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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

DGFT Empowers EPC to Issue Export Certificates for Medical Devices

MDSAP vs. ISO 13485: What's the Difference?

NEW

Upcoming Events this Month

MEDITECH - International Health Fair 2024

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

DGFT Empowers EPC to Issue Export Certificates for Medical Devices

Operon Strategist's latest update highlights a significant boost for India's medical device exporters. The DGFT has empowered the Export Promotion Council for Medical Devices to issue Registration-Cum-Membership Certificates (RCMC), easing export procedures and enhancing global competitiveness. Effective from June 23, 2023, this directive addresses key challenges faced by exporters under the RODTEP scheme, ensuring continuity with existing RCMCs issued by EEPC India. This initiative is set to propel India's medical device industry towards a projected growth to $50 billion by 2030, solidifying its position as a leading global manufacturing hub. Contact Operon Strategist today to explore how these regulatory advancements can optimize your export opportunities.

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Diagnostic Kit Manufacturing and Regulatory Compliance

The diagnostic kit industry is booming, driven by biotech advancements and a focus on accessible healthcare. This blog delves into the meticulous process of manufacturing diagnostic kits, including R&D, validation, and large-scale production, emphasizing the importance of high-quality standards and robust QC measures. It also highlights the stringent regulatory landscape, covering pre-market approvals, QMS, and post-market surveillance required by agencies like the FDA and EMA. Partnering with Operon4 Strategist can help manufacturers navigate these complexities, ensuring their products are safe, effective, and compliant, ultimately enhancing global health outcomes. Contact us for expert guidance on your diagnostic kit journey.

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A Comprehensive Guide to Ophthalmic Imaging Devices Manufacturing and Regulatory Compliance

Ophthalmic imaging devices have transformed eye care with advanced diagnostic capabilities. This blog details the meticulous manufacturing process, from R&D to quality control, and emphasizes the importance of regulatory compliance. Key regulations from agencies like the FDA, MDR, and CDSCO must be navigated to ensure device safety and efficacy. Operon Strategist offers expert guidance to help manufacturers meet these stringent standards, providing support with regulatory pathways, documentation, and quality management systems. Partner with Operon Strategist to ensure your ophthalmic imaging devices comply with global regulations and reach the market successfully. Contact us for more information.

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MDSAP vs. ISO 13485: What's the Difference?

Understanding the differences between ISO 13485 and the Medical Device Single Audit Program (MDSAP) is crucial for medical device manufacturers. ISO 13485 is an internationally recognized standard for quality management systems, focusing on consistent quality and regulatory compliance. In contrast, MDSAP streamlines regulatory audits across multiple countries through a single, comprehensive audit, reducing the need for multiple separate audits. Both standards are essential for ensuring the safety and effectiveness of medical devices and enhancing global market access. Operon Strategist offers expert guidance to help manufacturers navigate these complex compliance processes. Contact us to learn more about how we can support your regulatory needs.

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The Future of Dental Care: Dental Scanners Manufacturing and Ensuring Regulatory Compliance

Ophthalmic imaging devices have transformed eye care with advanced diagnostic capabilities. This blog details the meticulous manufacturing process, from R&D to quality control, and emphasizes the importance of regulatory compliance. Key regulations from agencies like the FDA, MDR, and CDSCO must be navigated to ensure device safety and efficacy. Operon Strategist offers expert guidance to help manufacturers meet these stringent standards, providing support with regulatory pathways, documentation, and quality management systems. Partner with Operon Strategist to ensure your ophthalmic imaging devices comply with global regulations and reach the market successfully. Contact us for more information.

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A Comprehensive Guide to Cybersecurity for Medical Devices and IVDs

Ensuring cybersecurity for medical devices and in vitro diagnostic devices (IVDs) is critical for regulatory compliance, patient safety, data privacy, and financial stability. With stringent regulations from bodies like the FDA and the European Commission, manufacturers must implement robust security measures throughout the device lifecycle. At Operon Strategist, we specialize in navigating these complex regulatory landscapes and implementing effective cybersecurity strategies. Protect your medical devices and IVDs from cyber threats, ensure compliance with global standards, and safeguard your business. Contact us today to learn how we can support your cybersecurity needs.

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From Design to Approval: The Journey of Breathing Apparatus Manufacturing with Operon Strategist

Breathing apparatuses play a crucial role in various industries, ensuring respiratory protection for workers in hazardous environments and supporting medical interventions. Manufacturing these devices requires adherence to strict regulatory standards to guarantee their safety, efficacy, and reliability. In this blog post, we explore the manufacturing process of breathing apparatuses and delve into the regulatory compliance landscape that governs their production.

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Intraocular Lenses Manufacturing Consultant

Operon Strategist's latest blog dives into the intricate world of manufacturing intraocular lenses (IOLs), essential for treating cataracts and correcting vision. Highlighting the stringent regulatory requirements from CDSCO in India to FDA 510(k) in the US and CE marking in the EU, the blog emphasizes the meticulous process of material selection, lens design, fabrication, and quality control in IOL manufacturing. Operon Strategist offers expert guidance in regulatory compliance, optimizing manufacturing processes, and setting up medical device facilities, ensuring seamless navigation through global standards for IOL production. Contact us today to explore how we can support your journey in the evolving field of medical devices.

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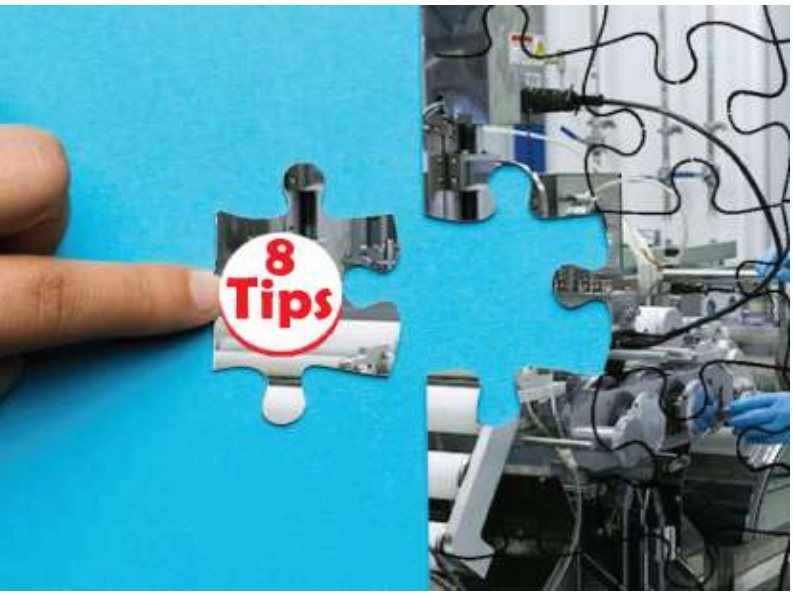

8 Essential Tips to Start Medical Device Startup Company

Are you ready to launch a medical device startup? Operon Strategist's latest blog offers essential tips for success in this dynamic industry. From identifying critical healthcare needs to navigating regulatory compliance and securing strategic funding, each step is crucial. Building a diverse team, creating prototypes, and developing a comprehensive go-to-market strategy are essential for success. Operon Strategist provides expert guidance in regulatory compliance, market entry, and manufacturing, ensuring your journey from concept to market is smooth and successful. Contact us today to discover how we can support your medical device startup ambitions.

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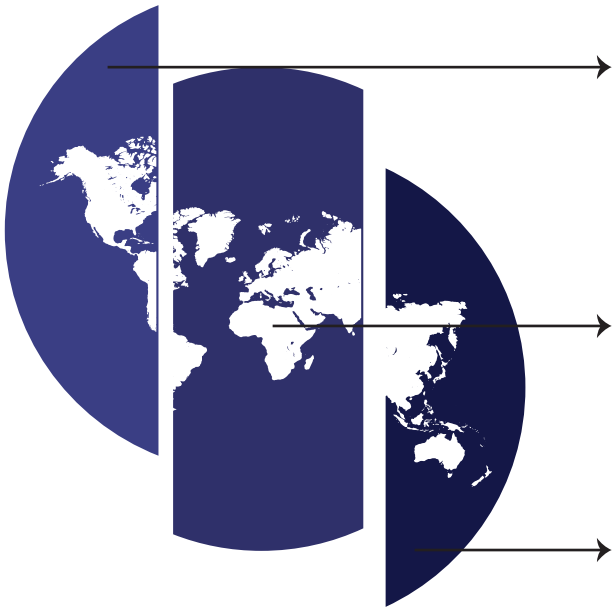
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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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