detailed investigations, but administrative inaction continues to hinder progress.

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Centre to Roll Out ₹1 Lakh Crore R and D Fund for Private Sector

The Indian government is set to roll out a ₹1 lakh crore fund to enhance private sector R&D initiatives. Announced by Economic Affairs Secretary Ajay Seth, the fund aims to address low private investment in R&D despite tax incentives. Scheduled to launch in the coming months, the initiative encourages risk-sharing partnerships with private entities to foster large-scale innovation.

Originally proposed in the Interim Budget 2024-25 by Finance Minister Nirmala Sitharaman, this fund underscores India's commitment to advancing commercial R&D and innovation. Unlock growth opportunities with Operon Strategist!

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Indian MedTech Eyes US Market as Trump Targets Cost Cuts and Supply Chain Shifts

With Donald Trump back in office, Indian MedTech manufacturers are poised to benefit from shifting US policies, including high tariffs on Chinese medical devices and a focus on cost reduction. This opens doors for Indian suppliers to enter the US market, supported by Trump's pro-India stance and domestic initiatives to boost MedTech production.

Experts predict stable political conditions and deregulation efforts will further enhance healthcare accessibility in the US, creating significant opportunities for Indian manufacturers. Explore US market opportunities with Operon Strategist

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Government Launches Rs 500 Crore Scheme for Medical Device Industry Growth

The Indian Government has launched a Rs 500 crore scheme to boost the Medical Device Industry. Key focus areas include manufacturing, skill development, clinical studies, and infrastructure enhancement. Five sub-schemes will support R&D clusters, reduce import dependency, build workforce capacity, and promote innovation.

Industry leaders have welcomed this initiative, emphasizing its potential to strengthen India's MedTech sector, currently valued at $14 billion and expected to reach $30 billion by 2030. Unlock MedTech growth opportunities with Operon Strategist!

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Niti Aayog Promotes State-Private Sector Collaboration for Better Healthcare at FICCI Heal 2024

FICCI HEAL 2024 emphasized the importance of State-Private Sector Collaboration for better healthcare in India under the theme 'Swasth Bharat, Viksit Bharat.' Key discussions focused on advancing primary healthcare, women's cancer care, and healthcare education. Highlights included:

- Successful hub-and-spoke models for diagnostics boosting patient reach and test volumes.
- Innovations in telemedicine and AI to improve urban and rural healthcare access.
- Regulatory reforms in medical education to enhance future healthcare capacity.

The event showcased the potential of public-private partnerships to drive quality, accessibility, and innovation in India's healthcare sector.

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PM Modi Inaugurates 5 PLI Projects to Boost India's Medical Device and Drug Manufacturing

Prime Minister Narendra Modi inaugurated five PLI (Production Linked Incentive) projects and laid the foundation for four Centres of Excellence to strengthen India's capacity in medical devices, bulk drugs, and healthcare innovation. The event also saw the launch of India's largest Jan Aushadhi Kendra, offering affordable medicines. These initiatives aim to advance self-reliance and affordability in India's healthcare sector. Learn how these projects can benefit your business.

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Validate Pre-Validated Regulatory Software in Your Existing QMS

This blog explores whether pre-validated regulatory software needs further validation for integration into Quality Management Systems (QMS). While ISO 13485 mandates software validation, it doesn't explicitly address pre-validated or delta validation. Similarly, ISO/TR 80002-2 and other guidance documents remain unclear. A risk-based approach can help identify gaps in pre-validation and recommend tailored validation strategies. Opinions among auditors and regulatory bodies are inconsistent, emphasizing the need for organization-specific justifications. Operon Strategist aids medical device manufacturers by clarifying validation requirements, optimizing processes, and ensuring compliance with ISO and MDR standards through expert guidance and customized solutions.

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Why Should You Consider GSPR as a Foundation for Your Medical Device Project?

The General Safety and Performance Requirements (GSPR) outlined in the EU MDR 2017/745 are crucial for ensuring medical device compliance and safety. This blog highlights why GSPR should be central to your project planning, helping you avoid costly delays, ensure risk management, and streamline technical documentation. By integrating GSPR early in the development process, you align your device with the "state of the art," reduce compliance costs, and improve audit preparedness. Learn how GSPR can set your project up for regulatory success with expert guidance from Operon Strategist.

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A Complete Medical Device Strategy: Alignment Across the Entire Lifecycle

A successful medical device strategy extends beyond regulatory approval and CE marking, focusing on aligning each stage of the device lifecycle— from design to post-market surveillance (PMS)—around a central purpose: meeting safety, quality, and performance standards. This blog covers the essentials of lifecycle alignment, including risk management, clinical evaluation, usability engineering, and the importance of biocompatibility. By ensuring traceability and a favorable benefit-risk profile, manufacturers can enhance device reliability and patient safety. Optimize your device lifecycle strategy with expert guidance from Operon Strategist.

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Checklist for the Grant of Import License in Form MD-15 for Medical Devices Under Medical Devices Rules, 2017

Importing medical devices into India requires obtaining a Form MD-15 license under the Medical Devices Rules, 2017. This blog provides a detailed checklist for fresh applications, endorsement of additional devices, and license retention. Key requirements include Form MD-14 submission, regulatory and quality certificates, detailed technical documentation, and compliance with CDSCO guidelines. Streamline your import license process with Operon Strategist's expert regulatory guidance!

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Conformity Assessment Procedures for Medical Devices under EU MDR 2017/745

Entering the European medical device market requires compliance with EU MDR 2017/745, with conformity assessment as a critical step. This process involves risk classification, technical documentation, clinical evaluation, and, in many cases, third-party review by a notified body. Manufacturers must meet stringent safety, health, and performance standards to obtain CE marking, enabling free movement within the EEA.

Learn how Operon Strategist simplifies the pathway to CE marking with expert guidance on risk classification, technical documentation, and QMS implementation.

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Guidance to QMS Documentation to Meet ISO 13485:2016 Requirements

ISO 13485:2016 compliance is essential for medical device manufacturers to meet global quality standards and ensure safety and effectiveness. This guide highlights the key QMS documentation required, including Quality Manuals, SOPs, risk management records, and CAPA documentation. It also provides best practices such as adopting digital document control, regular training, and staying updated with evolving regulations. Partner with Operon Strategist for comprehensive support in QMS documentation, risk management, and ISO 13485 certification readiness.

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GLIMPSES OF THE MEDICA EXHIBITION

Successful visit to Medica Germany! We've made valuable connections, received incredible feedback, and are excited to drive the future of healthcare innovation.

Messe Dusseldorf, Düsseldorf, Germany

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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.

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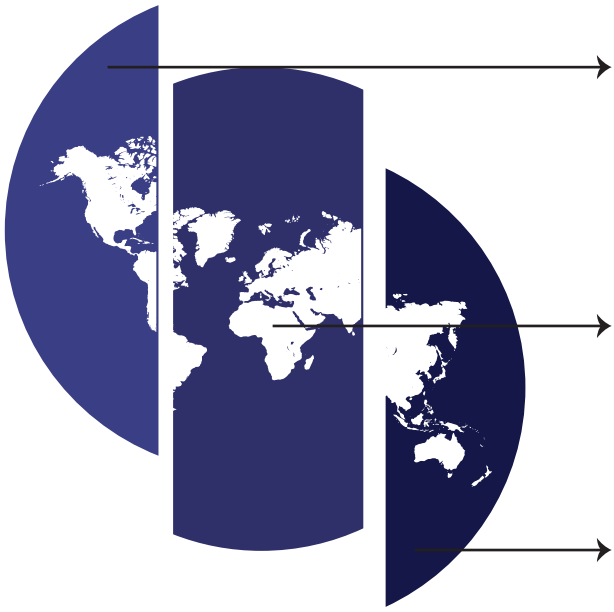

- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **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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