VOL.NO. 05 | ISSUE-05 | AUGUST-2026

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

LATEST NEWS & UPDATES

CDSCO Releases Final Guidance Document on Medical Device Software

Centre Invites Applications for Medical Device Cluster Infrastructure Under SMDI

NEW

Upcoming Events this Month

- Medicall Expo Chennai 24 - 26 July 2026
- Medtec Southeast Asia 08 - 10 July 2026

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

CDSCO Releases Final Guidance Document on Medical Device Software

The Central Drugs Standard Control Organisation (CDSCO) has released the final Guidance Document on Medical Device Software (MDSW) under the Medical Devices Rules (MDR), 2017. The guidance provides a clear regulatory framework covering software classification, regulatory submissions, technical documentation, QMS, cybersecurity, risk management, and post-market requirements.

It includes medical-purpose software using AI, IoT, digital therapeutics, and advanced data analytics.

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Centre Invites Applications for Medical Device Cluster Infrastructure Under SMDI

The Department of Pharmaceuticals (DoP), Government of India, has invited applications for the Common Facilities for Medical Devices Clusters initiative under SMDI 2. The scheme aims to strengthen domestic medical device manufacturing, reduce import dependence, and improve access to shared infrastructure. It will support facilities such as testing and calibration laboratories, sterilisation units, cleanrooms, tool rooms, and product development centres. The initiative is expected to help MSMEs reduce infrastructure and regulatory compliance costs while improving access to testing and certification services.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Government Releases Medical Device Scheme Data; PLI Investment Reaches ₹1,153 Crore, FDI Stands at ₹17,201 Crore

The Government of India has released updated data on key initiatives supporting the growth of the medical device and MedTech sector, including the PLI Scheme, Medical Device Parks Scheme, and SMDI. Under the PLI Scheme, actual investment has reached ₹1,153.07 crore, with ₹266.64 crore in incentives released up to FY 2024–25. The scheme has supported domestic manufacturing of advanced technologies such as CT and MRI systems, ultrasound equipment, heart valves, and stents. Medical Device Parks in Noida, Ujjain, and Kancheepuram provide shared infrastructure, with 210 manufacturing units allotted plots. SMDI supports import reduction, medical device clusters, high-precision technologies, MSMEs, and startups. Foreign direct investment in India's MedTech sector reached ₹17,201 crore between FY 2021–22 and FY 2025–26.

READ MORE

TO KNOW MORE

Cardiovascular Medical Devices: A Quick Guide to Manufacturing and Regulatory Compliance

This blog provides an overview of cardiovascular medical devices, including heart valves, coronary stents, endovascular grafts, angioplasty balloon catheters, pacemakers, and defibrillators. It explains that these devices are often associated with higher patient risk and therefore require careful design, manufacturing, quality control, and regulatory review.

The article further describes how Operon Strategist supports cardiovascular medical device manufacturers through regulatory compliance, device classification, technical documentation, manufacturing plant layout design, QMS implementation, ISO 13485 and 21 CFR Part 820 support, training, and turnkey medical device manufacturing solutions.

READ MORE

FDA Cleared vs FDA Approved Red Light Therapy Device Guide

This blog explains the regulatory difference between “FDA Cleared,” “FDA Approved,” and “FDA Registered” for red light therapy and photo biomodulation (PBM) medical devices. Most red-light therapy devices are classified as Class II medical devices and generally require FDA clearance through the 510(k) Premarket Notification pathway. They do not usually follow the Premarket Approval (PMA) process; therefore, manufacturers should use the term “FDA Cleared” after receiving 510(k) clearance.

The blog also explains that FDA establishment registration does not mean that a device has been cleared or approved.

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TO KNOW MORE

Hypodermic Needle Manufacturing: Process, Materials, Quality Control, and Regulatory Compliance

This blog provides an overview of hypodermic needle manufacturing, covering materials, production processes, quality control, sterilisation, packaging, and regulatory compliance. It explains key manufacturing stages, including stainless-steel tube preparation, cutting, needle grinding, cleaning, assembly, siliconisation, sterilisation, and sterile packaging. The blog highlights the importance of automation, validated processes, and in-process inspections to ensure precision, sterility, and consistent product quality. It also covers essential quality requirements such as needle sharpness, dimensional accuracy, hub strength, surface quality, and traceability.

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Classification of Drug-Device Combination Products: Complete Guide

This blog explains the classification of drug-device combination products, including prefilled syringes, insulin pens, auto-injectors, and drug-eluting stents. Classification is important because it determines the applicable regulations, approval pathway, technical documentation, and clinical evidence requirements. The Primary Mode of Action (PMOA) identifies whether a product is drug-led, device-led, or biologic-led.

Combination products may be classified as single-entity, co-packaged, cross-labelled products, or convenience kits.

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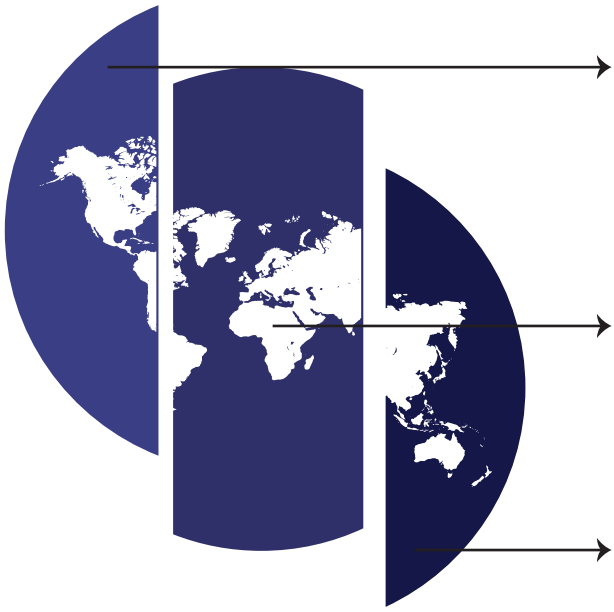
OUR SERVICES



- **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

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