31 JAN 2025

Quality Quotient

EDITION #6

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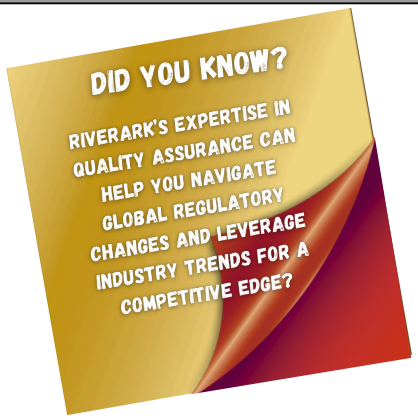


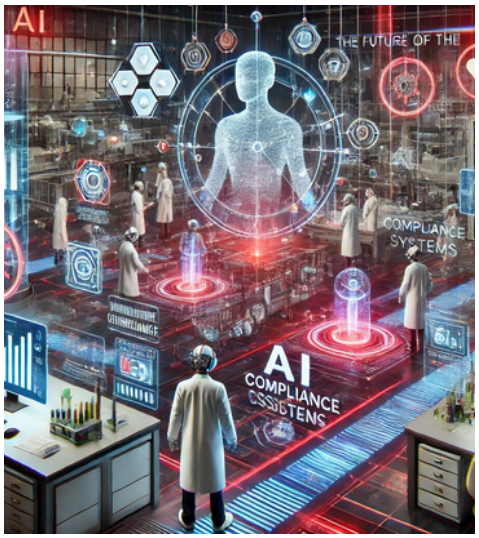
RiverArk®
Quality Delivered

First and foremost...

Pharmaceutical Quality Assurance in 2025: Regulatory Updates and Emerging Trends

The pharmaceutical industry is at a pivotal moment, with key developments shaping the future of quality assurance (QA). As part of RiverArk's commitment to staying at the forefront of these changes, we are proud to share recent updates and trends that will define 2025 and beyond.

Over the past month, several significant regulatory updates have emerged in the pharmaceutical, medical device, and bioscience research sectors. Looking ahead to 2025, these developments are expected to shape the quality assurance landscape.



Hot industry news

ICH E6(R3) Final Guidance Release

The long-awaited ICH E6(R3) guideline on Good Clinical Practice emphasizes a modernized, risk-based approach to clinical trials. This update integrates the principles of quality by design, ensuring robust trial design and oversight that prioritizes patient safety and data integrity.

FDA's Focus on Advanced Manufacturing Technologies (AMT)

The FDA's final guidance on AMT encourages the adoption of innovative manufacturing processes to enhance product quality and supply chain resilience. This marks a significant push toward modernizing pharmaceutical production and ensuring consistency.

Integration of AI in Pharmacovigilance

Regulatory bodies are increasingly exploring the role of artificial intelligence in pharmacovigilance. While AI can streamline processes like case safety evaluation, human oversight remains critical for nuanced decision-making. The FDA's Emerging Drug Safety Technology Meeting (EDSTM) program highlights the collaborative efforts to establish confidence in these technologies.

RiverArk voice:
Mariam Garelnabi

Product Engagement - How we at RiverArk do it?

As members of the marketing and business development team, we recognize the transformative role quality assurance (QA) plays in the pharmaceutical industry. QA is at the core of patient safety, regulatory compliance, and innovation—essential for maintaining trust in healthcare products. With the increasing complexity of global regulations and emerging technologies, the QA industry presents exciting opportunities for growth and impactful change.
Looking ahead to 2025, the QA sector is set to leverage advancements such as risk-based approaches, digital transformation, and global harmonization initiatives like ICH guidelines. These developments allow companies to address regulatory complexities and bridge knowledge gaps by fostering adaptability and continuous learning. Through innovative solutions, QA teams can ensure compliance while enhancing the efficiency of quality systems.

At the heart of this evolution are strong team dynamics and robust client relationships. Collaboration and shared expertise among consultants and QA professionals empower organizations to adopt tailored solutions that align with regulatory standards. Additionally, fostering trust and transparency with clients drives mutual success, ensuring that quality and safety remain top priorities.

Continued on next page....

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Hot industry news

FDA Removes Clinical Trial Diversity Guidance:

The U.S. Food and Drug Administration (FDA) has removed draft guidance requiring pharmaceutical and medical device companies to ensure diverse population participation in clinical trials. This action follows an executive order to dismantle diversity, equity, and inclusion policies across federal agencies. Critics argue that this may hinder understanding of drug responses across different populations.

Regulation of Online Weight-Loss Injections:

Pharmacies in the UK are calling for stricter regulations on the online sale of weight-loss injections due to anticipated increased demand. The National Pharmacy Association urges regulators to mandate thorough patient consultations prior to dispensing these injections online.

Potential Health Care Policy Shifts Under New U.S. Administration:

The election of Donald Trump brings potential policy changes that may influence the biotech sector, including regulatory practices, drug pricing negotiations, and the development of specific therapeutic areas. Some segments of the industry consider these changes may bring uncertainty whilst few are in favour thinking this will be less disruptive.

Upcoming Clinical Trial Results Impacting Pharma Stocks:

Significant clinical trial results in 2025 could greatly impact stock prices of key pharmaceutical companies. Companies like Eli Lilly, Novo Nordisk, BioNTech, Pfizer, and AbbVie are expected to release trial results that may influence market dynamics.

Challenges with 'UK Only' Labelling Scheme:

The UK's generic drug industry is facing challenges in meeting the new "UK only" labelling requirements for medicines entering Northern Ireland, mandated to start from January 1, 2025. The British Generic Manufacturers Association has warned of potential supply shortages due to compliance issues.

MHRA's Roadmap for Medical Device Regulation:

The Medicines and Healthcare products Regulatory Agency (MHRA) has published a roadmap outlining the revised timeline for implementing reforms to the UK's medical devices regulatory framework. The roadmap includes work streams on post-market surveillance, pre-market requirements, policy development, and software including AI & digital mental health products.

RiverArk voice:

Mariam Garelnabi

Product Engagement - How we at RiverArk do it?

... Continued

This partnership approach helps tackle inefficiencies, maintain audit-readiness, and set new benchmarks for industry excellence. For professionals in QA, the rewards go beyond technical achievements. Contributing to safer medicines, developing expertise, and being part of a supportive, forward-thinking team bring immense satisfaction. At RiverArk, we are proud to help organizations navigate these changes while fostering a culture of quality. The future of QA is bright, with boundless potential to drive excellence and innovation across the pharmaceutical landscape.

2024 RiverArk Audits at a glance

- **A**udited in 45 Countries
- Conducted audits in 20 states in the USA
- Delivered audits across 22 different therapeutic categories of products

2024 RiverArk Inspection Readiness Projects at a glance

- Worked with 11 clients to deliver inspection readiness
- Conducted mock inspections for readiness towards US FDA, MHRA, EMA, PDA and NMPA
- Prepared 143 SME's from various functions across multiple organisations for inspections

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