30 JUNE 2025

Quality Quotient

EDITION #11

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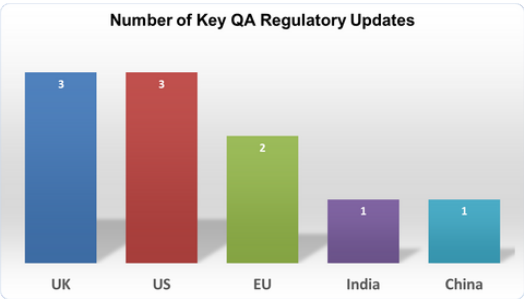
First and foremost...

Global Regulatory Highlights – June 2025

This month has seen significant regulatory updates that impact quality assurance across pharmaceuticals and life sciences. In the UK, the MHRA implemented sweeping reforms to medical device regulations, revised its fee structure effective July, and issued a recall of mercaptopurine due to contamination risks. In the US, the FDA launched a pilot program to fast-track high-quality CMC submissions, expanded its Quality Management Maturity (QMM) initiative, and released guidance to streamline eSubmissions.

The EU continued its regulatory alignment with the African Medicines Agency and updated GxP inspection approaches. India extended its GMP compliance deadline for SMEs to December 2025, easing the transition to WHO-aligned standards. China experienced supply chain disruptions, as CMOs re-prioritized domestic manufacturing due to global trade tensions.

These changes underscore the need for agile quality systems, proactive compliance strategies, and resilient supply chain oversight. RiverArk offers tailored support—from regulatory readiness and QMS upgrades to global supplier audits—to help clients stay ahead in a shifting landscape.



EMA Updates Third-Party Audit Q&As

EMA expanded its GMP Q&A document with new guidance on including third-party audit findings within Part C of the Qualified Person (QP) declaration.

QA Insight: Demonstrates evolving responsibility for documenting external audit outcomes and maintaining oversight.

RiverArk Can Help: Train QPs on audit reporting standards, design robust oversight protocols, and prepare compliant QP declarations.

FDA Draft Guidance for OTC Solid Dosage Changes

In mid-June, the FDA released a draft guidance outlining how manufacturers can make minor changes—such as form factor or excipients—to over-the-counter solid oral dosage forms (e.g. chewable or disintegrating tablets) under established monographs.

QA Insight: This offers flexibility in formulation innovation, but also demands updated change-control protocols, stability testing, and clear supporting data.

RiverArk Can Help: Audit current change-control systems, adapt SOPs, and ensure robust justification and documentation for dosage form modifications.

FDA Q-Sub Guidance for Medical Devices

At the end of May, the FDA issued final guidance on the Q-Submission process and a draft PreSTAR template for electronic pre-submissions . This clarifies expectations and improves workflow for early feedback from CDRH and CBER.

QA Insight: Leveraging these tools can reduce submission errors, miscommunications, and review delays.

RiverArk Can Help: Guide clients in building submission documents, mock-FDA meetings, and prepping electronic templates to align with agency expectations.

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RiverArk voice:

Ananya Nadgouda

Project and Process Analyst

GxP Project Management - Making Quality Decisions Through Risk & Resilience

When I first stepped into project management within a GxP consulting environment, I thought I had a good handle on risk. After all, risk registers, timelines, and contingency plans are part of any PM's toolkit. But working in regulated industries where quality, compliance, and patient safety are always at the forefront taught me that risk means more than missing a deadline or shifting scope.

In GxP projects, risk is layered. There's operational risk (will we meet our milestones?), compliance risk (are we aligned with current regulations?), and reputational risk (are we maintaining the trust of our clients and stakeholders?). Every deliverable, every decision, and even every delay has a potential knock-on effect not just on the project, but on the client's ability to remain inspection-ready or bring safe products to market.

What I've learned is that managing risk in this environment requires a different kind of attentiveness. It's not just about flagging issues; it's about spotting subtle signals early. A team member unsure about a requirement, a client quietly overwhelmed by documentation, a deliverable that doesn't quite align with SOPs. Resilience, in that sense, isn't just about reacting well under pressure; it's about preparing the ground to avoid the pressure in the first place.

One of the most valuable things I've taken from this work is the importance of communication. GxP projects involve multiple stakeholders such as auditors, consultants, quality leads, IT, etc., and here, clarity becomes everything.

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Hot industry news

FDA Expands Quality Management Maturity (QMM) Program

The FDA's 2025 rollout of the QMM program includes a streamlined maturity assessment focused on managerial commitment, business continuity, technical excellence, advanced quality systems, and staff empowerment.

Companies must apply by June 2025 to participate.

🔍**QA Insight:** This presents an opportunity to gain recognition, potential inspection leniency, and operational improvement.

Gilead's Lenacapavir (Yeztugo): First Twice-Yearly HIV Prevention Injection

On June 18, the FDA approved lenacapavir, branded Yeztugo, a twice-yearly injectable for HIV pre-exposure prophylaxis. Clinical trials showed near-100% efficacy in preventing HIV transmission.

From a quality assurance perspective, this means that ensuring consistency and sterility in long-acting injectable manufacturing is critical. Long-term stability, cold-chain logistics, and tracking traceability are all crucial QA considerations.

EMA Hosts Centralised Procedure Summit

On June 23, the EMA convened the 14th Industry Stakeholder Platform Meeting to engage users of its centralised marketing authorisation procedure.

Topics included CTIS deployment, submission bottlenecks, and regulatory expectations under evolving GxP frameworks.

Roche Enters Late-Stage Trials for New Antibiotic "Zosurabalpin"

Roche has began late-stage trials of zosurabalpin, the first Gram-negative antibiotic in 50 years, targeting drug-resistant ICU pathogens.

🔍**QA Insight:** Antibiotic development for priority pathogens requires rigorous microbiological controls, resistance monitoring, and GMP-compliant manufacturing.

Final Thoughts

Today's top regulatory headlines illustrate a global shift toward data-driven quality, harmonized protocols, and digital transformation. Whether adopting PMS analytics, preparing CTIS dossiers, or upgrading stability systems, QA professionals face new challenges and opportunities.

RiverArk offers customized solutions—from proactive PMS redesign and Q1-guided stability systems to CTIS readiness support, contamination control, and training across geographies. Contact us to stay ahead in this rapidly evolving landscape.

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When risks are shared openly and early, it builds trust. When teams feel safe to raise concerns, we can solve problems before they escalate. It's not always easy, especially when deadlines loom, but I've seen how this kind of transparency creates more resilient projects (and healthier teams).

Lately, I've also been thinking about how we can evolve our approach to risk management especially with the growing interest in using AI tools across the industry. There's real potential here, from helping identify project bottlenecks based on historical patterns, to flagging gaps in documentation or inconsistency in requirements. It's early days, but I can see how AI could support faster, smarter risk detection, if we pair it with human insight and context.

I've also had to learn how to be comfortable with uncertainty. Regulations change, client scopes evolve, priorities shift. You can't always predict what's coming, but you can build flexibility into your planning, document decisions carefully, and keep your team grounded in purpose: ensuring quality and compliance at every step.

Ultimately, GxP project management has taught me that resilience isn't about avoiding risk. It's about being ready to meet it with structure, awareness, and calm. It's about creating a culture where quality is built into the process, not added at the end. And most of all, it's about remembering that what we do matters not just to our clients, but to the people relying on their products to be safe and effective.

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