DID YOU KNOW?
WE'RE SPEAKING @RQA CONFERENCE IN BRIGHTON
5TH-8TH NOVEMBER 2024

RiverArk®
Quality Delivered

First and foremost...

The growing scrutiny from the FDA, EMA, and MHRA necessitates a heightened focus on inspection readiness for executive leadership in the coming year.

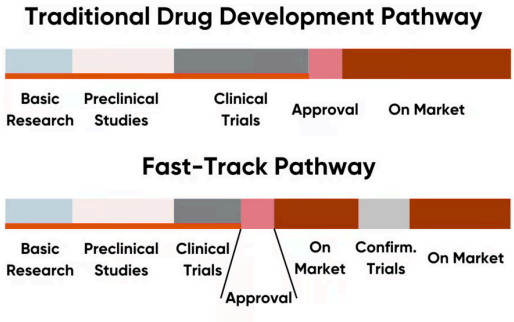
For instance in the Pharmacovigilance world, The Qualified Person for Pharmacovigilance (QPPV) is a cornerstone of inspection readiness, with a pivotal role in ensuring adherence to regulatory standards. Nonetheless, Quality Assurance (QA) departments frequently encounter obstacles that hinder their ability to satisfy inspection requirements. A common challenge is the misalignment between internal audit schedules and the regulatory timelines imposed by agencies or suppliers. This lack of synchronization can result in overlapping audits, resource shortages, and missed deadlines, each of which poses significant risks to the organisation.

Inspection Readiness checklist

For 2025, executive leaders should integrate QPPV oversight and external resources into their audit strategies, ensuring flexibility, resource alignment, and a proactive approach to inspection readiness. The stakes are too high for anything less than seamless execution.

Hot industry news

- **The FDA has sparked significant debate** with its recent decision to revise the accelerated approval pathway for certain high-profile drugs. In response to criticism about post-market surveillance, the agency is tightening requirements, demanding more robust clinical trial data before granting early approvals. This move adds further pressure on auditing and data integrity processes.



- **The FDA issued new guidelines for stricter cybersecurity measures** in Med Device industry, specifically targeting vulnerabilities in connected devices. QA teams must now incorporate cybersecurity checks into their auditing processes, as non-compliance could lead to delays in approvals and market entry.

- Merck and Moderna have announced an expanded partnership to develop mRNA-based vaccines. While this promises significant advances in vaccine tech, it introduces complex manufacturing and QA challenges. Regulatory bodies are already keeping a close eye on mRNA production facilities, demanding tighter controls over purity, stability, and scalability, which **will require enhanced auditing capabilities and real-time quality oversight.**

RiverArk voice:

Joshua Marsh

Senior QA Auditor
8+ years industry experience

In the digital age, maintaining data integrity is essential, especially in the pharmaceutical industry, where regulatory compliance is critical. The ALCOA+ principles—Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available—offer a framework for data integrity, also applicable to digital systems. Each principle emphasises precise documentation, accurate record-keeping, and secure, accessible storage.

Key Challenges in the Digital Environment:

- **Cybersecurity**: Robust access controls, strong password policies, firewalls, and encryption safeguard data integrity.
- **Data Migration and Integration**: Data integrity must be preserved during system transfers, and migration processes must be validated to ensure accuracy.
- **Cloud Computing**: Providers should meet stringent data security and integrity standards, given the rise of cloud-based storage.
- **Software Validation**: All software that generates, processes, or stores regulated data must be validated to meet regulatory requirements like 21 CFR Part 11.
- **Electronic Signatures:** Systems should comply with electronic signature standards to ensure traceability.

Fostering a Culture of Data Integrity is crucial. Regular training on ALCOA+, clear understanding of data responsibilities, continuous oversight, and updates as regulations evolve are essential for maintaining integrity in a rapidly advancing digital landscape.

VISIT OUR WEBSITE FOR CASE STUDIES