31 JULY 2022

Newsletter

EDITION #1

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Did you know? Our consultants are specialised in Cardiology/Vascular, Endocrinology, Gastroenterology, Neurology, Oncology, Pediatrics and Pulmonary / Respiratory Disease TAs with average 15 years of experience.

RiverArk®
Quality Delivered

First and foremost...

We've all heard of cases of a medium-sized medical device or pharma company facing challenges in quality oversight after mergers. In our client's case, despite a strong expertise in oncology diagnostics, their research group struggled with effective oversight, as highlighted by regulators.

RiverArk devised a three-pronged strategy to address this: developing a fit-for-purpose Quality Management System (QMS) compliant with specific regulations; creating a comprehensive risk evaluation and management plan with a three-tiered strategy for product, clinical study, and investigator site levels; and implementing a hybrid risk-based audit strategy combining traditional and risk-based assessments. This included process and investigator site audits, ongoing quality evaluations, and periodic risk re-evaluations.

The result was documented quality oversight, enhanced sponsor control, improved partner engagement, better inspection readiness, and realistic risk exposure assessment, ensuring robust quality control and compliance for future clinical trials.

Hot industry news

Eli Lilly has appointed a new Executive Vice President of Global Quality, bringing over 25 years of experience to the role, highlighting a focus on strategic quality initiatives.

Additionally, the industry is seeing a push for more sustainable practices, exemplified by a new RP-HPLC method for determining hypertension drugs that uses ethanol as a solvent, offering a more environmentally-friendly approach.

Data integrity and the implementation of FAIR data principles remain critical topics, with discussions on ensuring data reliability and transparency in pharmaceutical research and development.

Moreover, the sector continues to grapple with quality control issues. Recent FDA warning letters have highlighted persistent compliance problems, including failures in quality unit responsibilities and environmental monitoring lapses.

Figure 3. FDA Warning Letters by Industry Sector by FY

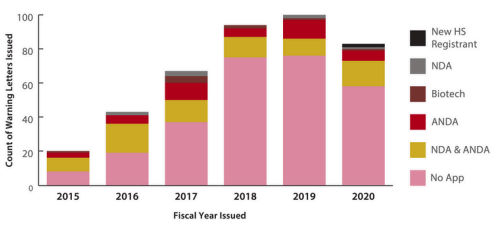

Figure 3 adapted from FDA warning letters https://www.thefdagroup.com/blog/2019-fda-warning-letter-inspection-observation-trends

RiverArk voice:

Ryan Tchen

Project manager 15+ years

In the highly regulated world of pharmaceuticals, ensuring the quality and safety of products is paramount. At RiverArk, we understand that robust project management is the backbone of effective Pharmaceutical Quality Assurance (QA) auditing processes.

Project management brings structure and clarity to QA audits, ensuring every phase is meticulously planned and executed. This systematic approach helps in identifying potential risks early, allocating resources efficiently, and maintaining strict adherence to regulatory requirements. Moreover, project management fosters clear communication and collaboration among cross-functional teams. It facilitates the integration of diverse expertise, from clinical research to regulatory affairs, ensuring comprehensive audits that leave no stone unturned.

For us, project management is not just a support function but a critical component of Pharmaceutical QA auditing. . At RiverArk, we are committed to excellence in project management, driving the success of our QA auditing processes and contributing to the greater good of healthcare.

VISIT OUR WEBSITE FOR CASE STUDIES