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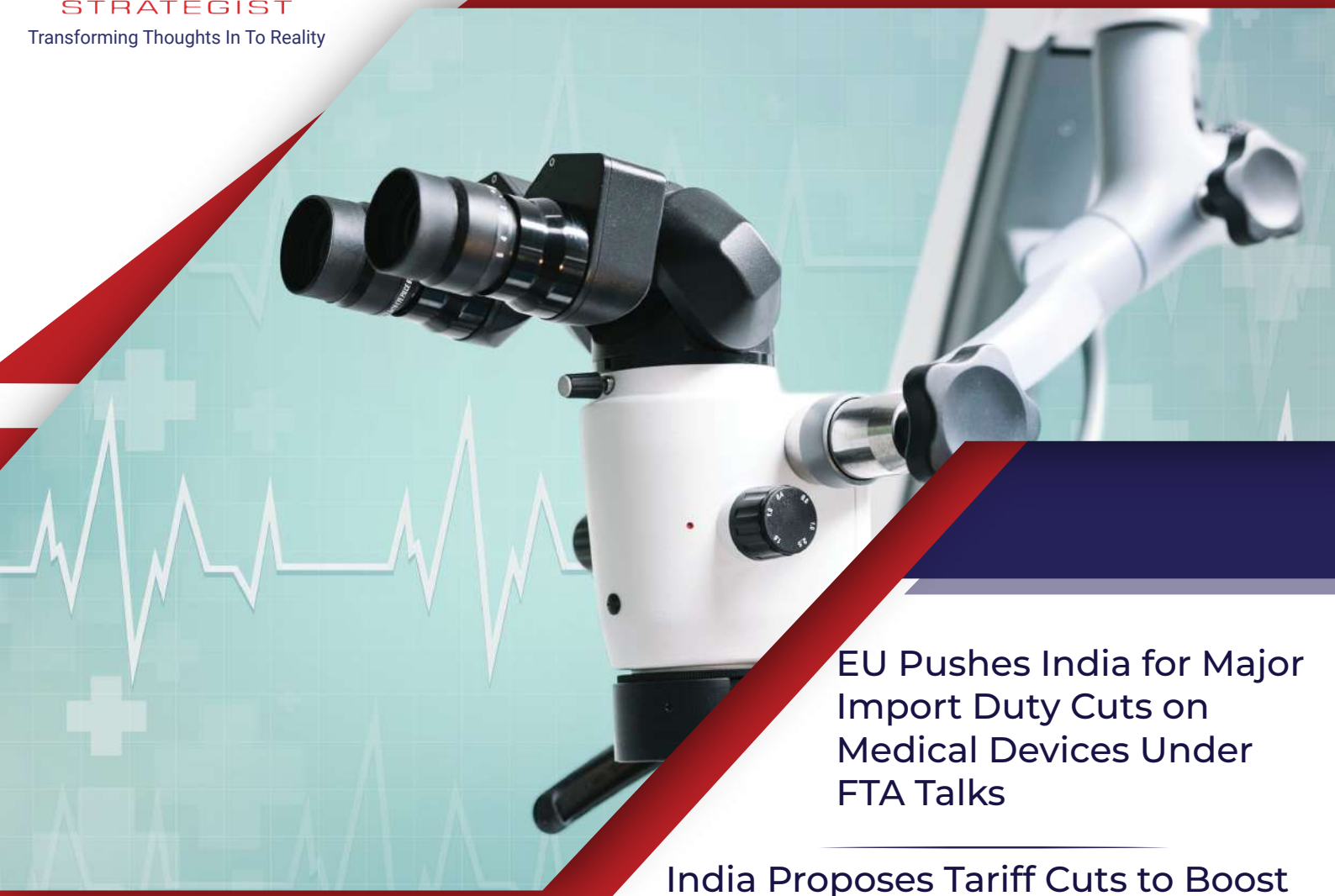
REGUVEDA

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.

OPERON STRATEGIST
Transforming Thoughts In To Reality

LATEST NEWS & UPDATES



EU Pushes India for Major Import Duty Cuts on Medical Devices Under FTA Talks

India Proposes Tariff Cuts to Boost MedTech Trade with the US

NEW

Upcoming Events this Month

- WHX Miami 2025
- MediExpo Korea

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

EU Pushes India for Major Import Duty Cuts on Medical Devices Under FTA Talks

The European Union is pushing India to slash import duties on medical devices as part of the ongoing India-EU Free Trade Agreement (FTA) negotiations. While the EU seeks greater market access, Indian manufacturers are raising concerns over reciprocity, non-tariff barriers, and potential harm to domestic production.

The Indian industry is calling for Mutual Recognition Agreements (MRAs) and regulatory harmonization to offset the impact of tariff cuts and ease exports to the EU.

Operon Strategist helps medical device manufacturers navigate complex trade and compliance challenges across global markets, including EU MDR and FDA requirements.

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Kerala Set to Emerge as Global Hub for Medical Devices and Ancillary Industries Within 5 Years: Dr. Satheesh Kumar

Kerala is rapidly emerging as a key player in the global medical device industry, with over 85 registered companies and a ₹9,000 crore sector turnover. Backed by government support, a skilled workforce, and strong academic infrastructure, the state is home to top manufacturers like Agappe Diagnostics, Terumo Penpol, and Dentcare.

Dr. C.S. Satheesh Kumar predicts Kerala will become globally competitive in MedTech within five years, driven by innovation and policy initiatives.

Operon Strategist is proud to support Kerala's MedTech growth with regulatory consulting, market entry strategies, and turnkey solutions for global compliance.

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MEDICAL DEVICES REGULATORY UPDATES

Medical Device News

India Proposes Tariff Cuts to Boost MedTech Trade with the US

India has proposed reducing its tariff gap with the US from 13% to below 4% in a strategic move to secure trade exemptions and deepen bilateral relations. The proposal includes duty elimination on 60% of tariff lines and preferential access for 90% of US goods, boosting opportunities in medical devices, aviation, telecom, and biotech.

India also seeks improved access for its exports like gems, textiles, marine products, and horticulture, and aims for strategic tech collaborations in AI, semiconductors, and pharma.

As India–US trade evolves, Operon Strategist is ready to help medical device businesses meet international regulatory standards and expand globally.

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India to Reduce Import Duties on PLI-Covered Medtech from the Sixth Year Under FTA

India has announced that import duties on medical devices under the PLI scheme will be reduced starting from the sixth year of its Free Trade Agreement (FTA) with the UK. This strategic delay balances boosting local manufacturing with consumer access to global innovations.

The FTA aims to double India–UK trade to USD 120 billion, with 90% of UK imports facing phased tariff reductions. Key medtech imports include orthopaedic appliances, radiography equipment, and breathing aids.

Supported by the PLI scheme, India is enhancing domestic production of advanced devices like MRI and CT scanners.

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A Guide to Medical Device Quality Assurance

In our latest blog, we dive into the essentials of Medical Device Quality Assurance (QA)—a cornerstone of product safety, performance, and regulatory compliance. Learn how a strong QA system, covering everything from design validation to post-market surveillance, helps manufacturers meet global standards like ISO 13485, FDA 21 CFR Part 820, and EU MDR 2017/745.
Discover how Operon Strategist supports you with tailored QA implementation, supplier audits, and regulatory approvals (CE, 510(k), CDSCO) to ensure your devices are market-ready and safe for patients worldwide.

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Are Medical Device Manufacturers Ready for the Real-World Evidence Era?

Global regulators like the US FDA and EU authorities are increasingly embracing Real-World Evidence (RWE) — data from real patient care settings — as a critical part of medical device approval and monitoring. This shift urges Medical Device Manufacturers to adapt by implementing robust data systems, post-market surveillance, and collaborative clinical programs. The blog explores how RWE strengthens safety claims, accelerates approvals, and builds trust, while also detailing regulatory trends across the US, EU, and emerging markets.

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Navigating Quality Challenges in the Medical Device Industry: Insights for 2025

As regulatory landscapes evolve in 2025, medical device manufacturers face increasing pressure to strengthen their Quality Management Systems (QMS). This blog highlights key quality challenges such as adapting to updated regulations (EU MDR, US QMSR), breaking down departmental silos, upgrading to industry-specific QMS tools, and integrating ISO 14971-based risk management throughout the product lifecycle.
Operon Strategist offers expert support in QMS development, regulatory compliance, and long-term market access.

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Investment Opportunities in Medical Devices

The medical device industry is booming—with projections surpassing USD 800 billion by 2030—driven by innovations in wearables, implantable, AI diagnostics, and smart drug delivery systems. However, navigating regulatory hurdles and market dynamics is key to maximizing returns.
This blog highlights top-performing segments, investment challenges, and strategic approaches for investors.
Operon Strategist offers expert consulting for regulatory approvals, manufacturing setup, and global compliance—ensuring your investments are smart, safe, and future-ready.

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Cybersecurity Compliance in Medical Devices: Navigating Global Regulatory Requirements

As medical devices grow more connected, cybersecurity compliance is essential to protect patient safety, ensure data integrity, and maintain regulatory approval. This blog breaks down evolving global requirements—from FDA's SBOM and risk management plans to EU MDR and Health Canada guidelines—and outlines critical manufacturer responsibilities like threat modeling, secure design, and post market surveillance.

Operon Strategist helps manufacturers navigate these complexities with tailored cybersecurity strategies, documentation support, and regulatory guidance for global approvals.

Read the full blog to secure your devices and market access with expert-led compliance solutions.

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Notified Bodies for Medical Devices: What You Need to Know

Entering the EU market? Then understanding Notified Bodies is essential. These independent organizations assess the conformity of medical devices under EU MDR and IVDR, enabling CE marking and market access. This blog explains when a Notified Body is needed, how to choose the right one, and the common challenges manufacturers face during the process.

Operon Strategist supports you with Notified Body selection, technical documentation, pre-audit readiness, and post-certification compliance — ensuring a smooth and successful certification journey.

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Top 5 Clinical Data Pitfalls in 2025 (and Smart Ways to Avoid Them)

In 2025, clinical trial success depends on compliant, accurate, and efficient data handling. This blog highlights the top 5 clinical data pitfalls—from using unvalidated tools and manual processes to poor data access control—and shares smart, regulatory-compliant fixes for each.

Operon Strategist helps MedTech companies avoid costly delays by offering expert support in clinical data management, EDC system selection, and CEP/CER preparation.

Read the full blog to ensure your clinical data process is audit-ready from day one.

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Facilitating CE Mark and EU-MDR Compliance for Medical Device Turnkey Plant Projects

Setting up a medical device manufacturing plant? This blog explains how integrating CE Mark and EU MDR requirements from the ground up ensures faster EU market entry and full regulatory compliance.

From ISO 14644 cleanroom design, ISO 13485 QMS implementation, and equipment validation (IQ/OQ/PQ) to audit readiness—turnkey solutions streamline every step.

Operon Strategist specializes in turnkey plant compliance, helping manufacturers build CE Mark-ready facilities with confidence.

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Mistakes to Avoid in Medical Device Clinical Trial Management and How to Fix Them

Clinical trials are critical for proving a medical device's safety and effectiveness—but missteps can lead to costly delays or rejection. This blog highlights 7 key pitfalls in trial management, including poor planning, regulatory non-compliance, inadequate site selection, and flawed data handling.
Learn how to fix these issues with strategic planning, risk management, and regulatory-aligned protocols.
Operon Strategist offers end-to-end clinical trial support—from ISO 14155 compliance to post-market surveillance—ensuring your trials stay on track.

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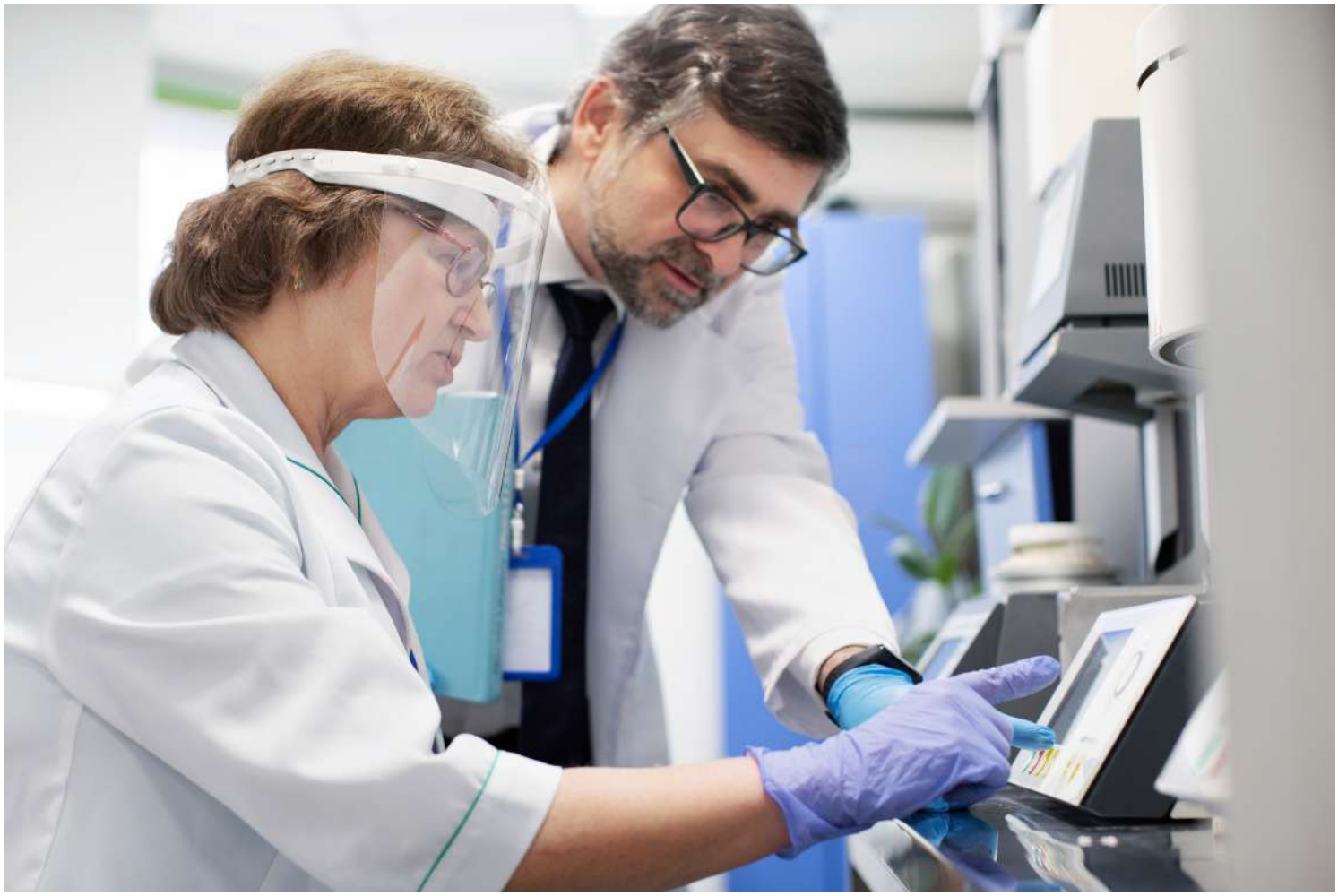

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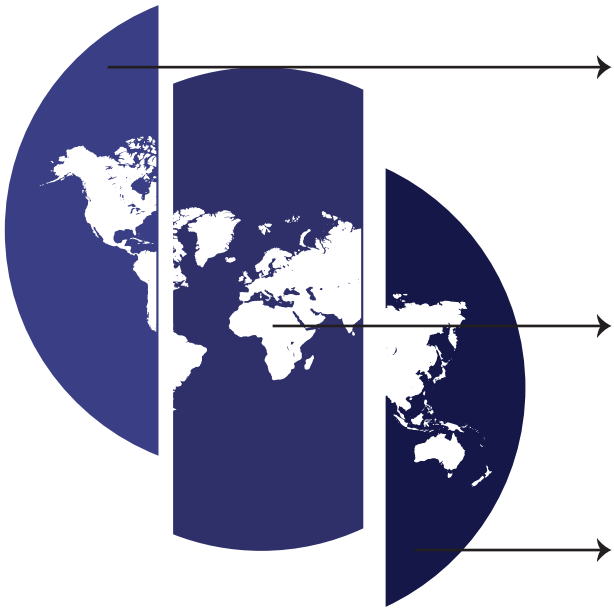
Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

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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