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Streamlining Compliance within Indian R&D Labs

The evolving compliance landscape presents a constant challenge for Indian research labs. Aligning with international standards such as the U.S. Food and Drug Administration (USFDA) Code of Federal Regulations Part 11 can boost research credibility and enhance export readiness. To help meet regulatory challenges, labs are switching to Electronic Lab Notebooks and Lab Information Management solutions, looking to unlock efficiency, productivity and opportunity.

Chris Stumpf, Director, Drug Discovery Informatics Solutions, Revvity Signals emphasizes that Indian labs aiming to supply drug products to regulated markets are increasingly implementing compliant digital infrastructure.

For Indian research laboratories in regulated industries such as pharmaceuticals, biotechnology and chemicals, the compliance landscape is undergoing a major shift, driven by updated regulatory frameworks.

For example, the New Drugs and Clinical Trials (NDCT) Rules 2019 aims to streamline clinical trial approvals and align India's practices more closely with international standards. The introduction of NDCT has been fueled by the elevation in India's standing as a global research collaborator. The data shows that there were more than 200 global clinical trials during 2023 involving Indian research organizations.

As Indian laboratories continue to integrate more closely with the global research sector and gain greater market share, regulators are ramping up their scrutiny. Oversight is growing from both domestic agencies such as Bureau of Indian Standards (BIS) and Central Drugs Standard Control Organization (CDSCO), and from international authorities such as the European Medicines Agency (EMA) and US Food and Drug Administration (FDA).

To align with global standards such as GLP, GMP and data integrity guidelines, research organizations are asked to prove that they possess robust and secure electronic record keeping systems, in line with the FDA's Code of Federal Regulations (CFR) Part 11. The regulation sets out the criteria for creating, modifying, maintaining, archiving and retrieving of electronic data, to ensure that it is credible, traceable and export-ready.

Pitfalls and Problems on the compliance journey

Traditional research environments often grapple with enduring compliance challenges arising from outdated data management practices. Many labs rely on manual data recording with fragmented information residing across departments, often in varying formats and isolated in specialized systems. Similarly, paper-based and hybrid records are prone to missing entries and unauthorized data changes. In both cases, retrieving, validating and using data can be a taxing, slow and frustrating task.

The inconsistencies in data integrity coupled with lack of traceability mean that many research labs fail to comply with regulatory audits. Inevitably this causes delays in product development and increases the time to market. To help drive adoption of GLP and GMP guidelines, the trend is towards centralized, standardized data management. Lab Information Management Systems (LIMS) and Electronic Lab Notebooks (ELNs) are now

almost baseline requirements for modern research, and establishing the foundations of compliance readiness through automation and real-time data, combined with enterprise-level security controls and data verification.

Alignment with global standards

Essentially, CFR Part 11 sets out the use of electronic records and signatures in select industries, particularly for those regulated by the U.S. Food and Drug Administration. The aim is to establish standards for authenticity and data integrity, which provide the equivalent of a paper trail in the electronic domain. While the FDA is a U.S. organization, in effect the CFR Part 11 rules establish the global standards.

Adopting a modern ELN will help to streamline documentation and processes, and the key to the selection is being able to fulfill the core criteria of CFR Part 11. The main requirements include access controls, audit trails, system validation, electronic signatures, system security, record protection and documentation for all systems involved in processing the electronic data.

For Indian companies seeking global reach, meeting CFR Part 11 standards is an entry qualification that must be achieved, and the only practical way is to ensure that the selected LIMS and ELN solutions offer suitable compliance-ready technical controls.

Indian labs aiming to supply drug products to regulated markets are increasingly implementing compliant digital infrastructure to meet expectations and this is only expected to grow. Available data indicates India is projected to have the highest annual compound growth rate (CAGR) in ELN adoption globally between 2025 and 2030, reflecting its rapid digital transformation.

With these adoption rates, Indian R&D pharmaceutical, biotechnology and chemical sectors are benefiting from a transformative business impact. With enhanced operational processes, the sector is better equipped to gain global market share. Over time, incorporating digital platforms will demonstrate to potential customers that Indian R&D labs have very strong relationships with global regulatory bodies, creating increased opportunities for collaboration and innovation.

Reaching out to new markets

As India works to enhance its position as a global R&D and manufacturing hub, alignment with international regulations such as 21 CFR Part 11 is clearly a strategic necessity for credibility, market access and innovation.

While adopting LIMS and ELN solutions do not instantly deliver regulatory compliance, they offer the essential digital capabilities that enable the critical workflows, processes and standards. Investing in compliance-ready capable electronic solutions and platforms with a strong global track record of success is the first step towards creating a streamlined organization that can comply with complex global regulations while simultaneously leading to the next phase of innovation and growth. ■

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