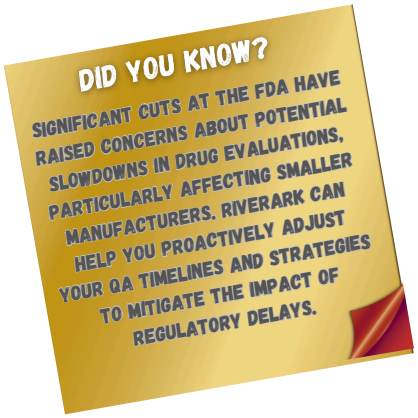


First and foremost...

RiverArk at the 2025 European QA Virtual Conference

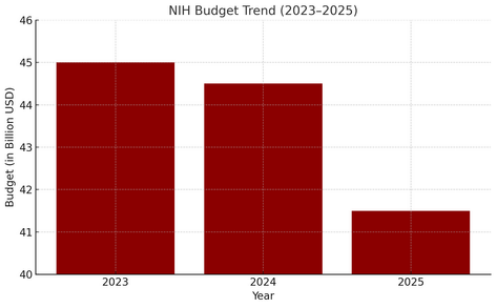
RiverArk proudly participated as a Gold Sponsor at the 2025 European QA Virtual Conference, held on May 20–21. This global event brought together quality assurance professionals from across the pharmaceutical, biotech, and medical device sectors. Our expert team delivered thought-provoking presentations on timely topics, from conflict resolution within QA teams to the evolving role of artificial intelligence in digitised quality systems. Featuring Milind Nadgouda, Daniel Bennett, Kim Ritchie, and Ashok Kumar, RiverArk's sessions exemplified our commitment to driving innovation and operational excellence across GxP environments.

UK MHRA Advances Medical Device Regulations

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has published new guidance on post-market surveillance for medical devices, set to take effect on June 16, 2025. Manufacturers must implement robust surveillance systems, including periodic safety updates and incident reporting, to ensure device safety and efficacy.

NIH Funding Cuts Impact Biotech Start-Ups

The Trump administration's $3 billion cut to the National Institutes of Health (NIH) budget has severely affected U.S. biotech start-ups. Many companies are halting projects and furloughing staff due to frozen grants and reduced investor confidence, potentially hindering future medical innovations.



EMA Strengthens Conflict of Interest Policies

Effective May 2025, the European Medicines Agency (EMA) has updated its conflict of interest policies. Experts with current interests in a product, including principal investigators, will be excluded from related procedures. A three-year cooling-off period now applies to experts with prior pharmaceutical employment. These changes aim to enhance transparency and trust in regulatory assessments.

RiverArk voice:

Daniel Bennett

Snr. Quality Consultant

Defining Records: A Case for Clear Documentation Practices in GxP Environments

There's a phrase in EU GMP Volume 4 that was a pleasant surprise the first time I read it. It struck me as a very good idea, and I wondered why other GxPs hadn't done something similar. From Part 1, Chapter 4: "The various types of documents used should be fully defined in the manufacturer's Quality Management System." Fully defined in the QMS. That seems like a solid approach.
EU GVP modules require records to be created to report and verify all activities, with a clear description of which documents are considered records, how they are stored, and for how long. This comes close to the same idea, though without stating it outright.

ICH E6 R2 alludes to it with the term "essential" documents, but rarely has so much confusion stemmed from such a vague definition. Sponsors and their teams move closer with their TMF indexes, yet meaningful, study-specific tailoring remains more honoured in the breach than the observance. Over time, I've come to believe this task belongs in the vendor engagement process, not just at study start-up.

While clinical trials involve more unforeseeable events than manufacturing, making complete definition a challenge, there's value in setting out procedures clearly to meet legal and regulatory requirements. SOPs and work instructions should not only detail what is done but also how it's recorded, by whom, when, and what to do when standard records aren't feasible.

Continued on next page....

30 MAY 2025

Quality Quotient

EDITION #10

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Hot industry news

Biotech Firms Explore Overseas Trials Amid FDA Upheaval

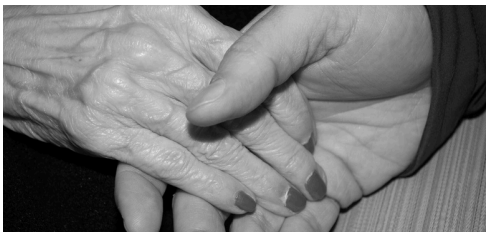
Due to recent leadership changes and restructuring at the FDA, some U.S. biotech companies are considering conducting early-stage drug trials outside the country to mitigate potential delays in regulatory reviews.
🔍 **QA Insight:** Conducting trials internationally introduces varying regulatory standards. QA professionals must ensure that quality systems are adaptable and compliant with both domestic and international regulations to maintain data integrity and trial validity.

Interest Grows in Amylin-Based Weight-Loss Drugs

Pharmaceutical companies are investing in amylin-based therapies as a new approach to weight loss, with ongoing developments and trials aiming to offer alternatives to GLP-1-based drugs. The development of novel therapies requires QA teams to establish new validation protocols and ensure that manufacturing processes meet regulatory standards for emerging drug classes.

FDA Proposes Mandatory Placebo Testing for All New Vaccines

The FDA has introduced a proposal requiring placebo-controlled trials for all new vaccine approvals, a move that could extend development timelines and increase costs for vaccine developers.
🔍**QA Insight:** This proposed mandate underscores the need for QA professionals to adapt clinical trial protocols and ensure robust data integrity measures are in place. QA teams will play a crucial role in overseeing the implementation of placebo controls and maintaining compliance with evolving regulatory requirements.



Therapeutic Plasma Exchange Shows Potential in Reducing Biological Age

A ground-breaking clinical trial has revealed that therapeutic plasma exchange combined with intravenous immunoglobulin can reduce biological age by an average of 2.6 years, offering promising implications for aging-related therapies.
🔍**QA Insight:** Emerging therapies targeting aging biomarkers require QA teams to develop novel validation methods and ensure the reliability of multi-omic data. Establishing standardized protocols for such innovative treatments is essential to maintain data accuracy and regulatory compliance.

New Injection Therapy Offers Sustained Blood Pressure Reduction

The KARDIA-2 trial has demonstrated that a semi-annual injection of zilebesiran significantly lowers blood pressure in patients with hypertension, presenting a long-term treatment alternative.

Long-acting injectable therapies necessitate meticulous QA oversight to ensure consistent dosing and sustained efficacy. QA professionals must focus on the stability of the formulation, proper storage conditions, and accurate administration protocols to guarantee patient safety.

AbbVie Secures FDA Approval for Antibody-Drug Conjugate in Solid Tumors

AbbVie has achieved a significant milestone with the FDA approval of its lead antibody-drug conjugate (ADC) for treating solid tumors, marking a pivotal advancement in oncology therapeutics. The approval of complex biologics like ADCs necessitates rigorous QA oversight to ensure consistency in manufacturing processes and adherence to regulatory standards. QA teams must be vigilant in validating analytical methods and maintaining product integrity throughout the production lifecycle.

RiverArk® Quality Delivered

RiverArk voice:

Daniel Bennett

Snr. Quality Consultant

... Continued

ICH E6 R3 brings us further along, stressing the need to incorporate quality and risk management early in trial design. Quality by design asks us to identify critical quality factors prospectively. It suggests a "structured content list for storage repositories may be used to prospectively identify essential records," though it stops short of treating record-keeping as a critical factor itself. Still, its definition of essential records is an improvement.

On the subject of clarifying which records are to be created and maintained, it's equally important to define how they are to be created. Does your organisation have a set of 'good documentation practices'? It's curious how often people refer to 'GDocP' as if it were a formally recognised GxP. Some companies have in-house versions, which is a start, but many do not. Since no global regulatory body has formally defined it, we shouldn't overstate its importance—but some risk-based guidance from qualified professionals wouldn't hurt, would it?

In another newsletter, I'll argue the same case for metrics: it's sensible to describe performance metrics explicitly in procedural documents. And yes, you should have some good performance metrics practices—GMetP.

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