VOL.NO. 03 | ISSUE-06 | SEPTEMBER-2024

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

India's First Center of Excellence in Medical Devices to be Established at IIT BHU Varanasi

Government to Launch New Scheme for Boosting Domestic Medical Device Industry

NEW

Upcoming Events this Month

· MEDICALL (Delhi)

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India's First Center of Excellence in Medical Devices to be Established at IIT BHU Varanasi

India's first Center of Excellence in Medical Devices is being established at IIT BHU Varanasi, focusing on E-mobility and biomedical devices. This pioneering initiative will unify medical device production under one roof and involve collaboration among multiple departments. IIT BHU Director, Professor Amit Patra, highlighted the project's impact and investor support, with plans to significantly expand faculty. Operon Strategist provides regulatory consulting and turnkey project management for the development of medical devices.

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Government to Launch New Scheme for Boosting Domestic Medical Device Industry

India will launch a new scheme next month to strengthen the domestic medical device industry, announced Secretary Arunish Chawla. The scheme, designed to reduce import reliance and support self-reliance, follows successful initiatives like the Production Linked Incentive (PLI) scheme. Operon Strategist will support manufacturers with regulatory consulting and plant setup to help them meet both national and international standards.

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TO KNOW MORE

Mandatory BIS Certification for Medical Textile Products: Ensuring Compliance and Quality

The Bureau of Indian Standards (BIS) has mandated that medical textile products, including surgical gowns and bandages, must obtain BIS certification under the Medical Textiles (Quality Control) Order, 2023. G. Bhavani from BIS emphasized the need for timely licensing and adherence to Indian standards. Meenakshi Ganesan outlined the wide range of medical textiles essential for healthcare. Operon Strategist provides expert guidance on compliance and certification, helping manufacturers meet regulatory standards efficiently.

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India to Introduce 20% Capital Subsidy for Domestic MedTech Component Production

India is set to launch a 20% capital subsidy scheme to encourage domestic manufacturing of MedTech components, including parts for digital X-ray, CT scan, and MRI machines. This move aims to reduce reliance on imports and lower the cost of medical imaging devices. Operon Strategist, a leading medical device regulatory consulting firm, is poised to help manufacturers navigate the regulatory landscape and capitalize on this new opportunity.

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ISO 14644 Clean Room Validation: Essential Tests and Best Practices

Ensuring your clean room meets ISO 14644 standards is crucial for the safe production of sterile medical devices. This blog outlines the essential tests required for clean room validation, including airborne particle concentration, HEPA filter leakage, air pressure differential, and more. Learn best practices for maintaining optimal cleanliness and sterility in your clean room environment. Operon Strategist offers expert consultation and comprehensive support to guide you through the complexities of clean room validation, ensuring full compliance with ISO 14644 standards. Contact us today to ensure your clean room is validated and compliant.

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Understanding CDSCO MD 7 and MD 9: Process and Regulatory Compliance

Understanding and complying with CDSCO MD 7 and MD 9 is essential for medical device manufacturers in India. This blog explores the classification of medical devices, the process of obtaining a manufacturing license, and the importance of adhering to regulatory frameworks. With expertise in regulatory compliance and turnkey project consulting, Operon Strategist offers comprehensive support to ensure your devices meet Indian standards, facilitating a smooth market entry. Whether setting up a new manufacturing plant or navigating the regulatory landscape, Operon Strategist is your trusted partner for success.

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The Necessity of ISO 13485 Certification for Class A and B Medical Devices

ISO 13485 certification plays a crucial role in ensuring the quality and regulatory compliance of Class A and B medical devices, although it is not always mandatory. This blog discusses the importance of implementing an ISO 13485-compliant Quality Management System (QMS) to strengthen CDSCO Form MD 7 applications and streamline the approval process. Operon Strategist offers expert consulting services to help manufacturers navigate these regulatory requirements, ensuring successful market entry for their devices.

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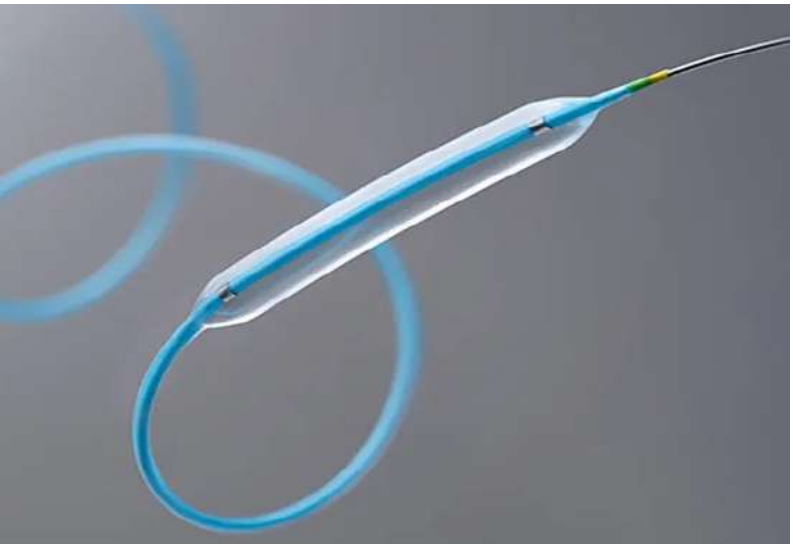

US FDA 510(k) Approval for Balloon Catheters

Balloon catheters are crucial medical devices used in various therapeutic procedures. This blog provides an overview of the essential documentation and testing requirements for obtaining US FDA 510(k) approval for balloon catheters. It highlights the importance of biocompatibility and performance testing, as well as the specific classifications under which balloon catheters fall. Operon Strategist offers expert guidance throughout the 510(k) submission process, helping manufacturers ensure compliance and secure approval for their devices efficiently.

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Innovative Technologies in Medical Device Manufacturing: Shaping the Future of Healthcare

In this blog, we explore how innovative technologies are transforming medical device manufacturing, driving efficiency, quality, and patient outcomes. From collaborative robotics and AI-powered analytics to automated packaging solutions and IoMT-enabled devices, these advancements are revolutionizing the industry. The blog highlights how these technologies help manufacturers meet growing demands while reducing costs and time-to-market. Operon Strategist is at the forefront, providing expert regulatory consulting services to ensure seamless integration of these innovations into compliant manufacturing processes. Discover how technology is shaping the future of healthcare.

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How to Manage the Design and Development of Medical Devices According to ISO 13485:2016

This blog delves into the critical process of managing the design and development of medical devices in compliance with ISO 13485:2016. It outlines key requirements, including documented procedures, design planning, verification, validation, and control of design changes. By adhering to these standards, manufacturers can ensure regulatory compliance, enhance patient safety, and deliver high-quality products to market. Operon Strategist offers expert guidance to navigate these complexities, helping you streamline processes and achieve successful regulatory approval. Learn more about elevating your medical device development with ISO 13485:2016.

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Right time to Submit USFDA 510(k): Timing Your FDA Application Strategically

This blog highlights the importance of timing in the USFDA 510(k) submission process, a crucial step for medical device manufacturers aiming to enter the U.S. market. It covers the benefits of early and accurate submissions, including gaining a competitive edge, ensuring efficient review, and achieving swift market approval. The blog also explains when a 510(k) is required, how to identify predicate devices and key differences between 510(k) and PMA processes. For manufacturers seeking expert guidance in navigating this complex process, Operon Strategist offers specialized support to ensure successful compliance with USFDA requirements.

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USFDA Releases New Guidance on AI in Medical Products

On March 15, the FDA unveiled a strategy for incorporating artificial intelligence (AI) into medical products, detailing collaboration among its centers and priorities such as fostering public health, advancing regulatory approaches, and supporting AI research. The strategy aims to enhance innovation while ensuring safety through standards, guidelines, and international cooperation. Operon Strategist offers regulatory guidance, helps navigate FDA frameworks, and ensures quality and ethical AI use in medical devices, supporting manufacturers in this evolving field.

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Medical Device News

Artificial Intelligence in Medical Devices

Artificial intelligence (AI) is revolutionizing the medical devices industry, driving innovation, enhancing diagnostic accuracy, and improving patient outcomes. From data management and manufacturing efficiency to remote surgery and telemedicine, AI is becoming an integral part of healthcare. As regulatory bodies like the FDA accelerate approvals for AI-driven devices, the future holds even greater promise for AI in medical devices. Explore how AI is shaping the next generation of healthcare and learn how Operon Strategist can help navigate the regulatory landscape for your AI-driven medical devices. Contact us today!

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GLIMPSES OF 8th ANNUAL SUMMIT

8th Annual MEDICAL DEVICE REGULATORY AND QUALITY SUMMIT 2024
22nd - 23rd AUGUST 2024

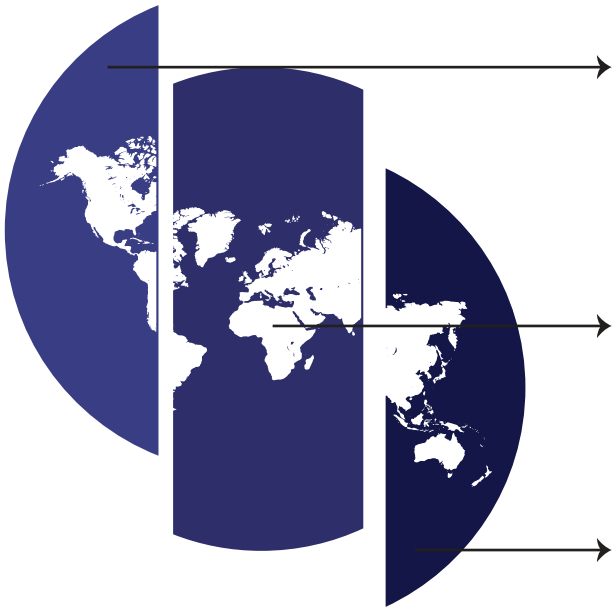
Attended the Live-in Session of the 8th Annual Medical Device Regulatory & Quality Summit 2024 on 22nd August 2024, to share our experience as a pane list
It was an honour to share our knowledge and insights on the changing role of regulatory affairs in the medical device manufacturing industry with such an engaged audience. Learned many things from our fellow pane lists and attendees, and we're excited to see how the industry continues to evolve in the years to come.

REGUVEDA

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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