Continuous compliance becomes critical for CRDMOs

Alok Mehrotra, Chief Quality, Engineering, and Safety Officer, Syngene International Ltd., spoke about how Indian CRDMOs are embedding quality and compliance into their operations through anytime audit readiness.

Global pharmaceutical manufacturing is entering a phase of tighter regulatory oversight. One of the most significant developments is the expansion of unannounced inspections by the U.S. Food and Drug Administration (FDA) at foreign manufacturing facilities producing foods, essential medicines, and other medical products intended for American consumers and patients.

The move builds on earlier pilot programs in India and China. It aims to ensure that overseas manufacturers are subject to the same level of scrutiny as domestic facilities in the United States.

Historically, many foreign facilities received advance notice before inspections, sometimes weeks in advance, while domestic manufacturers were inspected without warning. This difference raised concerns about regulatory parity and the ability to assess compliance under normal operating conditions.

Expanding unannounced inspections is intended to close that gap and ensure that products entering the U.S. market meet uniform safety, quality, integrity, and reliability standards.

Regulators are also placing greater emphasis on earlier preapproval inspections during biologics reviews. Scheduling inspections at the midpoint of the review cycle allows sponsors and manufacturing partners sufficient time to address observations before regulatory decisions are finalised. Together, these developments signal a regulatory environment in which compliance must be demonstrable at any time.

A proactive approach to regulatory scrutiny

For Indian Contract Research, Development, and Manufacturing Organisations (CRDMOs), however, this expectation is not entirely new. Many organisations began building systems for continuous audit readiness during the pandemic. Travel restrictions limited physical inspections, and regulators increasingly relied on virtual reviews and remote document access.

CRDMOs strengthened digital documentation systems, centralised quality platforms, and remote inspection capabilities to enable real-time access to operational and quality data.

These investments laid the groundwork for what is now widely described as an “Anytime Audit Ready” (ATAR) operating model. Instead of preparing for inspections periodically, organisations ensure that facilities, documentation, and operational records remain inspection-ready at all times.

According to the Indian Pharmaceutical Alliance (IPA), India’s pharma manufacturing base has made notable

strides in quality over the past decade. Between 2015 and 2025, the share of Official Action Indicated (OAI) outcomes for Indian plants fell from 12% to 8%, even as inspections became more frequent, stringent, and often conducted with little or no notice. In contrast, global pharma saw OAI rates rise from 9% to 13% over the same period. No Action Indicated (NAI) observations for Indian manufacturers increased. At the same time, Voluntary Action Indicated (VAI) cases declined, reflecting a shift toward institutionalised, risk-based, systems-driven quality practices rather than episodic compliance.

Building a culture of continuous compliance

At the heart of these improvements is the recognition that regulatory compliance cannot be treated as a periodic exercise. It must instead be embedded into everyday operations. This is where the Anytime Audit Ready philosophy plays a central role.

In practice, ATAR reflects a cultural transformation within CRDMOs. Quality is no longer viewed solely as the responsibility of assurance teams preparing for inspections. Instead, it is integrated into operational decision-making across functions, including development, manufacturing, documentation, and data management. Accountability is distributed across teams, reinforcing the expectation that every process and record must meet regulatory standards at all times.

Systems and governance underpinning continuous oversight

Digital systems have become essential enablers of this new compliance culture. Electronic Quality Management Systems (eQMS) and Electronic Document Management Systems (EDMS) enable organisations to maintain centralised control over documentation while providing real-time visibility into deviations, corrective and preventive actions, and change controls. Automated version control and training tracking ensure employees always work with current procedures and maintain documented competency.

CRDMOs are also strengthening governance structures that sustain operational discipline. Routine self-inspections and internal audits replicate regulatory reviews and help identify gaps before they become inspection findings. Supplier qualification programs ensure upstream partners meet the same expectations as manufacturing facilities. Structured data governance and disciplined change management frameworks further reinforce consistency across development and production environments.

Technology-enabled predictive quality and remote monitoring

Technology is also supporting more proactive operational management. Advanced analytics tools can detect process deviations, documentation inconsistencies, or operational bottlenecks early, allowing teams to intervene before issues escalate. Automation in laboratories and development environments helps standardise workflows and reduce variability, reinforcing a right-first-time approach to data generation and reporting.

The pandemic accelerated the use of remote inspections, and virtual regulatory engagement is now an established component of global oversight. Secure video platforms, digital document access, and assisted reality technologies allow regulators to review facilities and observe processes remotely.

Making audit readiness an everyday discipline

Looking ahead, regulatory oversight is likely to become increasingly data-driven, with greater reliance on digital evidence, real-time monitoring, and risk-based inspection models. For CRDMOs operating within global supply chains, this will require systems that continuously demonstrate traceability, consistency, and transparency across development and manufacturing activities.

Organisations that treat audit readiness as an inherent feature of operations will be better positioned to adapt to evolving regulatory expectations. As pharmaceutical development becomes more complex and supply chains become more interconnected, sustaining transparent, digitally enabled operational systems will remain central to maintaining regulatory confidence and global partnerships.

Authored by:
Alok Mehrotra
Chief Quality, Engineering & Safety Officer
Syngene International Ltd