31ST OCTOBER 2025

Quality Quotient

EDITION #15

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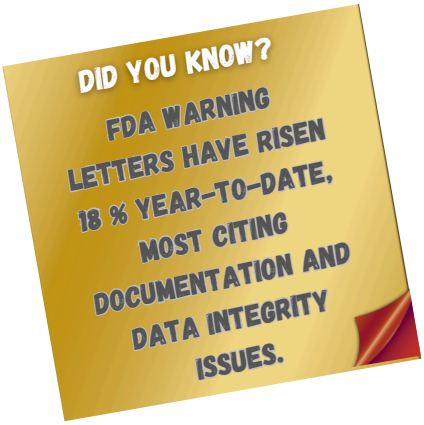
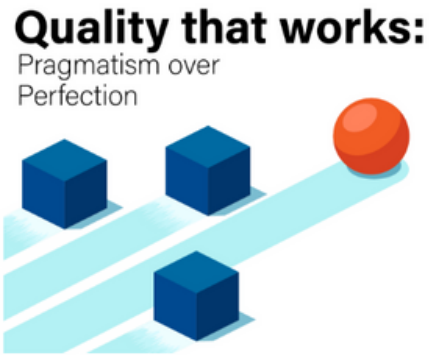


RiverArk at RQA 2025: Championing Innovation, Adaptability, and Quality Culture

RiverArk is proud to announce its participation as a Gold Sponsor at the upcoming Research Quality Association (RQA) 2025 International QA Conference, taking place at the ICC Belfast from 5–7 November 2025.

As one of the leading events for global QA professionals, the conference will bring together thought leaders, regulators, and industry experts to share best practices, new approaches, and forward-looking strategies shaping the future of quality in life sciences.

The RiverArk team will be on-site in Hall 1BCD throughout the conference. Delegates are warmly invited to visit RiverArk's stand to discuss how our tailored QA solutions are helping organisations navigate regulatory change, strengthen data integrity, and deliver operational excellence, even in times of economic and organisational restructuring.



🪄 Innovation Theatre Session: "Lean Times, Smart Quality: QA Adaptation to Budget Restructuring"

As part of this year's Innovation Theatres, RiverArk will deliver a special session titled "Lean Times, Smart Quality: QA Adaptation to Budget Restructuring." This interactive talk will explore how QA leaders can preserve excellence amid tightening budgets—using smarter resource allocation, digitalisation, and data-driven decision-making to sustain compliance and quality performance. The session encourages attendees to connect, recharge, and gain practical strategies for building resilient, value-focused quality systems.

🧠 Expert Sessions from RiverArk's Team

RiverArk's experts will lead a series of bespoke talks throughout the conference, offering deep dives into the human, cultural, and analytical sides of quality assurance:

- Milind Nadgouda – "Human Error or System Failure? Rethinking Root Cause Analysis" – Wednesday, 5 Nov at 15:30
- Kim Ritchie – "Adaptable Approach to Audits: Going Off Audit Plan" – Wednesday, 5 Nov at 16:30
- Ashok Kumar – "Quality in Focus: Going Beyond Metrics to What Truly Matters" – Thursday, 6 Nov at 14:15
- Milind Nadgouda – "The Human Element in QbD" – Thursday, 6 Nov at 15:30

These sessions reflect RiverArk's commitment to redefining quality as a strategic enabler—one that goes beyond compliance to drive innovation, efficiency, and long-term organisational success.

RiverArk looks forward to connecting with clients, partners, and peers in Belfast to explore how the right balance of innovation, culture, and compliance can transform quality systems into catalysts for growth.

RiverArk voice:

Tina Huang

Business Development Manager

Quality Culture Isn't Optional: What Startups Need to Get Right Early

In today's life sciences landscape, quality culture has shifted from a nice-to-have to a business-critical expectation. For established organisations, mature systems and multiple layers of oversight are often built in. But for startups, the path is more complex: How do you strike the right balance—embedding quality early while staying fast, flexible, and focused on growth?

Startups typically operate with lean resources, cross-functional teams, and ambitious roadmaps. Yet as product pipelines evolve, and partnerships and clinical milestones approach, a shift in focus becomes essential. Increasingly, regulators, partners, and investors aren't just asking if you're compliant—they're asking how quality is integrated into your operations. That shift has implications well beyond audit readiness.

From a business development perspective, we regularly engage with early-stage companies preparing for clinical trials, undergoing due diligence, or expanding globally. What we often see is that quality culture gaps aren't just regulatory risks—they're business risks. Challenges like delayed submissions, failed vendor audits, and missed partnership opportunities often stem from quality systems that haven't matured in step with a company's growth—creating risks that can slow progress and undermine trust.

What defines a strong quality culture in a startup? It's not about implementing complex systems for the sake of it. It's about making quality part of everyday decision-making. Industry trends consistently highlight the same pressure points. Are senior leaders involved in quality-related decisions, or just reviewing outcomes?

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Industry & Regulatory Highlights

FDA Fast-Tracks Biosimilar Approvals

The U.S. FDA has announced a plan to simplify biosimilar approvals, potentially eliminating some human clinical study requirements when strong analytical comparability data exist. From a quality assurance standpoint, the change signals that firms should revisit supplier qualification, control strategy, documentation of analytical bridging, and ensure their quality systems are prepared for increased scrutiny of biosimilar manufacturing pathways.

FDA Warns Philips over cGMP Failures

Following inspections of three facilities, the FDA issued a warning letter to Philips citing non-compliance with cGMP standards. Although Philips stated it doesn't expect significant commercial impact, the case underscores the ongoing importance of manufacturing quality, documentation, deviation handling and complaint management even for device manufacturers. For QA professionals across pharma/biotech, the lesson is clear: supplier/contractor oversight, cross-site audit harmonisation, and rigorous documentation of remediation activities cannot be taken for granted.

FDA Issues New NDA Filing Checklist and Expanded Access Guidance

The FDA has rolled out a new NDA checklist and finalized Expanded Access guidance to reduce "refuse-to-file" outcomes. From a QA/regulatory perspective, this means companies must ensure submission documents, data integrity practices, and audit-trail documentation are aligned with the updated checklist. It also underscores the continuing importance of tracking agency procedural changes and aligning the Quality Management System (QMS) to support streamlined regulatory workflows.

FDA Launches the CMC Development & Readiness Pilot (CDRP)

The FDA's CMC Readiness Pilot opened to help early-stage innovators identify CMC and quality risks before filing. For QA and CMC operations, participation in the CDRP means early alignment of process validation strategy, risk management, and quality oversight is more important than ever. Organizations should start assessing their readiness for this program, verifying risk-based control frameworks, data integrity mechanisms and supplier oversight structures.

Pharma Giants Collaborate to Harness AI for Drug Discovery

A new consortium led by Bristol Myers Squibb, Takeda Pharmaceuticals, AbbVie and Johnson & Johnson has pooled thousands of proprietary protein–small molecule structure datasets to train the AI model "OpenFold3". This federated approach enables collaboration without exposing sensitive data, with the goal of improving accuracy in predicting small-molecule interactions with proteins. As AI begins to underpin discovery workflows, quality assurance teams must prepare to validate and audit algorithm-driven processes, ensure data integrity of training sets and model outputs, and integrate AI governance within the QMS.

Indian Pharma Meet Highlights AI's Role in Drug Development & Safety

At a recent industry–academia event organised by the Indian Pharmaceutical Association (IPA), experts emphasised how artificial intelligence is reshaping drug discovery timelines, clinical trial processes and pharmacovigilance—especially in emerging markets. AI was highlighted as a tool to reduce typical development times of 10–15 years and to detect safety signals earlier. QA professionals should focus on how AI impacts safety monitoring, documentation, audit trails and vendor oversight. Integrating robust validation and governance of AI systems will become a critical component of modern quality frameworks.

Strategic Acquisition in Rare Diseases Signals Pipeline Shift

Novartis has agreed to acquire Avidity Biosciences for approximately US $12 billion, marking a major strategic move into late-stage rare disease therapies including RNA-based assets. The acquisition is intended to boost Novartis' pipeline ahead of upcoming patent cliffs and expand its biologic/oligonucleotide capabilities. For QA teams, the entry into high-complexity modalities (RNA, oligonucleotides, rare disease) means greater emphasis on manufacturing controls, process validation in novel platforms, and lifecycle risk management across modalities.

RiverArk voice:

Tina Huang

Business Development Manager

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Is vendor oversight structured, documented, and risk-based? In a world of remote teams and decentralised operations, can your data be traced reliably? And when issues arise, does your team perform thorough root cause analysis and implement meaningful CAPA—or just tick the box?

Startups don't need to replicate the complex structures of larger companies to meet these expectations. What's needed is a proportional approach: fit-for-purpose systems, deliberate planning, and clear accountability. Building scalable foundations early enables companies to adapt as their products, teams, and partnerships evolve. This means developing streamlined procedures, preparing thoughtfully for inspections, and ensuring transparent vendor oversight—all while managing limited resources and tight deadlines. By prioritising quality culture from the outset, startups can avoid costly setbacks and maintain the agility essential for growth.

In today's environment—where timelines are tight, data is scrutinised, and global regulations are converging—investing in quality isn't a luxury. It's a differentiator. It shows regulators that you're prepared. It shows investors that you're scalable. And most importantly, it shows patients that you're trustworthy. Building a strong quality culture early creates a foundation for sustainable growth, reducing risks and smoothing the path to market. It enables teams to respond swiftly to challenges without sacrificing compliance or integrity. Ultimately, quality becomes more than a checkbox—it becomes a strategic asset that drives confidence across every stakeholder.

For life sciences startups, launching a product marks a significant achievement. But embedding a strong quality culture from the start is what truly sets the foundation for long-term success. Quality isn't optional—it's essential to building a resilient, trusted company that can grow and thrive.

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