

## DID YOU KNOW?

RIVERARK CAN HELP YOUR ORGANIZATION PREPARE FOR AI-DRIVEN REGULATORY AUDITS BY VALIDATING DIGITAL HEALTH TOOLS AND CYBERSECURITY PROTOCOLS AHEAD OF FDA SUBMISSIONS?

First and foremost...

### EU injects €403 million into medical device innovation

On 22 July, the European Commission approved €403 million in public funding for 10 primarily SME-led projects to accelerate the integration of AI and digital technologies into medical devices—expected to catalyse an additional €826 million in private investment and create around 800 jobs

The scale-up in AI-enabled device development will amplify the need for robust QA processes around software validation, cybersecurity, and AI model governance during inspection and lifecycle monitoring.

### UK MHRA ups device registration fees

Effective 16 July, the UK MHRA raised its device registration fee from £240 to £261 per application. This aligns with broader regulatory cost adjustments post-Brexit, affecting cost forecasting for device manufacturers.

QA insight: QA teams must proactively track fee changes in planning and ensure financial compliance is built into registration workflows and supplier quality agreements.

### China tightens NMPA inspections on device trial data

As of 1 May, China's NMPA issued updated "Inspection Points for Clinical Trials of Medical Devices," emphasizing data integrity enforcement and addressing past issues of fabricated or falsified data.

QA insight: Device manufacturers conducting clinical evaluations in China must reinforce trial quality controls, data traceability, and audit-ready protocols in full alignment with these new mandates.



### FDA updates cybersecurity guidance for medical devices

In June, the FDA released revised guidance for demonstrating cybersecurity in pre-market submissions, underscoring increasing expectations for risk assessments, SBOMs, and post-market threat monitoring.

QA insight: QA and regulatory teams should integrate cybersecurity validation deliverables into QA checklists and ensure compliance with FDA expectations for ongoing vulnerability assurance.



RiverArk voice:

*David Nyoku*

Business Student



#### My Experience at Riverark

Being the first person to ever do work experience at RiverArk was a unique and memorable opportunity. Although the placement was virtual and only lasted a week—from March 3rd to 7th, 2025—it gave me deep insight into the values, mission, and day-to-day operations of a community-focused organisation. I felt proud to represent not only myself but also future students who may follow in my footsteps.

From day one, the RiverArk team made me feel welcomed and included, even through a screen. They didn't treat me like "just a student"—they saw me as someone who could contribute, learn, and grow. I was introduced to RiverArk's core work, which focuses on GxP compliance, auditing, and quality assurance for companies in the pharmaceutical and life sciences sector.

Throughout the week, I took part in a series of virtual team meetings, which gave me the chance to learn more about the company's structure, its day-to-day operations, and the different roles within the business. It was interesting to see how various team members contributed to client projects, from planning and carrying out audits to managing documentation and ensuring regulatory standards were being met. These sessions helped me understand how detailed and important compliance work is, and how every role plays a part in maintaining trust and quality in the industry.

One of the biggest challenges of doing virtual work experience is staying engaged without the in-person energy, but the RiverArk team made it easy.

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## Hot industry news

**Generative AI regulation heats up**

A global push towards new regulatory frameworks for GenAI and LLMs embedded in healthcare devices was spotlighted in a February paper, highlighting total-product life cycle adjustments, regulatory “sandboxes,” and quality assurance for AI-driven diagnostics.

QA insight: Establishing QA systems that continually validate AI outputs, monitor model drift, and include audit-ready documentation will be essential for future submissions and market compliance.

**Academic advances in early failure detection with ML**

A May publication evaluated generative ML models designed to detect early failures in medical devices—such as surgical staplers—using real-time sensor data, showcasing potential QA tools to proactively identify malfunctions.

Incorporating ML-based fault detection into in-line QA systems offers early defect capture, reducing recall risk and strengthening CAPA processes.

**New course offerings bolster QA skills**

Two key training events were announced for mid-July: an FDA Recalls Masterclass (July 29–30) focused on CAPA and recall readiness, and a supplier-qualification best-practices seminar (July 16–17) addressing cross-border quality system requirements.

QA insight: QA professionals should leverage these targeted courses to stay on top of CAPA efficiency, supplier oversight, and recall preparedness—reinforcing compliance culture and inspection readiness.

**FDA places clinical hold on Sarepta gene therapy trials after 3 deaths**

On July 18, the FDA announced clinical holds on Sarepta's gene therapy programs for limb-girdle muscular dystrophy, following three participant deaths. They also revoked the product's platform designation and urged the company to suspend distribution of Elevidys, though Sarepta refused. FDA Commissioner Marty Makary emphasized that “swift action” is warranted when patient safety is at risk.

Heightened vigilance around safety signals means QA teams must reinforce pharmacovigilance protocols, adverse event reporting, and audit trails in trial oversight to support rapid regulatory intervention.

**Medpace stock soars on strong Q2 showing rebound for CROs**

Following a robust Q2 earnings report on July 22, Medpace Holdings rallied over 40% in pre-market trading. It reported \$603M revenue and \$3.10 EPS—outpacing expectations—prompting an upward revision to full-year guidance. However, analysts warn that waning trial funding and slower decision cycles may temper continued growth.

CROs and sponsors should embed QA metrics into site performance reporting and resource planning to maintain quality amid fluctuating trial volumes.

**Merck launches Phase 3 global trials for once-monthly HIV PrEP pill**

On July 14, Merck initiated the EXPRESSIVE Phase 3 trials for MK-8527—an oral, once-monthly HIV prevention pill—in 16 countries, including sub-Saharan Africa in partnership with the Gates Foundation.

Scaling QA across international sites will require harmonised oversight standards, real-time monitoring systems, and aligned documentation to manage global compliance.



RiverArk voice:

*David Nyeku*  
Business Student



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They were organised, communicated clearly, and gave me meaningful tasks. I learnt how to manage my time effectively, take professional notes, and present my ideas clearly in a virtual setting. These are skills I know will help me far beyond this one week.

Being the first student to ever do work experience there, I also gave feedback on how the virtual placement could be improved for future participants. I highlighted what worked well—such as the daily structure, supportive staff, and interactive tasks—and shared ideas for what could be added, like icebreakers and a mini project to present at the end of the week. It felt good to know that my experience could help shape a better programme for others.

In just five days, I gained a clearer understanding of what it means to work in a professional setting, especially one with purpose and heart like RiverArk. I developed my communication, time management, and problem-solving skills, and most importantly, I learned the value of listening and being open to learning in every moment.

I'm truly grateful for the chance to be the first work experience student at RiverArk. It may have only been a week, but it left a lasting impression on me—and hopefully I left one on them, too.

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