30 APR 2025

Quality Quotient

EDITION #9

30TH APRIL 2025 | WWW.RIVERARK.COM | YOUR GLOBAL QA PARTNER

First and foremost...

RiverArk at the 2025 SQA Annual Meeting: Leading with Quality

RiverArk proudly participated as a Platinum Sponsor at the 41st SQA Annual Meeting and Quality College, held from April 6–11, 2025, in Orlando, Florida, which was attended by 675 people including exhibitors. Our team engaged with industry professionals, sharing insights and showcasing our commitment to excellence in quality assurance.

Key Contributions:

- **Interactive Workshop:** Milind Nadgouda, Loveleen Kukreja, and Josh Marsh led a session on "CAPA from Regulatory Observations," providing practical strategies for addressing compliance challenges.
- **Speaking Engagement:** The duo also presented "Ensuring PV System Excellence: The Interplay of PV QMS and QA," alongside Larry Thomas, Vice President of Quality and Regulatory Affairs of Spectrum Chemical Mfg Corp., discussing the integration of pharmacovigilance systems within quality frameworks.

- **Poster Presentations:** Topics included "QA Considerations for Real-World Evidence Trials," "The QPPV's Impact: Enhancing PV System Performance and Safety," and "Project Management in the GxP QA World," offering attendees a glimpse into our innovative approaches to quality assurance.
- **Exhibition Booth:** Our Business Development team, represented by Mariam Garelnabi and Tina Huang, and our CEO - Madhavi Nadgouda, connected with attendees at Booths 203/205, discussing RiverArk's quality services and solutions.

Why It Matters:

RiverArk's active presence at the SQA Annual Meeting reflects our ongoing leadership in shaping the future of quality across the life sciences. By sharing thought leadership, real-world solutions, and regulatory insights, we're not only supporting our clients but also advancing QA best practices across the global GxP landscape.

For more details on our participation and insights from the conference, visit our official announcement: https://riverark.com/join-us-at-the-41st-sqa-annual-meeting-and-quality-college-in-orlando/

RiverArk voice:

Joshua Marsh

Senior QA Auditor

Navigating the new landscape: ICH M10 and Bioanalytical Method Validation

Bioanalysis is a key component in the trialling of any investigational medicinal product (IMP) and generates the pharmacokinetic, toxicokinetic, and bioavailability/bioequivalence data used for new drug application (NDA) submissions. Accurate and precise bioanalytical methods ensure the integrity of clinical and non-clinical data. Therefore, the data generated from bioanalytical studies safeguards patient safety and drug efficiency. Thorough validation of bioanalytical methods demonstrates that a method is fit for its intended purpose and provides confidence in the data generated.

The implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) M10 guidance has significantly impacted bioanalytical method validation. This guideline aims to harmonise global regulatory expectations, replacing the previous guidance documents from the EMA and FDA.

The main advantage of the ICH M10 is its global harmonisation. The reduction of various guidance across multiple territories streamlines the drug development process and reduces costs. The increased clarity and specificity regarding certain validation parameters, like incurred sample reanalysis (ISR) and stability, enhance the consistency and reliability of data from bioanalytical analysis.

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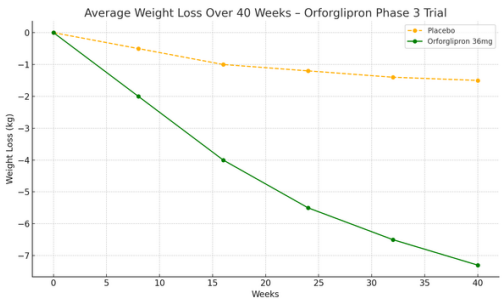
Hot industry news

🧬 Biomarkers Streamline Trials—But Add QA Complexity

The integration of biomarkers like plasma pTau217 in Alzheimer's trials is revolutionizing clinical design, making it faster and less invasive. However, this evolution brings new QA responsibilities, including validating exploratory endpoints, enhancing biobank oversight, and ensuring patient data traceability.

🌟 Clinical Breakthrough: Orforglipron Emerges as First Oral GLP-1 for Weight Loss

In a major stride toward accessible obesity treatments, Eli Lilly's oral weight-loss drug orforglipron has shown substantial efficacy in its Phase 3 trial. The study, involving 559 adults with type 2 diabetes, revealed that participants on the highest dose (36mg) lost an average of 7.3kg over 40 weeks, alongside improved blood sugar control. Unlike injectable GLP-1 therapies like Ozempic, orforglipron is tablet-based, shelf-stable at room temperature, and requires no refrigeration—offering significant advantages in patient convenience and cold chain QA logistics.
🔍 **QA Perspective:** This innovation brings new QA challenges—from oral formulation consistency and GI tolerability monitoring, to reevaluating cold-chain-dependency in storage protocols. The simplified administration may increase patient adherence—but also demands strong post-market surveillance systems.



EMA Validates Gilead's Lenacapavir for HIV Prevention

The European Medicines Agency (EMA) has validated Gilead Sciences' Marketing Authorization Application for lenacapavir, a twice-yearly injectable for HIV prevention. Supported by Phase 3 PURPOSE trials, lenacapavir demonstrated a 96% risk reduction in HIV infections, showing superiority over daily oral PrEP options. This advancement could significantly impact HIV prevention strategies across Europe.

Lenacapavir's EMA Validation: A Case Study in PV-Quality Integration

New Standards in Long-Acting Drug Oversight

The EMA's validation of Gilead's lenacapavir brings long-acting injectables into the spotlight. With its twice-yearly dosing schedule, lenacapavir demands an evolved approach to pharmacovigilance (PV) and QA integration. Batch consistency, cold-chain control, and adverse event reporting systems must operate at peak precision.
📌 **QA Watchpoint:** Align QMS with emerging product profiles—especially for long-acting injectables where quality signals may take longer to emerge post-administration.

MHRA's 2024/25 Plan: A Blueprint for QA Innovation

The MHRA's strategic shift toward tech-enabled oversight (SafetyConnect, RegulatoryConnect) signals regulators' expectations for digital maturity. QA leaders must embrace digital QA systems and predictive quality analytics to stay ahead. The retooled ILAP pathway is also an opportunity for QA teams to engage earlier in development with faster approvals in mind.
💡 **QA Opportunity:** Map your digital QA roadmap. Look for pilot opportunities with MHRA's new tools, especially for early-phase programs seeking ILAP designation.

FDA Workforce Disruption: A QA Wake-Up Call

Impact on Regulatory Oversight and Compliance

The recent mass dismissal of FDA tobacco compliance staff is more than a tobacco control issue—it's a cautionary tale for QA professionals. Regulatory enforcement functions can shift dramatically under political or economic pressure, underscoring the need for internal quality systems that are resilient, proactive, and not overly reliant on external audits to identify risks.
🔎 **QA Insight:** Use this moment to revisit internal audit schedules, training plans, and inspection readiness—especially for compliance-critical areas like labeling, distribution, and manufacturing.

🌍 Expanding Clinical Trial Sites: QA at Scale

As sponsors broaden their investigator pool and CRO consolidations reshape the site landscape, QA must adapt to maintain consistency. This expansion necessitates robust site qualification processes, remote monitoring tools, and harmonized SOPs to manage variability and uphold quality standards.

RiverArk®
Quality Delivered

RiverArk voice:

Joshua Marsh

Senior QA Auditor

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In the past, laboratories would implement validation strategies covering the requirements of EMA and FDA guidance if the data would be needed for NDAs in multiple nations. A method validated in accordance with the ICH M10 guidance should not require additional method validation even if the laboratory doesn't know where the NDA will be submitted.

While many of the requirements for bioanalytical method validation are consistent between the ICH M10 and EMA and FDA guidance (such as precision and accuracy, and selectivity) some parameters have changed. These changes include criteria applied to ISR and stability assessments. The changes required reflect the current best practices for method validation. Methods validated under EMA and FDA guidance can be shown to meet the requirements of ICH M10 with partial validation. A strategy that is common across the industry.

In summary, the ICH M10 guideline has ushered in a new era for bioanalytical method validation. While it demands careful adaptation and resource allocation, its benefits in terms of global harmonisation, enhanced data reliability, and risk-based approaches are undeniable. We must remain vigilant in ensuring that our organisations are effectively implementing these guidelines, thereby maintaining the highest standards of data integrity and patient safety.