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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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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

FDA Has Now Regulated Laboratory Developed Tests as Medical Devices

In a significant development, the US Food and Drug Administration (FDA) has introduced a groundbreaking rule change that will impact the regulation of Laboratory Developed Tests (LDTs) and In Vitro Diagnostic Products (IVDs). Under these new regulations, LDTs are set to be classified and regulated as medical devices by the FDA.

This proposed rule aims to bring clarity to the FDA's stance by explicitly stating that In Vitro Diagnostic Products fall under the category of medical devices as defined by the Federal Food, Drug, and Cosmetic Act. Notably, this categorization applies specifically when the IVDs are developed by a laboratory.

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Medical Device News

6 Month Extension for CDSCO Class C & Class D Non-Notified Medical Device

The Ministry has received representations from various associations and stakeholders who have expressed concerns about the potential disruption to business continuity resulting from the implementation of the licensing regime for Class C and D medical devices from October 1, 2023.

To ensure the regulation of medical devices, MoHFW introduced G.S.R. 102 (E) on February 11, 2020, outlining a phased approach to regulate these devices. According to this notification, Class C and D medical devices will come under a licensing regime starting from October 1, 2023.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

DoP's Guidelines for the Medical Devices Sector: Building a Skilled Workforce

The Department of Pharmaceuticals (DoP) has unveiled operational guidelines for its Human Resource Development scheme within the Medical Devices Sector. The initiative is set to train approximately 5,400 students over a span of three years, aiming to bridge the divide between industry and academia.

The scheme aligns with the Medical Device Policy's goals, which include achieving a $50 billion market size by 2030 and reducing India's reliance on imported high-end medical devices.

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Medical Device News

India Enhances Patient Safety with New IVD Device Classification

In a significant development aimed at strengthening medical device regulation and patient safety, the Central Drugs Standard Control Organization (CDSCO) of India has recently classified in-vitro diagnostic (IVD) medical devices. This classification, conducted under the provisions of the Medical Devices Rules (MDR) – 2017, represents a proactive effort to enhance the safety, quality, and performance of IVD devices used across various clinical domains.

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CE Mark vs FDA Approval For Medical Devices

In the realm of medical devices, achieving regulatory approval is a pivotal milestone that can open doors to global markets and pave the way for widespread patient access. Two prominent regulatory pathways that often come to the forefront are the CE Mark certification for the European market and FDA approvals in the United States. While both signify adherence to rigorous safety and quality standards, they represent distinct routes with their unique sets of requirements and implications.

In this blog, we embark on a comprehensive exploration of CE Mark vs FDA approvals, shedding light on the key differences, advantages, and considerations associated with each, to help manufacturers and stakeholders make informed decisions on their regulatory journey.

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Medical Device News

A Quick Guide to the Medical Device Regulatory Requirements in Lebanon

Lebanon is in a great location in the Middle East, making it a good place for medical device companies to grow. The medical device market in Lebanon mostly relies on imports, which means there's a lot of potential for companies from outside the region.

But even though the market looks good, it can be hard to get into because of all the rules you need to follow. You must register your products, make sure they meet the rules, and get approvals. All of these steps can slow down your plans to start selling your medical devices in Lebanon. In this blog we will study medical device regulatory requirements in Lebanon.

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CE Marking for Software as Medical Device (SaMD)

Software has become a crucial component of medical equipment in the constantly changing field of healthcare. Software is essential to modern medicine, from patient management systems to diagnostic instruments.

The term Software as a Medical Device is defined by the International Medical Device Regulators Forum (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." In this blog, learn how Operon Strategist helps to navigate the complex process of CE marking for software as a medical device as a CE marking consultant.

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Medical Device News

Ensuring Regulatory Compliance in Medical Devices Assembly for India's Market

The global medical device manufacturing industry is experiencing rapid growth, expected to expand by 11.6% (as per Masterson). This growth surge presents an opportunity for professionals in manufacturing, healthcare, and engineering to explore or advance their careers.

Wish to Diversify in Medical Device Industry? Enter manufacturing by the assembly of components is an excellent start. Even if you lack prior experience, medical assembly offers a front-row view of the medical device production process. So, let's understand how you can be a medical device manufacturer.

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SaMD Classification and Submission as per USFDA

SaMD refers to software applications designed to perform medical functions, transforming the way we diagnose, treat, and monitor patients. To ensure the safety and effectiveness of these digital tools, regulatory bodies like the U.S. Food and Drug Administration (FDA) have established a framework for their classification and submission.

This blog aims to help manufacturers and developers navigate the complex regulatory environment while bringing their SaMD products to market successfully. Operon Strategist is here to provide you with a comprehensive guide to SaMD classification and submission as per the US FDA.

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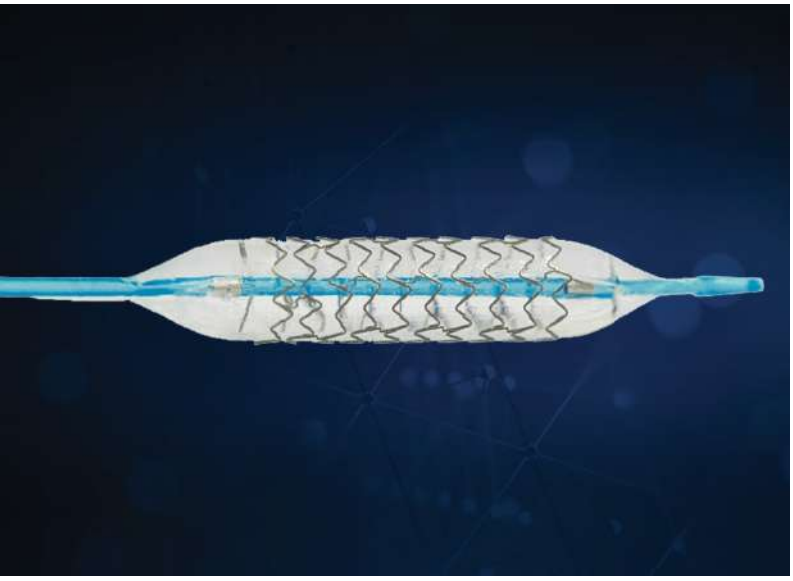
Medical Device News

A Comprehensive Guide to Stent Manufacturing



In the vast landscape of healthcare, stents stand as unsung heroes, silently working their magic in the realm of cardiovascular and vascular treatments. These unassuming devices have not only saved countless lives but have also redefined medical possibilities. In this comprehensive guide, we will embark on a fascinating journey into the world of stent manufacturing.

We will peel back the layers, uncover the intricate process, explore the materials that make it all possible, and shine a light on the profound significance of these small yet life-changing marvels.

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5 Essential Tips for Medical Device Manufacturing Site Selection

Choosing the right location for your medical device manufacturing is a critical decision that can significantly impact the success of your business. Factors such as access to a skilled workforce, regulatory environment, and transportation networks play a crucial role in determining the ideal site for your medical device manufacturing.

Here are five essential tips for site selection for your medical device manufacturing:

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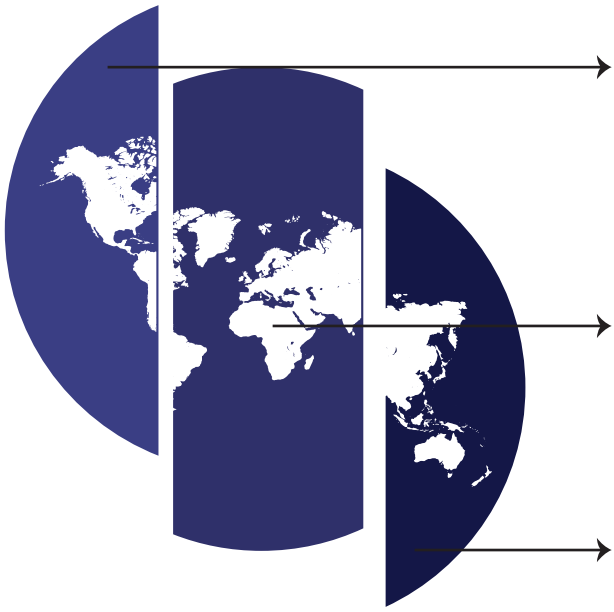

- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **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

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