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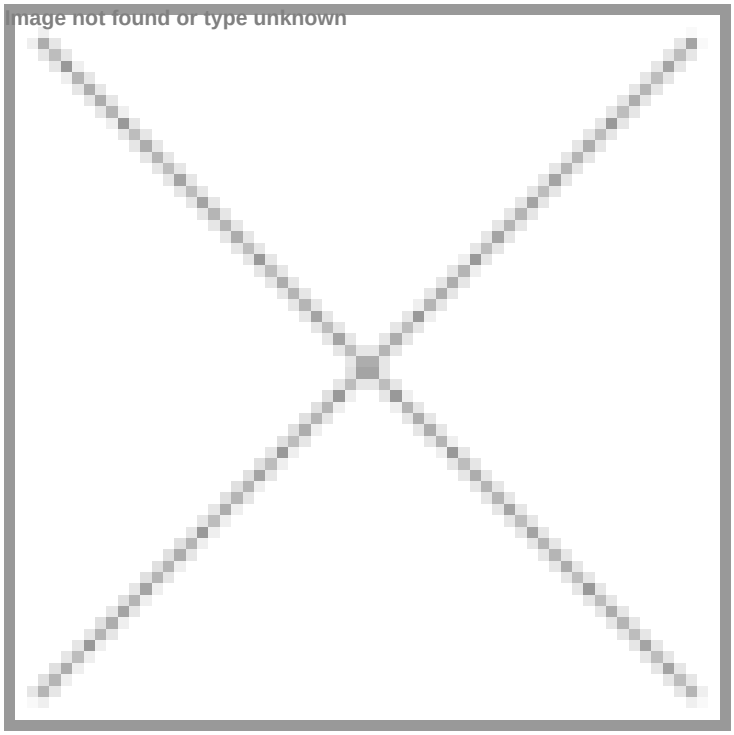
Technology's role in strengthening quality culture in Indian CDMOs

23 September 2025 | Views | By Alok Mehrotra, Chief Quality Officer, Syngene International

As pharmaceutical operations grow more complex, the integration of technology into quality systems is setting a new benchmark



At the heart of pharmaceutical manufacturing lies a simple principle: medicines must be safe, effective, and reliable every single time. For Contract Development and Manufacturing Organizations (CDMOs), this requires more than regulatory compliance; it demands a quality culture that permeates every level of the organization. Indian CDMOs have been strengthening this culture steadily, and the results are visible. According to a 2024 study by the Indian Pharmaceutical Alliance and McKinsey, the proportion of US Food and Drug Administration (US FDA) “Official Action Indicated” (OAI) classifications for Indian facilities declined from 26% in 2014 to 13% in 2023, outperforming the global average of around 15%. Over the same decade, OAI notices to Indian firms dropped by nearly 50%, pointing to a more mature ecosystem of oversight.

What underpins this progress is an evolution from static compliance to continuous improvement. Surveillance programmes now consolidate data across manufacturing systems, highlighting early signals of potential deviations and enabling timely interventions. The adoption of Industry 4.0 principles in pharma—often referred to as Pharma 4.0—is introducing predictive analytics, artificial intelligence (AI) models, and digital dashboards, giving teams the ability to anticipate risks rather than simply react to them. This alignment of culture with technology ensures that quality is not just maintained, but continually reinforced.

Internal audits and a state of readiness

A strong quality culture is tested not during inspections, but in the day-to-day discipline of operations. Indian CDMOs are embedding this discipline by moving towards a state of “Anytime Audit Ready” (ATAR). Automated Quality Management Systems (QMS) and Electronic Document Management Systems (EDMS) provide a real-time view of deviations, Corrective and Preventive Actions (CAPAs), and change controls, ensuring that data always meet ALCOA+ integrity standards.

This readiness is further sustained through multiple layers of oversight. Self-inspections address weaknesses before they become findings. Internal audits simulate regulatory reviews and strengthen preparedness. Gemba walks, supported by mobile tools, allow managers to verify that procedures are followed on the shop floor. Daily checks, weekly reviews, and long-term surveillance provide continuity, while regulatory intelligence systems ensure Standard Operating Procedures (SOPs) remain aligned with evolving global guidelines. Crucially, accountability is being decentralized: by making quality a Key Performance Indicator (KPI) for all employees, not just Quality Assurance (QA) teams, organizations are embedding ownership into the culture itself.

Technology is also transforming how competence is maintained. Learning Management Systems (LMS) deliver structured training and track completion, giving regulators visibility into compliance. Scenario-based simulations address variability across teams and strengthen a “right-first-time” approach. Together, these measures ensure that audit readiness is not a one-off exercise, but an everyday reality.

Remote inspections and the role of technology

The pandemic accelerated a shift that is now permanent: the rise of remote inspections. Regulators increasingly use secure video platforms and assisted reality devices to review facilities in real time. For CDMOs, this requires the same rigor as a physical audit—procedures must be visible, records must be accessible, and staff must be prepared to engage seamlessly.

- **Real-Time Collaboration:** Remote inspections create opportunities for immediate collaboration during quality investigations, troubleshooting, and technology transfers. This not only shortens response times but also helps improve equipment uptime and issue resolution.
- **Training and Knowledge Transfer:** High-definition recordings of walkthroughs and processes can be archived in the cloud, serving as a valuable resource for onboarding new personnel and transferring knowledge across teams. By transforming inspection outputs into training material, CDMOs strengthen organizational competence while ensuring consistency.
- **Efficiency and Technical Success:** Client subject matter experts (SMEs) can now participate virtually in technology or method transfers. This eliminates travel, accelerates timelines, and improves overall throughput. Importantly, it also raises the technical probability of success (TPS) for transfers by enabling closer, more frequent oversight without geographical barriers.

Toward a digital-first quality culture

As pharmaceutical operations grow more complex, the integration of technology into quality systems is setting a new benchmark. Paperless workflows, real-time monitoring, predictive analytics, and remote oversight are embedding compliance into daily execution. For Indian CDMOs, this shift is already underway. At Syngene, for example, these efforts are visible in the use of secure remote inspection technologies such as RealWear, digitised checklists, and electronic batch records. Together, they help sustain a state of continuous audit readiness. These digital initiatives are reinforced by a broader shift toward decentralised accountability, ensuring that quality is embedded across teams and processes rather than being managed in isolation.

This evolution signals both progress and opportunity for Indian CDMOs. By combining a strong quality culture with digital tools, organizations can go beyond meeting today’s compliance requirements to proactively shaping tomorrow’s standards. Those that see quality not just as a safeguard but as a strategic advantage will build stronger partnerships, operate with greater efficiency, and secure a lasting place for India in the global pharmaceutical supply chain.

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