

USFDA inspection on the rise over Indian Medtech industry

BANGALORE, INDIA, March 14, 2025 /EINPresswire.com/ -- Indian pharmaceutical, nutraceutical, and medical device manufacturers are making significant progress in strengthening Good Manufacturing Practice (GMP) compliance, positioning the country as a major player in the global healthcare and MedTech supply chain. With the evolving geopolitical landscape and the growing adoption of the "China Plus One" strategy, India is emerging as a preferred and dependable global supplier.

The US FDA's FY 2023 Annual Report highlighted that the agency conducted 2,953 inspections globally during the fiscal year, including 2,499 routine surveillance checks and 454 for-cause evaluations. While data for FY 2024 is yet to be released, the Government Accountability Office (GAO) reported that FDA inspections included 621 overseas and 444 domestic visits in 2023—showing a 36% decline compared to pre-pandemic levels in FY 2019.

In India specifically, the FDA carried out 110 routine surveillance audits and 45 for-cause inspections, amounting to a total of 155 evaluations in 2023. Encouragingly, the agency's inspection activities are gradually returning to pre-pandemic levels, with an estimated 40% increase in overall inspections anticipated for FY 2024–25. Data indicates that approximately 66% of small and medium-sized FDA-registered facilities in India encounter Form 483 observations or



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fail to address them promptly, primarily due to compliance gaps.

A Structured and Proactive Compliance Strategy must be considered by manufactres

- **Management Commitment and Resource Allocation:** Successful GMP implementation in FDA-regulated industries relies on strong leadership and adequate resources. Committed management ensures investments in infrastructure, equipment, and technology, while a skilled Quality Assurance and Regulatory Affairs (QARA) team oversees compliance, documentation, and audits. Without proper infrastructure and expertise, even well-designed plans may fail, underscoring their critical role in maintaining quality and compliance.
- **Building a strong QMS Framework:** Develop a QMS aligned with 21 CFR Part 211 (pharmaceuticals), 21 CFR Part 111 (nutraceuticals), and [21 CFR Part 820](#) (medical devices). Maintain SOPs, and work instructions, and organize quality records for effective process controls. Implement good documentation practices and conduct regular data audits to identify inconsistencies.
- **Simulate FDA inspections through mock audits** to assess preparedness, strengthen responses, and train teams to demonstrate compliance. Address any findings promptly and submit clear corrective action plans to the FDA as necessary.
- **Employee Training and Audit Preparedness:** Offer comprehensive training on GMP guidelines, CAPA processes, and inspection readiness. Maintain detailed training records for audit compliance. Regularly conduct mock audits to familiarize staff with FDA inspection protocols and enhance their confidence in addressing auditor queries.
- **Establishing an Effective CAPA System:** Implement a robust CAPA framework to address non-conformities. Conduct root cause analyses and introduce preventive measures to reduce recurring issues, ensuring long-term compliance and operational efficiency.
- **Supplier Qualification and Material Control:** Evaluate and approve suppliers to ensure high-quality raw materials and components. Maintain traceability records for all materials and enforce incoming material testing to confirm compliance with specifications and control plans.
- **Addressing Laboratory Practice Deficiencies:** Inadequate laboratory oversight can lead to serious compliance issues, such as mishandling Out-of-Specification (OOS) results and incomplete deviation investigations. Non-compliant or poorly executed stability studies may also fail to meet FDA standards, jeopardizing product quality and regulatory approval.
- **Labelling and Packaging Compliance:** Errors in labelling and packaging, particularly in the nutraceutical sector, can lead to misbranding violations. Many nutraceutical products fail to meet 21 CFR Part 101 labelling requirements, resulting in misleading claims or incomplete ingredient disclosures. These issues can undermine regulatory compliance and consumer trust.

- Establishing Complaint Handling and Post-Market Surveillance Systems: Develop systems to track, investigate, and resolve customer complaints effectively. Ensure timely reporting of adverse events and prompt corrective actions. Implement continuous post-market surveillance to monitor product compliance and proactively address emerging issues.
- Partnering with Experienced [FDA Consultants](#): Collaborate with firms with expertise in GMP implementation, pre-audit assessments, and managing FDA Form 483 responses. Leverage their experience to streamline CAPA execution and improve regulatory preparedness.
- Utilizing Technology for Compliance Management: Leverage technology-driven solutions to streamline documentation, enhance data integrity, and improve audit readiness. Audit management software monitors findings, tracks corrective actions, and digitises quality records for better traceability and efficiency.

By integrating these strategies, manufacturers can strengthen compliance, reduce regulatory risks, and ensure consistent success in FDA audits.

Indian manufacturers must strive to strengthen GMP compliance and cater to the rising demand for high-quality healthcare products. Currently, the need for effective implementation of GMP with zero deficiencies during [US FDA inspection](#) must be given high priority. Achieving FDA audit success requires a proactive strategy focused on strong management commitment, comprehensive employee training, rigorous process validation, and meticulous documentation practices. By emphasizing continuous improvement and leveraging technology to streamline compliance workflows, manufacturers can meet regulatory requirements and enhance their reputation for quality and reliability on a global scale.

With the US FDA's growing presence in India, staying ahead of evolving regulatory expectations is essential—not only for successful audits but also for sustained market access, especially amid the China Plus One strategy reshaping global supply chains.

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