30 SEPTEMBER 2025

Quality Quotient

EDITION #14

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

First and foremost...

RiverArk at World Drug Safety Congress Europe 2025

WORLD DRUGSAFETY CONGRESS EUROPE

RiverArk is excited to announce our participation as a Gold Sponsor at the World Drug Safety Congress Europe in Amsterdam, 7–8 October 2025.

You can find us in Hall 3, Booth 13, where our team will be showcasing how RiverArk's tailored QA solutions can help advance safety, compliance, and quality in today's complex pharmaceutical landscape.

If you're attending, be sure to stop by our booth to meet our experts, explore how we're supporting global pharma and biotech partners, and learn more about our commitment to raising the quality bar across the industry. You also stand a chance to win one of our mystery prizes!

We look forward to connecting with you in Amsterdam!

FDA Strengthens Oversight on Obesity Drug API Imports Over Safety Concerns

On September 5th, 2025, The U.S. Food and Drug Administration (FDA) announced enhanced controls and tighter scrutiny on imports of active pharmaceutical ingredients (APIs) used in obesity drugs, citing mounting safety concerns and past instances of contamination. Under the new regime, import inspections will increase, and firms will face stricter verification requirements for API suppliers, particularly in higher-risk jurisdictions. The move underscores growing regulatory insistence on supply chain integrity and quality oversight, especially for high-demand therapeutic classes.

Manufacturers and CDMOs supplying obesity or metabolic therapy APIs should re-evaluate supplier qualification audits, certificate of analysis (CoA) support, and risk mitigation plans to align with the FDA's elevated expectations.

This regulatory tightening reinforces the importance of rigorous supplier qualification, inbound quality checks, and verification of documentation, especially for key APIs in high-profile drug classes.

RiverArk® Quality Delivered

RiverArk voice:

Loveleen Kukreja

Principal QA Auditor

Meet Elsa: FDA's AI Leap Toward Faster, Smarter Scientific Reviews

In a significant move toward digital transformation, on 02 Jun 2025 the U.S. Food and Drug Administration (FDA) unveiled a new generative AI tool named Elsa, designed to enhance operational efficiency across the agency, including streamlining scientific reviews.

FDA Commissioner Marty Makary praised the early and cost-effective rollout, stating, "Today's rollout of Elsa is ahead of schedule and under budget, thanks to the collaboration of our in-house experts across the centers."

Elsa is already being used to accelerate clinical protocol reviews, reduce the time required for scientific evaluations, and help identify high-priority inspection targets. This tool assists FDA reviewers by summarizing adverse events, evaluating safety profiles, and rapidly comparing drug packaging inserts—key tasks in the regulatory decision-making process.

VISIT OUR WEBSITE FOR CASE STUDIES

30 SEPTEMBER 2025

Quality Quotient

EDITION #14

31ST AUGUST 2025 | WWW.RIVERARK.COM | YOUR GLOBAL QA PARTNER

Hot industry news

Pharma Giants Rush to Onshore U.S. Manufacturing Ahead of Tariff Deadline

Facing an imminent 100% tariff on imported branded drugs starting October 1 (unless U.S. production is underway), multinational pharmaceutical firms are scrambling to bolster on-shore capacity and stockpile inventory. Companies with limited U.S. footprint risk heavy duty exposure. Roche and Novartis affirmed they anticipated exemption, citing ongoing construction of new U.S. manufacturing sites. Several other firms are reportedly accelerating capital commitments and revalidating supply chain routes. For quality assurance functions, this shift mandates rigorous change control, technology transfer oversight, validation of new or expanded facilities, and sustained control of cross-site comparability.

QA teams will need to ensure seamless process transfers, alignment of control strategies, and consistency of specifications across legacy and new sites to maintain “state of control.”

AI and Automation Take Centre Stage in Quality, Supply Chain, Training

At the recent PDA Regulatory Conference, a recurring theme was how artificial intelligence (AI) and automation are reshaping the pharmaceutical quality landscape. Companies are increasingly deploying AI in quality monitoring, predictive analytics for supply chain risk, and automated training modules for staff. Observers emphasized that while technology can drive efficiency, human oversight, robust algorithm validation, and data governance remain indispensable. The conference sessions also stressed the importance of cultivating a strong organizational quality culture to complement digital tools.

As pharma embraces intelligent systems, QA functions must build frameworks for model validation, auditability, traceability, bias assessment, and change management of algorithmic processes.

Small Biotechs Lean on Big Pharma Collaboration to Accelerate Rare Disease Programs

In a recently published series, SynaptixBio’s CEO highlighted how agile biotech firms are forging partnerships with large pharma to shepherd rare disease assets efficiently through development and manufacturing scale-up. The collaboration model enables small firms to access robust QA/QC infrastructure, regulatory experience, and risk-sharing pathways while focusing on early-stage innovation. Even so, alignment on quality standards, process harmonization, and data interoperability remains a pivotal challenge across partnering organizations.

For QA leads, these partnerships demand due diligence on alignment of quality systems, cross-auditability, common specifications, and governance of joint CAPA and deviation handling.

Continued Process Verification: A Pillar of Sustained Quality in Pharma

A recent article reasserted the importance of Continued Process Verification (CPV) (or Ongoing Process Verification in the EU) as a core requirement in lifecycle management of pharmaceutical products. After initial process qualification, CPV practices monitor key process parameters and critical quality attributes over time, detect trend drifts, and trigger timely corrective or preventive actions. Regulators expect CPV protocols to be predefined, statistically robust, and documented with clear decision rules and governance. The article underscores that CPV is not optional — it is foundational to maintaining a validated state.

QA and manufacturing teams should revisit CPV protocols, ensure trend detection tools are adequate, define action thresholds, and maintain oversight of process performance through product life.

RiverArk®
Quality Delivered

RiverArk voice:

Loveleen Kukreja

Principal QA Auditor

... Continued

With drug approval timelines ranging from six to ten months, tools like Elsa are expected to play a pivotal role in supporting timely and thorough reviews. Importantly, Elsa operates within a secure FDA environment and does not train on industry-submitted data, ensuring the protection of confidential research information.

Following a successful experimental phase, the FDA confirmed in May that it would fully integrate AI across its operations by June 30. Elsa marks a major step in that direction, signaling the agency’s commitment to embracing innovation while maintaining high standards of regulatory oversight.

Final thoughts

September has been a month of significant shifts in the global life sciences landscape, with regulators tightening oversight on critical supply chains, accelerating approval pathways with the help of AI, and preparing far-reaching changes to GMP guidelines. For QA professionals, the common thread is clear: adaptability and vigilance remain paramount.

From evolving process verification requirements to onshoring strategies driven by tariffs, and from rare disease collaborations to the rapid rise of intelligent quality systems, the industry is navigating both opportunity and challenge. RiverArk remains committed to guiding our partners through these transitions with clarity, compliance, and confidence.

As we move into the final quarter of 2025, let’s continue to embrace innovation while upholding the highest standards of quality and patient safety.

VISIT OUR WEBSITE FOR CASE STUDIES