First and foremost...

PIPA
Pharmaceutical Information & Pharmacovigilance Association

RiverArk is proud to announce that we will be exhibiting at the annual PIPA Conference 2025 – 10th & 11th September at The Mandolay Hotel, 36-40 London Road, Guildford, Surrey. GU1 2AE

Hot industry news

FDA Decisions and Approval Timelines Under the Lens

Date: August 2025
Multiple FDA decisions this month spotlight both innovation and regulatory intricacies:

- PharmaTher Holdings awaits approval for KETARX—a racemic ketamine formulation—originally delayed due to deficiencies in quality, manufacturing, and microbiology; decision due August 9.
- Insmed's Brensocatib for bronchiectasis is under priority review, with a verdict expected August 12. If approved, it would be the first therapy specifically targeting this chronic lung disease.

Continued...

- Tonix Pharmaceuticals' sublingual fibromyalgia candidate TNX-102 SL faces an FDA decision around August 15.
- Chimerix/Jazz Pharma's Dordaviprone for H3 K27M-mutant diffuse glioma is expected to be addressed by the FDA on August 18.
- Regeneron seeks to expand EYLEA HD's label and dosing schedule, with a decision slated for August 19.

These pending regulatory milestones underscore the importance of rigorous documentation, manufacturing controls, and microbial validation—critical areas for quality assurance to ensure applications are submission-ready.

Oral GLP-1 Weight-Loss Pills Near Regulatory Finish Line

Date: August 26, 2025

Pharmaceutical giants are racing to launch the first oral GLP-1 weight-loss medications. Eli Lilly's Orforglipron and Novo Nordisk's oral semaglutide are in late-stage trials, delivering up to 12.4% and 15% average weight loss, respectively. Regulatory reviews are expected by late 2025. Other players—Structure Therapeutics, Merck, AstraZeneca, Roche, Viking Therapeutics—are also advancing oral GLP-1 agonists, while Pfizer has exited the race over safety concerns. The oral format promises simpler manufacturing and distribution, potentially opening a multibillion-dollar market opportunity.

Manufacturing oral drugs elevates standards for formulation consistency, stability testing, and regulatory compliance versus injectables—a pivotal shift for QA teams preparing for scale-up.

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Psychology MSci Student - Intern

My Month with RiverArk

My month-long internship at RiverArk represented far more than a simple work experience; it marked a pivotal moment in my personal and professional development. Coinciding with my twentieth birthday, this opportunity served as a meaningful transition into both adulthood and the professional world. It felt very symbolic in its own way. I felt as if I had taken one big step into being an actual adult.

Going in, I wasn't sure what to expect. But from day one, RiverArk's culture made a lasting impression on me. I was met with a warm and welcoming environment, surrounded by genuinely supportive people. While the team operated with impressive efficiency and coordination, there was an underlying foundation of mutual respect and genuine care for one another. What particularly struck me was how approachable and down-to-earth the CEOs were, taking the time to connect with people on a personal level.

During my time here, I learned a lot about myself, about work, and about what a career might look like. One of the biggest takeaways for me was realising how much I enjoy creative and analytical tasks, particularly around user experience and design. Working on the company website was especially rewarding. It aligned perfectly with one of my university modules focused on User-Centred Design, and it confirmed that this is something I'd like to pursue further. Just as importantly, I also discovered which parts of marketing I enjoyed and which parts I did not, which is something I have not fully realised before, allowing me to have a knd of clarity I'll be carrying forward.

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Hot industry news

MannKind Eyes $300M Acquisition to Boost Pipeline

Date: August 25, 2025
MannKind Corporation is set to acquire scPharmaceuticals and its diuretic candidate targeting chronic kidney disease and heart failure, in a deal worth roughly $300 million upfront. The acquisition aims to bolster MannKind's therapeutic portfolio and development pipeline.

Integration of scPharmaceuticals' manufacturing and formulation processes will demand thorough QA alignment—comparability assessments, tech transfer protocols, and harmonized quality systems.

Exelixis and Gilead Among Firms Restructuring Staff

Date: August 2025
Industry-wide layoffs continue to ripple through life sciences:

- Gilead is laying off five staff (scientific and technical services) at its Oceanside, California site, effective by October 10 following WARN reporting.
- Iovance Biotherapeutics is reducing its workforce—affecting under 20% of total employees—as part of a strategic restructure to extend cash runway.
- BioSpace also reports Exelixis cutting ~130 roles as it closes its Pennsylvania facility, with potential relocation of roles to its California headquarters.

Workforce downsizing impacts continuity and oversight. QA leaders must reassess critical roles, manage knowledge retention, and ensure staffing changes don't compromise compliance or audit readiness.

EU Pharmaceutical Legislation Reform – Advancing Toward Enactment

The European Parliament adopted its position on a sweeping reform package around April 10, 2025, aiming to enhance medicine access, support innovation, streamline approvals, fight antimicrobial resistance, and incorporate environmental standards. The next phase: negotiation between Parliament and the Council—so implementation in the months ahead is highly likely.

Companies should prepare for evolving GMP expectations, sustainability metrics, and possibly new QA alignment requirements.

MHRA Review of Medicines and Medical Devices Act – Stakeholder Survey

On July 21, 2025, the UK government launched a call for evidence (MHRA + DHSC) to evaluate how effectively the Medicines and Medical Devices Act 2021—and related regulations—are performing.

Feedback deadline: September 19, 2025. Meanwhile, new pre-market device regulation in Great Britain is scheduled for 2026, driven by a revised regulatory roadmap.

Input from QA and RA teams could shape future device standards and compliance expectations.

Germany's Medical Research Act – Centralized Ethics for Clinical Trials

• Germany's Medical Research Act, effective in stages through mid-2025, introduces centralized ethics review starting July 1, 2025, along with streamlined procedures for ionizing-radiation-involved trials and standard contract clauses. A draft cabinet bill is under Federal Council review and expected to be finalized around July 11, 2025.

QA teams working on clinical trials must adapt QA oversight and documentation to align with these central ethical review timelines and new contractual standards.

Visit www.RiverArk.com for more updates, case studies and industry insights.

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Over the course of this fast-but-impactful month, being pushed outside my comfort zone has allowed me to grow. RiverArk helped me explore my strengths and also helped me gain more skills. I saw my video editing skills improve, but I also noticed the gaps in them, and thus, I will continue to enhance them outside of this internship. This experience gave me much-needed clarity about my future. While I'm currently pursuing an MSci in Psychology, I've always known I wanted to move toward a niche career path. Being at RiverArk gave me a chance to see different possibilities and to understand more about how I want to shape my future.

As one of the first cohorts of students to intern at RiverArk, I feel deeply honoured. I have learnt a lot about the professional world, while also learning stuff about myself. Although it was a short stay, I believe the growth was immense. I am grateful for every engaging conversation, every piece of feedback, every opportunity to apply what I have learned, and every moment that nudged me closer to understanding my future path.

Thank you, RiverArk, for helping me not only begin my twenties but also for helping me start my first steps into the professional world.