

First and foremost...

Inspection Readiness in Pharma SME:

In this edition, we spotlight a critical inspection readiness project for a U.S.-based SME. With 250 employees and a focus on two therapeutic areas, the company was on the verge of registering its flagship product after extensive multinational trials. However, the path was far from smooth.

The Challenge: The startup faced significant hurdles, including non-compliance at clinical investigator sites and insufficient oversight from their CRO. As inspections loomed from both local and international authorities, it became clear that a robust and immediate solution was essential.

RiverArk's Outcome: Our proactive and strategic approach culminated in successful inspection management, paving the way for the smooth registration of the product.



Inspection Readiness processes were mandated and training accomplished in 6 weeks



10 Audits were accomplished within 7 weeks



The risk evaluation performed on the various elements of the project was adequate & acceptable to the regulators

Hot industry news

- The FDA's recent data on **Good Manufacturing Practices (GMP)** highlighted the most common citations given during inspections. These included failures in maintaining procedures for CAPA and control of nonconforming products. This reflects the agency's continued vigilance in ensuring that pharmaceutical companies adhere to strict quality standards in manufacturing.
- Recently, the International Council for Harmonisation (ICH) has been revising M4Q(R1) guidelines, to improve the efficiency of drug registration and lifecycle management, which could impact the **QA processes for mental health treatments**.

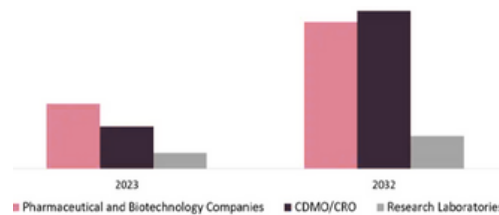


Figure 1: Pharmaceutical QA market: End use dynamics (USD billion. Source: emergentresearch.com)

- The Pharma QA market is expanding as CROs and CDMOs prioritise quality assurance (Figure 1)** Robust QA ensures compliance with regulatory standards, enhances risk management, and supports technological advancements. For CROs and CDMOs, this means improved reliability, reduced errors, and greater client trust, driving growth and industry success.



RiverArk voice:

Ashok Kumar

Principal GxP QA Auditor, 15+ years experience

Auditing and inspection preparation play vital, yet distinct, roles in ensuring compliance in regulated industries.

The Role of Auditing

Auditing is crucial for quality assurance and compliance. Internal audits assess whether an organization's processes and practices meet established standards. They systematically identify weaknesses and areas for improvement, helping uncover compliance issues before they escalate.

Inspection Preparation

Inspection preparation is more targeted, focusing on getting an organization ready for a specific upcoming inspection. It involves reviewing documentation, training staff, conducting mock inspections, and addressing known deficiencies. The goal is to ensure full compliance with regulations on the inspection day.

Complementary Roles

While auditing and inspection preparation are distinct, they complement each other. Regular audits enhance inspection readiness by identifying issues early, refining processes, ensuring documentation is up-to-date, and training staff. However, relying solely on audits is risky, as they may not cover specific inspection targets or anticipate inspectors' unpredictable questions.

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