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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

Centre Releases Revised List of Refurbished Medical Equipment for High-End Imports

MDCG 2024-11: New Guidance on IVD Qualification

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

Centre Releases Revised List of Refurbished Medical Equipment for High-End Imports

The Union Ministry of Environment, Forest, and Climate Change (MoEFCC) has released a revised list of high-end refurbished medical equipment approved for import, including MRI, CT, PET-CT, and radiography devices. Import conditions require strict adherence to compliance and safety regulations, ensuring imported equipment meets quality standards and safety protocols. The policy has stirred industry concerns, with domestic manufacturers urging restrictions on such imports to protect local manufacturing growth and patient safety.

Need guidance on importing refurbished equipment? Operon Strategist assists with navigating regulatory requirements, ensuring compliant and efficient import processes. Reach out today!

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MDCG 2024-11: New Guidance on IVD Qualification

The Medical Device Coordination Group (MDCG) has published MDCG 2024-11, a new guidance document clarifying qualification criteria for in vitro diagnostic medical devices (IVDs) under the IVDR (EU) 2017/746. This updated guidance, replacing previous MEDDEV guidelines, introduces important clarifications, such as the inclusion of certain software as IVDs when used in diagnostic data analysis or clinical decision-making. Additionally, it specifies that tests used solely in production monitoring (e.g., for pharmaceuticals) are not classified as IVDs.

Need assistance with IVD qualification? Operon Strategist provides expert regulatory guidance to streamline your IVD compliance with the latest MDCG requirements. Contact us to learn more!

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India Rejects Clinical Trial Waivers for In-Vitro Diagnostics Despite International Approvals

The Indian government has rejected clinical trial waivers for In-Vitro Diagnostics (IVDs), even if these devices are approved in other countries. The Drugs Technical Advisory Board (DTAB) emphasized the need for local performance assessments due to unique biological and environmental factors. This decision reinforces India's commitment to ensuring diagnostic efficacy. Operon Strategist is available to assist manufacturers in navigating regulatory compliance for IVDs in India. Need help with IVD compliance? Contact Operon Strategist today!

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EU Urges Urgent MDR and IVDR Revision for Innovation and SMEs

The European Parliament has adopted a resolution highlighting the urgent need to revise the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). The resolution aims to alleviate challenges faced by the medical device industry by balancing innovation and patient safety. Key proposals include reducing administrative burdens, supporting small and medium-sized enterprises (SMEs), streamlining product re-certification processes, and ensuring transparency in notified body fees. It also emphasizes fast-tracking approval for innovative technologies and expanding the MDR framework to include e-health applications. The European Commission is expected to present actionable solutions by Q1 2025.
Contact us to learn more!

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

MvPI Releases Updated Version of Medical Devices Adverse Event Reporting Form

The Materiovigilance Programme of India (MvPI) has released an updated adverse event reporting form for medical device stakeholders, including manufacturers, importers, and healthcare professionals. This revision aims to streamline the reporting process and enhance the timely identification of adverse events. The form requires detailed information about the device, its classification, and the nature of the adverse event. Confidentiality is assured for both patients and reporters. Operon Strategist is ready to assist companies in complying with these new reporting requirements and setting up effective post-market surveillance systems.

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PLI Investments to Hit ₹2 Lakh Crore: MedTech Gains from Tech Transfers

The Production Linked Incentive (PLI) Scheme is projected to drive investments in India to ₹2 lakh crore by next year, up from ₹1.46 lakh crore as of August 2024. Announced by Minister Piyush Goyal, this initiative has already generated substantial growth across key sectors, including medical devices, electronics, and pharmaceuticals. The medtech industry, in particular, benefits from technology transfers that enhance local production capabilities and reduce reliance on imports. The government remains committed to supporting industry stakeholders with streamlined approvals and greater market access.
Looking for support in the MedTech sector? Contact Operon Strategist for expert regulatory consultancy!

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TO KNOW MORE

Comprehensive Guide to Setting Up an IVD Manufacturing Plant

Setting up an In Vitro Diagnostics (IVD) manufacturing plant requires strategic planning, regulatory adherence, and expert guidance. Our latest blog covers the essentials, from initial investment estimates (7–15 Crores) and recommended plant size (6500–15000 sq. ft.) to the primary segments like clinical chemistry, hematology, and microbiology. We also outline compliance requirements for regulatory bodies such as CDSCO (India), CE Marking (Europe), and US FDA. With Operon Strategist's expertise in regulatory filings, plant design, and turnkey solutions, establishing your IVD unit can be seamless and efficient.
Ready to get started? Discover how we can assist in every step of the process!

READ MORE

How to Sell Medical Devices in European Countries: A Step-by-Step Guidance

Navigating the European market for medical devices can be complex, with strict regulations like the EU MDR and EU IVDR shaping the pathway to successful market entry. This blog offers a clear, step-by-step guide on classifying your product, identifying key regulations, meeting quality and technical documentation requirements, appointing an EU Authorized Representative, and completing necessary registrations. Finally, it emphasizes the importance of post-market surveillance to maintain compliance. For expert guidance on achieving a smooth entry into Europe's regulated market, turn to Operon Strategist for support.
Ready to expand into Europe? Get in touch to learn how we can help!

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Understanding the Creation of a Declaration of Conformity (DoC) for Medical Devices

A Declaration of Conformity (DoC) is a legally binding document that certifies a medical device's compliance with the EU Medical Device Regulation (MDR). Essential for market entry in Europe, the DoC outlines key information, including device identification, conformity assessment procedures, harmonized standards, and more. Errors in the DoC can result in legal challenges or market delays, making accuracy crucial. Operon Strategist simplifies the DoC creation process by guiding manufacturers through the regulatory requirements, documentation, and Notified Body coordination, ensuring a smooth path to EU market entry. Need expert help with your DoC? Contact Operon Strategist today!

READ MORE

7 Must-Have QMS SOPs Every Medical Device Start-up Needs to Implement Early

Building a solid Quality Management System (QMS) is essential for medical device start-ups aiming to ensure regulatory compliance and operational efficiency. This blog highlights the seven crucial Standard Operating Procedures (SOPs) every start-up should prioritize, including Design and Development, Document Control, Risk Management, and Supplier Approval. Implementing these SOPs early can help streamline processes, maintain quality, and ensure audit readiness.

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FDA Regulatory Pathways for New Medical Devices (Innovative): Navigating 510(k), De Novo and PMA Processes

For medical device manufacturers eyeing the U.S. market, understanding FDA regulatory pathways—510(k), De Novo, and PMA—is essential for a smooth product launch. This blog explores each pathway, from 510(k) for devices with existing predicates, De Novo for innovative, moderate-risk devices, to PMA for high-risk products requiring extensive clinical data. Manufacturers can also leverage pre-submission meetings with the FDA for guidance on regulatory expectations.
To know more Contact us today!

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Understanding of Harmonized Standards: Your Guidance to European CE Marking Compliance

Ensuring compliance with European CE marking standards is critical for medical device manufacturers entering the EU market. This blog explains how harmonized standards streamline the process, ensuring safety, effectiveness, and quicker market access. These standards, developed by European bodies, offer a path to demonstrating product quality while reducing regulatory risks and delays.
Need help with CE marking? Operon Strategist provides expert guidance through the compliance process, helping you meet regulatory standards efficiently. Reach out today to simplify your CE marking journey!

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Medical Device Cybersecurity Practices: Essential Steps for Device Safety

As Medical Devices become increasingly connected, safeguarding them against cyber threats is crucial to protect patient safety and data integrity. This blog highlights key steps and best practices for medical device cybersecurity, from initial planning and secure development to ongoing monitoring and updates. With the FDA's emphasis on cybersecurity, implementing these measures is essential for regulatory compliance and device resilience.
Looking for expert guidance? Operon Strategist provides specialized consulting to help manufacturers integrate cybersecurity practices, ensuring regulatory compliance and enhanced device security. Reach out today for support!

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How to Nail GSPR Compliances For Medical Devices: A Complete Guidance

Ensuring General Safety and Performance Requirements (GSPR) compliance is crucial for medical device manufacturers seeking EU MDR approval. This guide outlines a structured approach to GSPR documentation, from determining each requirement's applicability to providing clear compliance evidence. Key tips include using a traceability matrix, selecting state-of-the-art standards, and organizing documentation early in the development process. Operon Strategist's GSPR template further simplifies compliance, providing a checklist of evidence and a step-by-step guide.

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GLIMPSES OF THE GLOBAL HEALTH EXHIBITION

Thrilled to announce the amazing response we received at The Global Health Exhibition in Saudi Arabia 2024! Our commitment to innovation and collaboration in healthcare is stronger than ever. Thank you to everyone who visited our booth and shared in our vision for a healthier future!

Global Health Exhibition

Malham, Riyadh, Saudi Arabia

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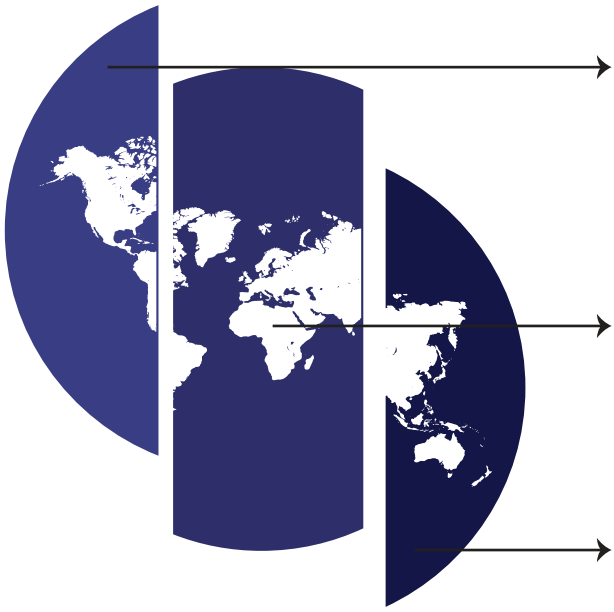
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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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