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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

Gujarat's Medical Device Park at Nagalpar Near Rajkot: Operational by End Of 2024

The Government of Gujarat's ambitious medical device park in Nagalpar, near Rajkot, which will be established on 250 acres with a financial grant-in-aid of Rs. 250 crores from the Centre, will be operational by the end of 2024.

The medical device park in Rajkot district, which has been conceptualized as a commercially and economically successful initiative, is expected to generate 100-150 million USD in investment over three years

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Medical Device News

European MedTech Industry Calls for Regulatory Change in IVDR and MDR

In a significant development, the European medical technology industry has issued an open letter to the European Commissioner for Health and Food Safety, Stella Kyriakides, urging regulatory changes. The industry expresses its reservations regarding the current Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). There is growing apprehension that these regulations, which became effective in May 2017, are not progressing as expected.

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Medical Device News

US FDA Plans to Issue Electronic Export Documents for Medical Device Industry from January 2024

(CDRH) is ushering in a significant change in the way export documents for medical devices are handled. Effective January 2, 2024, the transition from traditional paper documents to electronic export documents will commence. The new electronic export documents for human medical device products regulated by CDRH will be provided in PDF format through the CDRH Export Certification Application and Tracking System (CECATS). These electronic documents will encompass several essential certificates, including:

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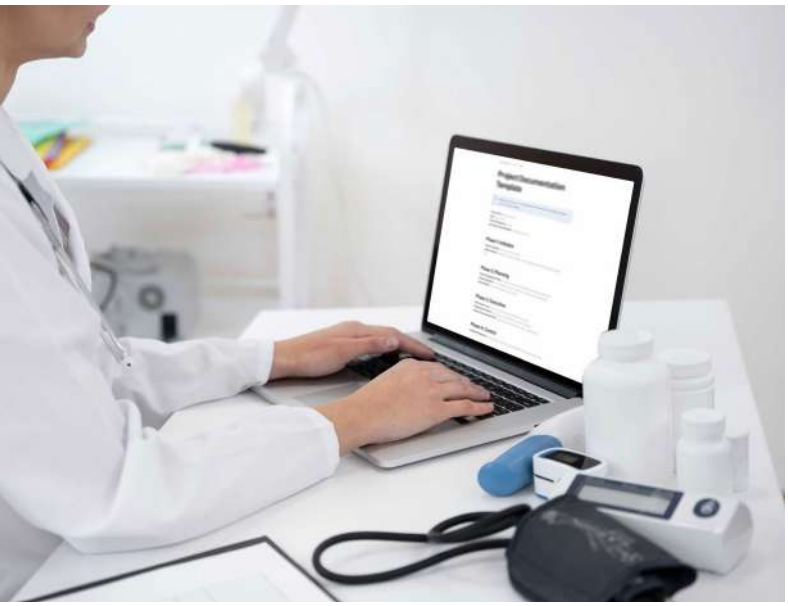
Medical Device News

The Government has Approved an Education Scheme for the Medical Device Sector



The government has given the green light to a ₹480 crore initiative aimed at nurturing a skilled workforce to propel the growth of the medical devices industry. This three-year scheme is set to offer financial support to government institutions, enabling them to offer a range of courses related to medical devices while elevating their standards to global levels.

This move comes on the heels of the recent announcement of the National Medical Device Policy for 2023, which aims to bolster the medical devices sector, aiming for

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FDA Published Draft Guidance on Best Practices for Selecting Predicate Devices for 510(k) Notifications

On September 6, 2023, the US Food and Drug Administration (FDA) took a significant step towards enhancing and modernizing the 510(k) Program, aimed at providing greater predictability, consistency, and transparency in the 510(k) premarket review process. Specifically, the FDA released a set of three draft guidance, with a focus on improving the selection of predicate devices for 510(k) notifications.

The new draft guidance outlines four "best practices" that should be followed when choosing a predicate device to support a 510(k) submission. Under existing regulations, manufacturers are required to submit a 510(k) notification at least 90 days before introducing their device into interstate commerce for commercial distribution.

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Medical Device News

Wearable Medical Device Registration in Singapore

In the quickly developing world of medical care innovation, wearable medical devices have arisen as a progressive development. These devices, going from wellness trackers to far-off remote patient monitoring systems, have changed the way we approach wellbeing and health. However, before these devices can advance toward the hands of consumers in Singapore, they must initially navigate the unpredictable labyrinth of administrative consistency set out by the Health Sciences Authority (HSA). This blog plans to demystify the process of wearable medical device registration in Singapore.

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Medical Device Registration in LATAM Countries

In recent years, the healthcare industry has witnessed significant growth in Latin American countries. Latin America, often referred to as "Latam," comprises a diverse group of countries and territories in the Americas where Romance languages, primarily Spanish and Portuguese, are spoken.

As a result, the demand for medical devices has surged, creating lucrative opportunities for manufacturers worldwide. However, entering these markets can be a complex and challenging process, primarily due to varying regulatory requirements across different countries in the region. This blog will shed light on the

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A Guide to Surgical Suture Manufacturing

Paying close attention to detail and adhering to tight quality control procedures are essential when producing surgical sutures. To maximize wound healing and scar aesthetics, surgeons choose the best suture materials for tissue approximation. The choice of sutures and needles varies widely across surgeons, and awareness of the numerous possibilities available enables doctors to form their own preferences.

Surgical suture is an equipment used to hold bodily tissues together and round the edges of cracks following surgery or damage.

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Medical Device News

3 Way Stop Cock Manufacturing

A stopcock is a specialized valve used to regulate and control the flow of liquids or gases in medical tubing or catheters. When it comes to stop cock manufacturing, precision and quality are paramount. We'll delve into the different types available and shed light on the significance of CDSCO manufacturing registration in ensuring product quality and safety. So, let's start exploring!

A three-way stopcock is a special valve with three openings used in medical devices like IV lines. It can control the flow of fluids in three directions: off (closed), straight through (connecting two parts), and to the side (for adding medicines or extra fluids).

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EU Regulations for Marketing Medical Device Combination Products

Medical Device Combination Products, as defined in CFR, encompass combinations of medical devices, drugs, and/or biologics. These components can be physically combined or packaged together for use. These products leverage the strengths of each component for enhanced therapeutic benefits.

Take drug-eluting stents (DES) as a drug-device combination product example. It involves a medical device—a metal scaffold placed in arteries—and a drug coating. The device props open arteries, while the drug prevents scar tissue growth. This synergy embodies CFR's concept of combining medical devices and drugs for improved treatment outcomes.

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Medical Device News

Disposable Surgical Drapes Manufacturing

Welcome to the world of disposable surgical drapes—a fundamental element of healthcare's commitment to sterility. Behind the scenes of bustling operating rooms and sterile environments, these simple sheets play a vital role in safeguarding both patients and healthcare professionals. In this blog, we'll break down the essentials, covering the materials used in their construction, the meticulous testing procedures, their wide-ranging applications, and the different types designed for various medical needs.

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5 Tips for Getting Ready for an FDA Inspection

A FDA 510(k) inspection is a review procedure used by the Food and Drug Administration of the United States (FDA) to assess the efficacy and safety of particular medical devices before they may be marketed in the country. To ensure compliance with FDA guidelines, a careful review of the device's design, intended usage, and manufacturing procedures is required to get for FDA 510(k).

As a medical device manufacturer, the prospect of an FDA inspection may seem daunting, inducing stress and uncertainty. However, being well-prepared is the key to achieving a successful outcome.

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Medical Device News

Regulatory Requirements for Dialysis Machines in India

In India, a mandatory registration is required for the import or production of dialysis equipment. This procedure is governed by the Central Drugs Standard Control Organization (CDSCO).

An import/manufacturing license from the Central Licensing Authority or a State Licensing Authority is required for manufacturers or importers of medical goods and equipment, such as dialysis machines. After October 1, 2021, if a medical device is made or imported without a registration or license, it will be considered to have been done so against Indian law.

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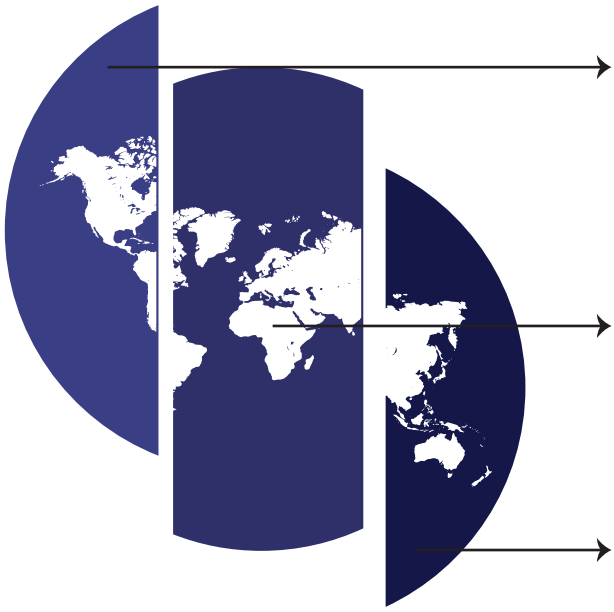

- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **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

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