VOL.NO. 04 | ISSUE-06 | SEPTEMBER-2025

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

Centre begins talks on new rules for refurbished medical device imports

MHRA Launches Survey on In-House Manufacturing Exemption for Medical Devices

NEW

Upcoming Events this Month

- India MedTech Expo 2025
- Gujarat Medical Expo 2025

Know More

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

Centre begins talks on new rules for refurbished medical device imports

The Government of India has begun consultations to draft regulations for refurbished medical device imports, currently managed through MoEFCC-issued NOCs. The new framework may set minimum service life, approved device categories, and stricter compliance requirements. While domestic manufacturers push for restrictions, hospitals argue refurbished devices improve affordable access to advanced technology in tier-II and rural markets. A draft policy for public consultation is expected soon.

Operon Strategist can guide stakeholders through evolving CDSCO regulations, import licensing, and compliance for refurbished medical devices.

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MHRA Launches Survey on In-House Manufacturing Exemption for Medical Devices

The UK MHRA has launched a survey on the in-house manufacturing exemption, which lets health institutions produce and use devices without full regulatory requirements. The consultation focuses on expanding access, strengthening PMS obligations, and supporting NHS community care goals. Stakeholder input will influence future MDRR reforms and compliance guidance.

Operon Strategist helps manufacturers and health institutions stay compliant with UKCA/CE marking, PMS requirements, and regulatory reforms.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

FDA Issues Warning Letters to Medical Device Companies for CGMP Violations and Unauthorized Marketing

The FDA has issued warning letters to Mectronic Medicale S.R.L. and Visgeneer, Inc. for violating CGMP, QSR, and unauthorized device marketing regulations. Mectronic was cited for making unapproved claims and lacking proper design controls, while Visgeneer failed to maintain complaint handling records and market clearance for its devices.

Operon Strategist helps manufacturers ensure full compliance with FDA 510(k), QSR, and reporting regulations—minimizing risk and supporting smooth U.S. market access.

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Asia-Pacific Roundup: Malaysia and Singapore Start Pilot to Fast-Track Medtech Launches

Malaysia's MDA and Singapore's HSA have launched a six-month pilot (Sept 1–Feb 28) to fast-track approvals for Class B–D medical devices. The program enables abridged reviews—cutting timelines by up to 50%—for devices already approved in either country, aiming to speed patient access and reduce duplication.
Other key updates:
India (CDSCO): Alert on theft of insulin & Wegovy; new bar/QR code excipient detail deadline set for March 1, 2026.
Philippines (FDA): Clarified compassionate use rules (no renewals); warning issued on counterfeit vaccines.

This pilot strengthens regulatory reliance in Asia and positions Malaysia and Singapore as leaders in regional medtech collaboration.

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TO KNOW MORE

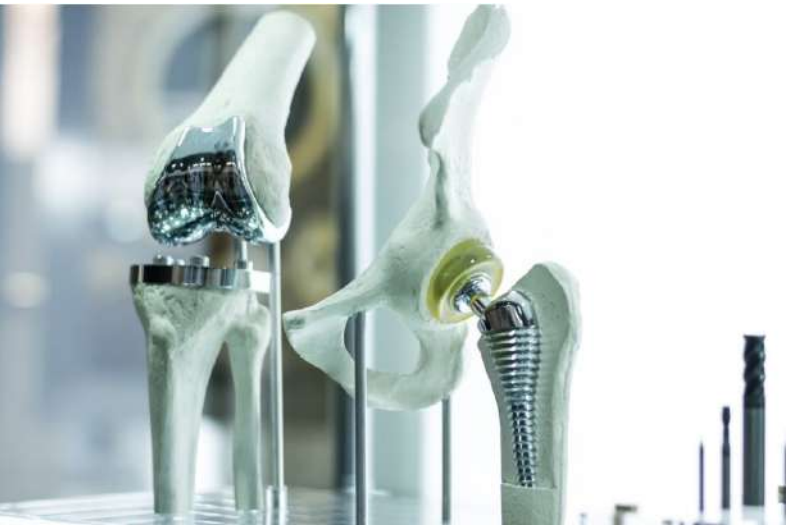
GLP-1 Pen Injectors: Regulatory Classification & Market Growth

GLP-1 pen injectors are transforming diabetes and obesity care with safe, convenient, and patient-friendly drug delivery. Classified globally as drug-device combination products, they must comply with both pharma and medical device regulations, including GMP, ISO 13485, ISO 14971, and ISO 11608. With demand projected to reach 2 billion units annually by 2032, manufacturers face huge opportunities—but only with strong regulatory compliance.

Operon Strategist supports companies with product classification, ISO implementation, dossier preparation, global submissions, and turnkey consulting for GLP-1 pen injectors.

READ MORE

Why Additive Manufacturing is a Game-Changer for Medical Technology



Additive Manufacturing (3D printing) is revolutionizing medical devices by enabling custom implants, faster prototyping, lightweight designs, and on-demand production. It reduces waste, supports patient-specific solutions, and drives innovation in biomaterials. However, challenges like regulatory compliance, quality consistency, scalability, and material validation must be carefully managed.

Operon Strategist helps manufacturers navigate these challenges with regulatory strategy, QMS setup, validation services, and global submission support—ensuring safe, compliant, and market-ready AM devices.

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Dynamic Risk Management for Software-Enabled Medical Devices

With the rise of software-enabled devices, traditional static risk management methods like spreadsheets fall short. Dynamic Risk Management (DRM) offers a connected, real-time approach that links risks, design requirements, and verification tests—ensuring full traceability, fewer errors, and faster compliance with ISO 14971, FDA QSR, and EU MDR/IVDR.
Operon Strategist helps manufacturers implement DRM systems that strengthen patient safety, streamline regulatory submissions, and accelerate time-to-market for innovative medical devices.

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FDA Clinical Data Requirements for Medical Devices

Clinical data plays a vital role in U.S. FDA submissions, depending on the pathway—510(k), De Novo, PMA, or HDE. While most 510(k) devices are cleared without clinical studies, De Novo and PMA submissions often demand robust clinical evidence, and HDE requires safety and probable benefit data for rare conditions. Understanding these requirements early helps avoid costly delays and regulatory setbacks.

Operon Strategist supports manufacturers with clinical strategy planning, trial design, and FDA-ready submissions to ensure faster approvals and compliance.

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Biological Testing Methods of Medical Devices

Biological testing ensures medical devices are safe, biocompatible, and compliant with global standards like ISO 10993. These tests—such as cytotoxicity, sensitization, irritation, systemic toxicity, hemocompatibility, and implantation—evaluate how device materials interact with the human body. Proper testing not only protects patients but also supports regulatory approvals with the FDA, CE, CDSCO, and global authorities.

Operon Strategist helps manufacturers select the right tests, coordinate with certified labs, and prepare documentation for faster market approvals and risk-free compliance.

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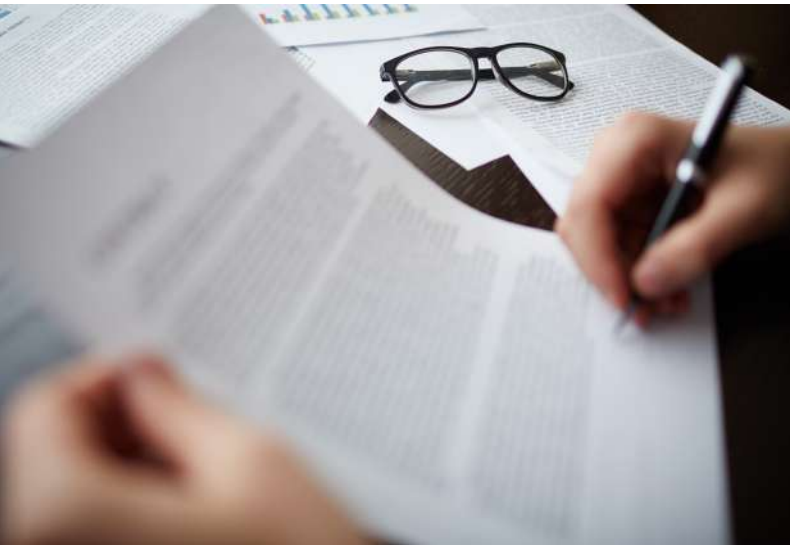

Device Master Files (DMFs) in Medical Device Manufacturing

Device Master Files (DMFs) play a crucial role in medical device manufacturing by ensuring regulatory compliance, protecting intellectual property, and streamlining product approvals. A DMF contains detailed information on device design, materials, manufacturing processes, quality controls, and sterilization, enabling CDSCO and global regulators to assess products without exposing proprietary data.

Operon Strategist assists manufacturers with preparing regulator-ready DMFs, managing updates, and ensuring compliance with CDSCO and international standards—helping you accelerate approvals and expand global market access.

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Operon Strategist at Inventicon 2025 – Sharing Insights on Evolving Device Regulations

Operon Strategist's Founder & CEO, Mr. Anil Chaudhari, participated as a panelist at Inventicon 2025 in Delhi, where leaders from the medical device sector discussed evolving regulations, compliance, and patient safety.

The panel emphasized the role of safety standards, quality improvement strategies, and bridging gaps between design and manufacturing to ensure effective and reliable devices. With over 150 delegates, the session provided actionable insights for navigating regulatory challenges.

Operon Strategist continues its mission to guide manufacturers and startups in achieving compliance while keeping quality and patient safety at the forefront.

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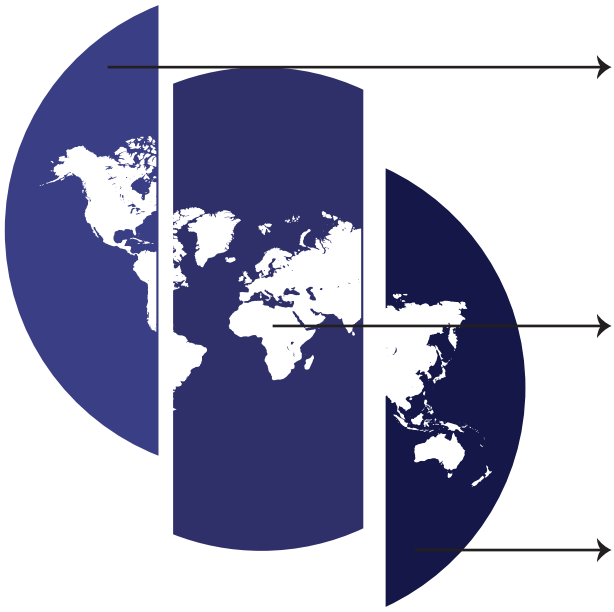
A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

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

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