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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

Government Launches NSWS Portal to Simplify Medical Devices Approvals

GeM Portal Enables Direct Selling to Government: Over 300 Medical Device Manufacturers Join the Initiative

European Commission Proposes Extensions for IVDs and EUDAMED

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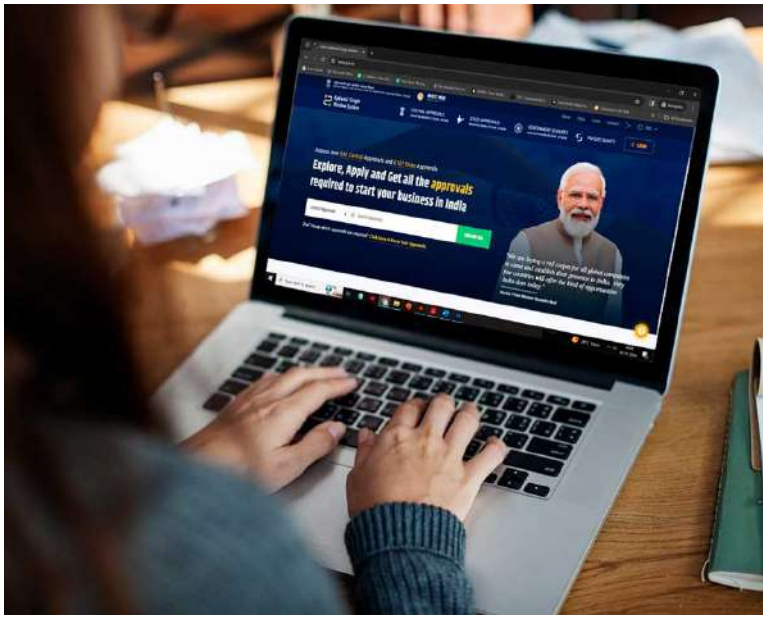
MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Government Launches NSWS Portal to Simplify Medical Devices Approvals



India's Directorate General of Health Services has launched the National Single Window System (NSWS) Portal to simplify and streamline the approval process for the medical devices sector. Developed in collaboration with TCS and led by Invest India, the NSWS portal operates independently from existing platforms like SUGAM and cdscomdonline. The portal, active from January 1, 2024, offers a streamlined process for obtaining approvals, licenses, and registrations in the medical devices industry. Stakeholders are encouraged to transition to the NSWS portal, as the existing cdscomdonline portal will be deactivated from January 15, 2024.

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Medical Device News

GeM Portal Enables Direct Selling to Government: Over 300 Medical Device Manufacturers Join the Initiative

Government eMarketplace (GeM), the public procurement platform under the Commerce Ministry, has recently inked a memorandum of understanding (MoU) with the Association of Indian Manufacturers of Medical Devices (AiMeD). The collaboration aims to enable AiMeD's members to directly sell their products to the government through the GeM portal.

GeM announced the partnership to facilitate the seamless integration of over 300 medical device manufacturers associated with AiMeD onto the public procurement portal. This move is anticipated to establish direct market linkages between manufacturers and government buyers across India, eliminating intermediaries.

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European Commission Proposes Extensions for IVDs and EUDAMED

The European Commission has proposed extensions for In Vitro Diagnostics (IVDs) and the EUDAMED database to address critical concerns. The proposal aims to extend transition periods for specific high-risk IVDs, such as those used in blood and organ donation testing, to mitigate the risk of shortages. Additionally, the proposal advocates for a gradual roll-out of the EUDAMED electronic systems, providing comprehensive information on devices in the EU market and improving monitoring of device availability. Manufacturers may be required to give prior notice before interrupting the supply of critical medical devices and IVDs, enhancing preparedness and ensuring a stable supply chain. Operon Strategist, a medical device regulatory consultant, offers expert guidance on navigating these regulatory changes for compliance and success in the evolving European IVD landscape.

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CE Marking for Software as Medical Device (SaMD)

Discover the crucial role of software in medical devices and ensure compliance with CE Marking by exploring our recent blog on "CE Marking for Software as a Medical Device (SaMD)." Operon Strategist, your dedicated CE Marking consultant, is here to guide you through the intricate process, from understanding SaMD and SiMD distinctions to the steps involved in securing CE certification under EU MDR guidelines. Explore real-world examples, learn about the classification process, and unlock the path to success in the dynamic field of healthcare innovation.

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Right Strategy to Bring Medical Devices in Indian Market

Operon Strategist highlights a comprehensive strategy for bringing medical devices into the rapidly growing Indian market. Despite India's medical devices market being valued at $11 billion and projected to reach $50 billion by 2025, the blog underscores the importance of understanding regulatory requirements, conducting thorough market research, and adapting products to local needs. The strategy also emphasizes the significance of establishing strong distribution channels, forging partnerships, effective marketing, and continuous improvement based on feedback. Operon Strategist, a trusted medical device regulatory and project management consulting company, offers expert guidance and personalized plans for successful market entry and compliance in India.

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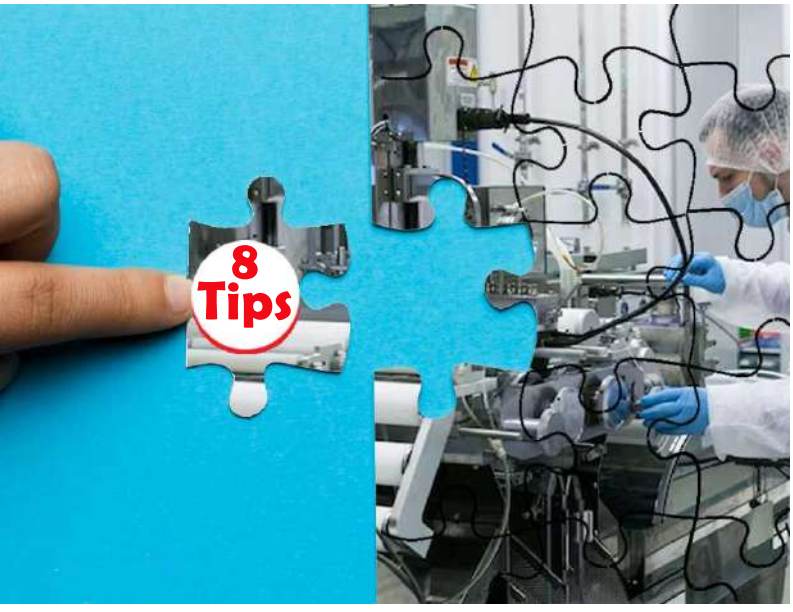
8 Essential Tips to Start Medical Device Startup Company



Operon Strategist shares 8 essential tips for entrepreneurs venturing into the dynamic realm of medical device startups. These tips include recognizing critical healthcare needs for innovation, conducting in-depth market research, building a proficiently diverse team, creating prototypes and validating concepts, managing regulatory compliance, strategically acquiring funding, developing a comprehensive go-to-market strategy, and embracing ongoing innovation. The blog emphasizes the significance of these strategic steps for success in the healthcare industry and encourages entrepreneurs to stay committed to their goals, collaborate effectively, and remain adaptable in pursuit of innovation. Operon Strategist offers specialized support in areas such as manufacturing plant layout design, regulatory compliance, and market entry, ensuring a seamless journey to success in the medical device startup landscape.

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Dos and Don’ts for Medical Device Startups

Operon Strategist provides valuable insights into the dos and don'ts for aspiring medical device startups. The blog emphasizes thorough market research, strategic planning, and budget allocation as crucial dos for success. It encourages startups to partner with reliable medical device contract manufacturers for regulatory assistance and cost-optimized manufacturing. On the don'ts side, the blog highlights the importance of not underestimating the regulatory strategy, avoiding miscommunication, and being cautious about overinvestment in pilot programs. Operon Strategist offers expert guidance and support to navigate regulatory challenges and ensure a successful market entry for medical device startups.

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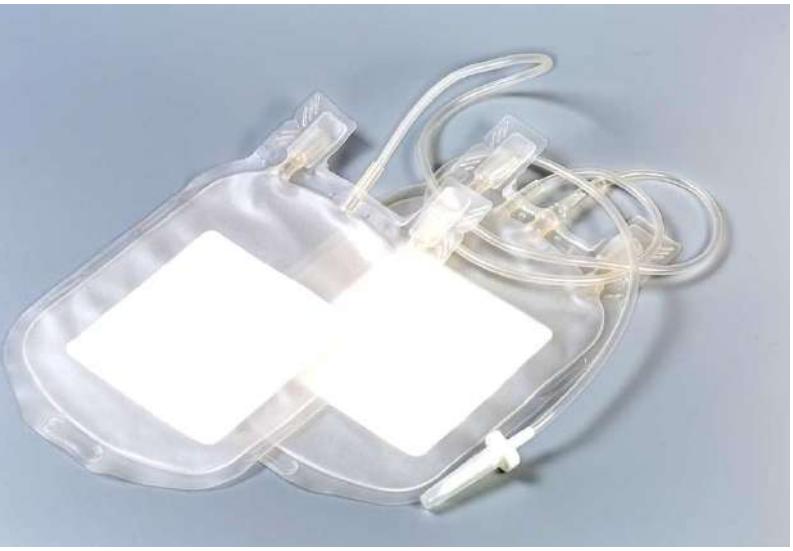
Blood Bag Manufacturing – Regulatory Aspects



Operon Strategist provides insights into the regulatory aspects of blood bag manufacturing, emphasizing the critical role these specialized medical containers play in ensuring a secure and effective blood supply. The blog highlights key functions, market dynamics, and the composition of blood bags, underscoring the advantages they offer over traditional glass bottles. Operon Strategist is positioned as a trusted ally for manufacturers in the complex world of regulations, offering support in plant setup, validation, regulatory compliance, quality management systems, risk management, documentation, training, and post-market surveillance

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Revolutionizing Healthcare: The Role of Operon Strategist in Point-of-Care Testing Devices Manufacturing

In the ever-evolving field of healthcare, point-of-care testing (POCT) devices have become revolutionary, providing swift and decentralized diagnostic solutions. These devices offer immediate results, facilitating quicker clinical decision-making and ultimately enhancing patient outcomes. Working behind the scenes, companies such as Operon Strategist play a crucial role in guiding manufacturers through the complex process of POCT device manufacturing. As a regulatory consulting powerhouse, Operon Strategist brings its expertise to a global stage, assisting medical device manufacturers in setting up efficient plants and ensuring strict compliance with regulatory standards.

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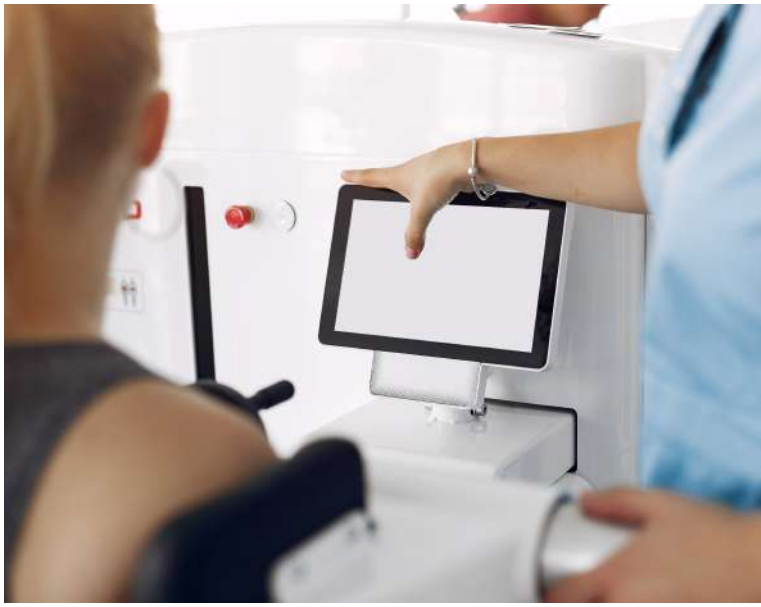

IEC 62304: Path to Medical Device Software Compliance

IEC 62304 serves as a global standard for medical device software, establishing a consensus framework for processes spanning the entire product lifecycle.

In the ever-evolving landscape of medical device software development, adherence to industry standards is not just a best practice but a crucial necessity. At the forefront of these standards is the IEC 62304:2006/Amd 1:2015, a comprehensive guideline for the lifecycle processes of medical device software.

In this blog post, we'll explore the significance of specialized consultation services, particularly focusing on the expertise provided by Operon Strategist, in ensuring seamless compliance with IEC 62304.

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Looking Ahead to 2024: Emerging Trends and Innovations in the Diagnostics Sector

In the ever-evolving landscape of healthcare, diagnostics holds a central position, acting as the cornerstone guiding the entire continuum of care. Looking forward, we witness substantial shifts in healthcare, propelled by technological advancements, evolving consumer expectations, and proactive governmental strategies.

Several pivotal trends are poised to shape the future of diagnostics. These include the widespread embrace of biosensors and the increasing use of companion diagnostics, the rise of direct-to-consumer testing and automation, and the transformative impact of AI and advanced analytics on pathology and radiology.

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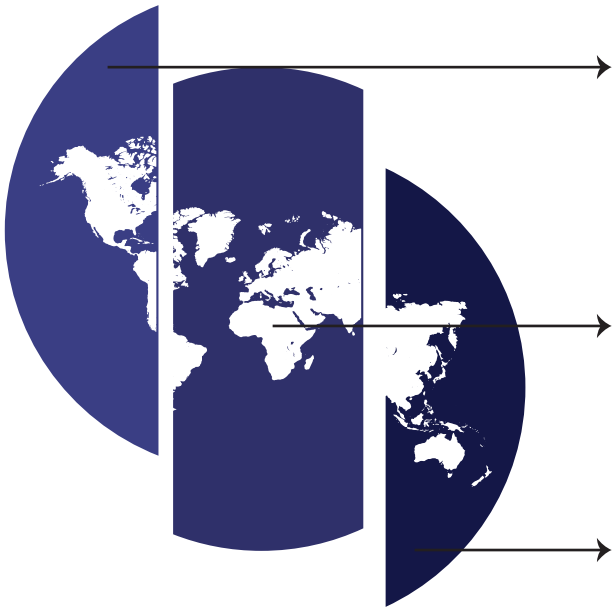

- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **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

CONTACT US

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