

DID YOU KNOW? MORE THAN 30% OF OUR CLIENTS SWITCHED FROM OTHER CONSULTANCIES TO US— AND THEY NEVER LOOKED BACK!



First and foremost...

As we enter Q4, the pharma industry faces a recurring challenge: under-resourced QA departments. This creates a critical need for immediate action, as the consequences of an incomplete or poorly managed audit can be severe.

Failing to meet audit timelines or quality expectations can lead to significant legal repercussions, damaging reputations, and delaying drug approvals.

Last-minute audits demand a sharp grasp of the regulatory landscape and exceptional agility to navigate shifting regulatory standards. In these high-pressure situations, the stakes are high, and mistakes are not optional (Figure 1).

This is where industry-focused expertise becomes invaluable. Unlike generalised approaches that may not address underlying issues and the complexities of specific regulatory environments, a more tailored strategy is essential.

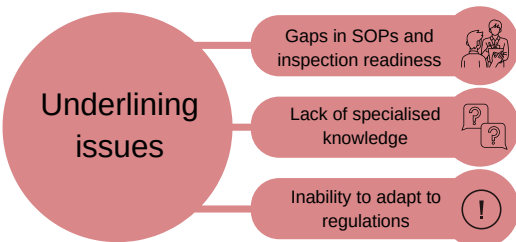


Figure 1: Urgent audit requirements often expose underlying issues and risks. The three most common ones are listed above.

At RiverArk, we are accustomed to these audits being able to quickly assess risks, mobilise specialised teams, and implement bespoke solutions that align with the precise needs of the project. In urgent audits, having a QA partner who adapts to the deadlines and embodies compliance can make the impact in maintaining regulatory harmony.

Hot industry news

FDA's New Draft Guidance on Decentralised Clinical Trials (DCTs): The FDA recently released a draft guidance focused on improving decentralised clinical trials (Figure 2), highlighting quality considerations for data management, remote monitoring, and ensuring patient safety. This impacts how clinical trials are conducted and monitored, necessitating adjustments in QA processes.

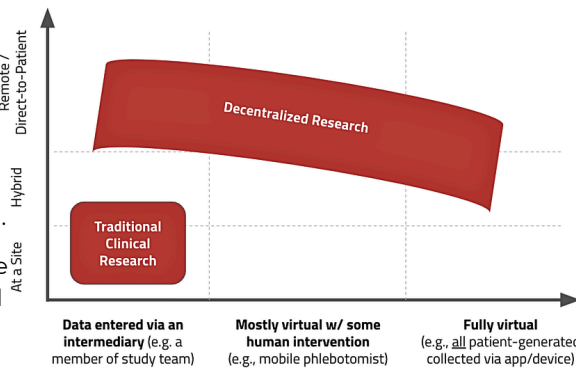


Figure 2: Decentralised studies have two components: decreased reliance on an intermediary, and on physical location. Figure adapted from ElectraLabs

- **Pfizer's Strategic Workforce Optimisation:** Pfizer has initiated a strategic workforce optimisation plan, resulting in layoffs affecting various departments, including QA. The company is adjusting its workforce to better align with its evolving pipeline of specialty drugs and vaccines.
- **Bristol-Myers Squibb (BMS) Consolidation Efforts:** BMS has announced a plan to consolidate some of its operations, which includes reducing headcount in QA and compliance roles in certain locations. This is part of a broader effort to increase efficiency and redirect resources toward key growth areas such as cell therapy and oncology.



RiverArk voice:

Kim Ritchie

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8+ years industry experience

Good Clinical Practice (GCP) is a recognised quality standard for clinical trials involving human participants, guiding every stage from design through to reporting. To ensure this standard is upheld, a quality management system is implemented throughout the trial process, and GCP audits play a crucial role in maintaining compliance. These audits are an essential, independent assessment of clinical trial activities and documentation, aimed at evaluating adherence to GCP regulations and guidelines.

Being selected for a GCP audit does not imply any wrongdoing or suspicion of non-compliance. Selection is based on a risk-based approach, where various factors are considered, such as the site's enrolment of a large number of participants or the complexity of the study. These audits should not be a source of anxiety, as they are designed to ensure that everyone involved shares the same primary objectives: compliance with regulations, the generation of reliable and accurate data, and, most importantly, safeguarding the rights, safety, and well-being of all trial participants throughout the study.

GCP audits serve as a crucial pillar for building trust and ensuring the integrity of clinical trials. At RiverArk, we emphasise that these audits should be viewed not merely as regulatory requirements but as valuable opportunities for operational improvement and enhanced data reliability. By embracing GCP audits, organisations can foster a culture of continuous improvement, ultimately safeguarding patient safety while advancing innovation in their clinical research efforts.

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