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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.

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Transforming Thoughts In To Reality

## LATEST NEWS & UPDATES

Ministry of Textiles Introduces Quality Control Order for Medical Textiles

Government to Strengthen Quality Monitoring of Imported Medical Devices with Risk-Based Approach

NEW

**Upcoming Events this Month**

- MEDICALL (Delhi)
- GLOBAL HEALTH EXHIBITION (Saudi Arabia)

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## MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

### Ministry of Textiles Introduces Quality Control Order for Medical Textiles

Starting October 1, 2024, the Ministry of Textiles will enforce the Medical Textiles (Quality Control) Order, 2023, setting stringent quality standards for products like sanitary napkins, baby diapers, reusable sanitary pads, and dental bibs. This move aims to enhance public health and safety by ensuring compliance with performance metrics such as pH levels, hygiene, biocompatibility, and biodegradability. Manufacturers, importers, and retailers must secure BIS certification to meet the new standards, while SHGs and small-scale enterprises are exempt.


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### Government to Strengthen Quality Monitoring of Imported Medical Devices with Risk-Based Approach

The government is implementing a new risk-based approach to enhance the quality control of imported medical devices. This initiative includes random sampling for most devices and comprehensive testing for critical diagnostic kits, ensuring public health safety. A guidance document has been released to help port officers make informed decisions, outlining a three-tier sampling process, including visual inspections, Minilab screening, and full laboratory testing for high-risk items like vaccines and blood products.

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MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## CDSCO Issues Draft Guidance on Risk-Based Approach for Monitoring Quality at Ports of Import

The Central Drugs Standard Control Organization (CDSCO) has released a draft guidance document outlining a risk-based approach to monitor the quality of imported drugs, cosmetics, and medical devices in India. This strategy focuses on high-risk products and includes a three-tiered sampling process: desktop inspections, field testing, and comprehensive compendial testing. The draft is open for public feedback within 30 days, aiming to enhance public health protection by ensuring compliance with quality standards at ports.

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## CDSCO Launches 30-Day Consultation on Updated GCP Guidelines

The Central Drugs Standard Control Organization (CDSCO) has opened a 30-day consultation period for proposed updates to India's Good Clinical Practice (GCP) guidelines. The revisions aim to enhance the current document by integrating advanced digital health technologies, such as wearables, into clinical research. Key updates include new definitions for data acquisition tools, e-consent, and decentralized clinical trials, along with an emphasis on computerized systems validation. The guidelines also address quality assurance and ethics, with expanded guidance on research involving medical devices and marginalized communities.

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## MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

### PMJAY Expansion: India Inc Calls for Timely Payments to Hospitals Amid Scheme Expansion


The Indian government has expanded the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) to include health coverage for citizens aged 70 and above, offering Rs 5 lakh per year in benefits. While this initiative aims to alleviate medical expenses for seniors, industry leaders have voiced concerns about the need for timely payments and fair reimbursement rates for hospitals, particularly smaller facilities that may struggle with the increased patient load. Experts stress that without adequate financial support, these hospitals may be unable to maintain service quality, potentially impacting healthcare availability for the growing elderly population, which is expected to surge to 246 million by 2050.

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### MPIDC Allocates Land to 36 Industries in Ujjain Medical Devices Park, Projects Rs 1,855 Crore Investment

The Madhya Pradesh Industrial Development Corporation (MPIDC) has allocated land to 36 medical device companies at the newly established Medical Devices Park in Ujjain, aiming to boost production and exports of medical equipment. These industries have proposed a collective investment of approximately Rs 1,855 crore and are expected to generate around 6,908 jobs. The park will focus on manufacturing a variety of medical products, including self-testing kits, dental implants, and surgical adhesives. MPIDC is offering incentives to attract more investment, further enhancing Madhya Pradesh's position in the healthcare manufacturing sector.

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MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## Centre Notifies Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024

The Indian government has introduced the Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024 to regulate unethical practices in the medical device industry. Key provisions include the establishment of Ethics Committees for Marketing Practices to address complaints within 90 days, strict guidelines for medical device promotion to prevent misleading claims, and a ban on gifts and hospitality for healthcare professionals. Companies are also required to disclose their expenditures related to educational activities and product evaluations. Operon Strategist offers expert consulting services to help navigate these new regulations and ensure compliance.

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## FDA Releases Draft Guidance on Predetermined Change Control Plans (PCCPs) for Medical Devices

The U.S. Food and Drug Administration (FDA) has issued draft guidance outlining its proposed policies for Predetermined Change Control Plans (PCCPs) for medical devices. This guidance specifies the information manufacturers should include in PCCPs, which allow certain device modifications without requiring a new marketing submission. The FDA provides examples of appropriate modifications and emphasizes the need for these changes to maintain or improve the device's safety and effectiveness. Manufacturers must also note in the labeling when a device has an authorized PCCP. For expert assistance in navigating these new regulations, contact Operon Strategist today!

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# TO KNOW MORE

## Understanding the Responsibilities of Economic Operators Under the EU MDR 2017/745

The EU MDR 2017/745 significantly redefines the roles and responsibilities of economic operators in the medical device supply chain, including manufacturers, authorized representatives, importers, distributors, and persons responsible for regulatory compliance. This regulation mandates strict adherence to quality and risk management systems, proper documentation, and post-market surveillance to ensure the safety and compliance of medical devices in the EU market. Each operator has specific duties, from registering devices in EUDAMED to taking corrective actions for non-conformities. For professional guidance in navigating these complex requirements, contact Operon Strategist, your trusted EU MDR consultant.

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## Benefits of Setting Up a Medical Device Manufacturing Unit in Saudi Arabia

Saudi Arabia's strategic location, government support, and growing infrastructure make it an ideal hub for medical device manufacturing. The Kingdom's Vision 2030 initiative promotes economic diversification, offering benefits like subsidies, tax exemptions, and priority purchase programs for locally made devices. Saudi Arabia also provides access to the MENA region and global markets, advanced technological facilities, and a skilled workforce. With a clear regulatory framework from the SFDA, businesses can efficiently bring products to market. Operon Strategist offers expert consulting services to help manufacturers navigate regulatory approvals and set up compliant, efficient facilities in Saudi Arabia.

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## Documents Required for MD 15 License (CDSCO Import License): A Guide for Medical Device Importers

The MD 15 license is essential for importing medical devices into India, regulated by the CDSCO to ensure quality and safety. Key documents needed include a Power of Attorney, valid manufacturing license, free sale certificate, ISO 13485 certificate, inspection reports, and CE certificates, among others. Each document demonstrates compliance with both national and international standards, streamlining the approval process and ensuring patient safety. Operon Strategist offers expert consulting services to help medical device importers compile necessary documents and navigate regulatory requirements smoothly.

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## Navigating NB Opinions for CE Marking and US FDA Regulatory Guidance for DDCP

This blog highlights the complexities of obtaining market approval for Drug-Device Combination Products (DDCP) in the EU and US. It explains the role of Notified Body (NB) opinions under the EU MDR and the US FDA's regulatory framework for combination products. Key points include understanding the product's primary mode of action (PMOA), ensuring clear documentation, and complying with safety and quality standards. The blog emphasizes early engagement with regulatory bodies and offers insights into the differences between the EU and US approval processes. Operon Strategist provides expert consulting to help manufacturers navigate these regulations and streamline the approval process.

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## TO KNOW MORE

### Indigenous Medical Device Manufacturing: A Global Push Towards Self-Sufficiency

This blog explores the global movement towards indigenous medical device manufacturing, with a focus on countries like Saudi Arabia, Oman, and India. Governments are implementing strategic initiatives to reduce reliance on imports and boost local production by offering incentives such as tax benefits, subsidies, and streamlined regulatory processes. The blog highlights the benefits of local manufacturing, including improved healthcare access, economic growth, and enhanced national security. Operon Strategist provides regulatory consulting and turnkey project management services to support manufacturers in navigating these complex regulatory landscapes.

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### Custom Clearance of Your Medical Devices

This blog explores the challenges faced by the medical device industry in navigating custom clearance processes, especially with new systems like Malaysia's DagangNet e-permit. Key concerns include increased lead times, administrative complexity, and costs. The blog offers insights into solutions such as streamlined procedures, regulatory clarity, and joint industry proposals for smoother transitions. It highlights the importance of managing time-sensitive devices and the role of third-party logistics. Operon Strategist provides expert guidance to ensure smooth and compliant custom clearance for medical devices.

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## 8 Key Steps to Establishing a Risk-Based CAPA Process

This blog outlines the essential steps to developing a robust, risk-based Corrective and Preventive Actions (CAPA) process, a critical component for quality management in medical devices, pharmaceuticals, and manufacturing industries. Key steps include understanding regulatory requirements, identifying and prioritizing risks, establishing a CAPA plan, implementing actions, monitoring effectiveness, and fostering continuous improvement. The blog emphasizes compliance with standards like ISO 13485 and FDA regulations. Operon Strategist offers expert consultancy services to ensure your CAPA process is compliant and effectively integrated into your quality management system.


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## Best Practices for Internal Auditing of ISO 13485:2016 QMS

Internal audits are essential for maintaining a strong Quality Management System (QMS) and ensuring compliance with ISO 13485:2016 and FDA regulations. This blog highlights the key benefits of internal audits, including identifying gaps, ensuring regulatory compliance, and enhancing readiness for external audits. It also provides a step-by-step guide to conducting effective audits, from planning to executing corrective actions. Operon Strategist offers expert consulting services to assist with internal audits, ensuring your QMS is robust and audit-ready.

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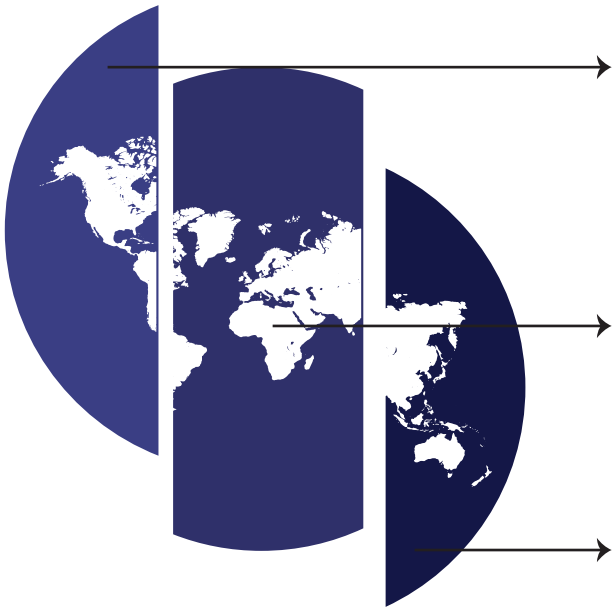
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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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