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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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Transforming Thoughts In To Reality

LATEST NEWS & UPDATES

MHRA to Recognize Medical Devices from EU, US, Canada, and Australia

NEW

Upcoming Events this Month

FIME, Florida,Miami | India Health 2024

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

MHRA to Recognize Medical Devices from EU, US, Canada, and Australia

On May 21, 2024, the Medicines and Healthcare products Regulatory Agency (MHRA) announced it will recognize medical devices that meet regulations in the EU, US, Canada, and Australia, streamlining the process for UK market entry. Manufacturers must comply with applicable laws, UK post-market surveillance, English labeling, and other standards to qualify for "certification of international recognition." Four pathways to UK market access include recognition and self-registration, reliance on CE Certificates, device-specific requirements, and abridged assessments. The MHRA aims to finalize this by 2025, allowing a transition period for existing UKCA mark holders. For expert guidance on navigating these new regulations, contact Operon Strategist.

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Medical Device News

CDSCO Urges Medical Device Firms to Pay Retention Fees to Avoid License Cancellations

The Central Drugs Standard Control Organisation (CDSCO) has issued a crucial reminder to medical device companies to ensure timely payment of retention fees to maintain their licenses and registration certificates under the Medical Devices Rules (MDR), 2017. Failure to pay these fees on time can result in the suspension or cancellation of approvals. Although licenses and certificates are issued indefinitely, their validity depends on the punctual payment of fees every five years. Companies are urged to comply with these regulations to avoid disruptions in their operations. For expert guidance on navigating CDSCO regulations, contact Operon Strategist.

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MEDICAL DEVICES REGULATORY UPDATES

Continuation of Import and Manufacturing for Class C & D Medical Devices: Regulatory Update

The Ministry of Health and Family Welfare (MoHFW) has announced that Class C & D medical devices will require licensing from October 1, 2023, as per notification S.O. 648 (E) and G.S.R. 102 (E). To prevent business disruptions, existing importers or manufacturers who apply for an import or manufacturing license by September 30, 2023, can continue their operations for up to three months from the order issuance date or until the Central Licensing Authority makes a decision on their application. For expert consultation on CDSCO import and manufacturing licensing, contact Operon Strategist.

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Indian Government Strengthens Medical Device Safety with New Reporting Mandate

On May 15, 2024, the Ministry of Health & Family Welfare issued a new circular mandating all medical device license holders to establish robust systems for adverse event reporting. This initiative, overseen by the Central Drugs Standard Control Organization (CDSCO), emphasizes Post-Market Surveillance (PMS) to ensure the safety and performance of medical devices. The Materiovigilance Programme of India (MvPI) will play a key role in monitoring and analyzing adverse events. License holders are encouraged to access guidance documents and training via the IPC website. For expert compliance guidance, contact Operon Strategist.

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MEDICAL DEVICES REGULATORY UPDATES

Testing and Evaluation of Medical Devices and IVDs – CDSCO Circular

The Ministry of Health and Family Welfare, Government of India, has mandated that registered laboratories conduct quality, safety, and performance tests for Medical Devices (MDs) and In Vitro Diagnostics (IVDs) under Chapter X of the Medical Device Rules (MDR) 2017, effective since January 1, 2018. These rules supersede the Drug Rules 1945 for MDs and IVDs. Medical devices must comply with standards set by the Bureau of Indian Standards (BIS) or, if unavailable, international standards such as ISO or IEC. However, it has been noted that some devices are not tested according to available BIS standards. Ensuring compliance with BIS standards is essential for maintaining device quality and performance. For expert guidance through the regulatory landscape, consider partnering with Operon Strategist for professional consulting services to ensure your products meet regulatory requirements efficiently. Contact us to learn more about how we can support your regulatory needs.

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The Essential Role of Plastic Molding in Disposable Medical Devices

Disposable medical devices are vital for modern healthcare, providing safety and preventing infections. This blog explores the importance of plastic molding in manufacturing these devices, emphasizing its precision, cost-effectiveness, and versatility. It also covers common molding techniques like injection molding and blow molding. Additionally, it highlights the critical role of regulatory compliance, with guidance on navigating the complex requirements from global regulatory bodies. Operon Strategist offers expert consultation services to help manufacturers achieve compliance and market success. Contact Operon Strategist for Expert Medical Device Regulatory Consultation.

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Navigating 21 CFR Part 820: Compliance and Requirements for Medical Device Manufacturers.

Explore the essential requirements of 21 CFR Part 820, also known as the Quality System Regulation (QSR), established by the FDA. This comprehensive guide covers key sections such as quality system requirements, design controls, document controls, and more. Learn how adhering to these regulations ensures the safety, effectiveness, and compliance of medical devices in the United States. Contact Operon Strategist for Expert Guidance on 21 CFR Part 820 Compliance.

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Disposable Plastic Syringe Registration Process (USFDA, European CE, SFDA and Other Regulatory Countries)

Discover the intricate world of disposable plastic syringe registration across major regulatory frameworks. From the USFDA's 510(k) submissions to CE marking under EU MDR and beyond, this blog explores the essential steps and requirements for market entry. Learn about the materials, manufacturing processes, and quality control measures that ensure these vital medical devices meet global safety and efficacy standards. Contact Operon Strategist for Expert Consultation on Medical Device Registration.

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The Essential Requirements for Software as a Medical Device (SaMD Compliance)

Developing Software as a Medical Device (SaMD) requires strict adherence to regulatory and risk management standards to ensure safety and efficacy. Regulatory bodies like the FDA and IMDRF guide SaMD classification and compliance with standards such as 21 CFR Part 820, ISO 14971, and IEC 62304. Embracing Quality Management Systems (QMS) is crucial for developing impactful SaMD solutions that transform patient outcomes. Contact Operon Strategist to Streamline Your SaMD Compliance Journey.

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Understanding Technology Transfer in Medical Devices

Technology transfer in medical devices involves transitioning intellectual property, design specs, manufacturing processes, and regulatory documents from R&D to production. This accelerates innovation, market expansion, cost-efficiency, compliance, and quality. Key phases include preparation, installation, and utilization, focusing on Quality Management Systems, consistent manufacturing, regulatory submissions, and post-market surveillance. Overcoming challenges like IP protection and regulatory hurdles requires early stakeholder engagement, clear communication, risk management, and continuous improvement. Operon Strategist offers expert consultation for seamless technology transfer and compliance, driving innovation and enhancing global healthcare.

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Top 10 Tips for Medical Device Assembly Quality Control

Ensure top-quality medical device assembly with these expert tips: Maintain meticulous documentation and supplier evaluation for compliance and integrity. Implement robust component traceability and rigorous process validation for reliability. Use effective inspection techniques and automated error detection for efficiency. Invest in comprehensive training and proactive nonconformance handling for consistent quality. Foster continuous improvement and proactive risk management to drive excellence. Elevate your assembly process with Operon Strategist's tailored solutions. Contact us now for regulatory consulting and quality management services.

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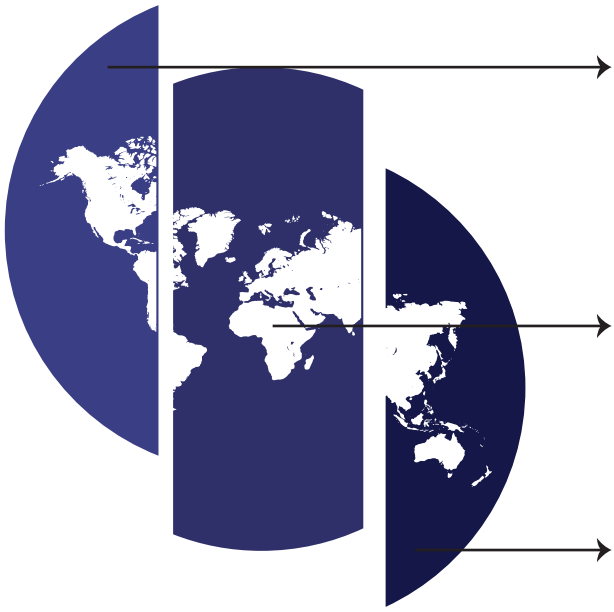
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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

For more details regarding licence process and regulatory services .

enquiry@operonstrategist.com

+91-9370283428

Office No.14, 4th Floor, MSR capital,
Morwadi, Pimpri, Pune 411 018