

DID YOU KNOW?

A well-designed risk management file can reduce post-market issues by up to 40% – proving that in QA, paranoia really does pay off.

First and foremost...

Pharma manufacturing is going digital: a new AI-enabled “digital twin” platform uses real-time process data to create virtual replicas of production lines, optimising operations and flagging anomalies in real time.

According to project leads, the system’s AI agent “can be extended beyond anomaly detection to support quality monitoring, production scheduling and resource planning”. This ontology-driven model – developed by Cambridge and Singapore’s A*STAR – combines first-principles engineering models with AI inference to continuously simulate a plant. It will soon be commercialised by a spin-off, marking a move to embed advanced QA technologies in industry.

Notably, one market analysis values the global Pharma 4.0 space at ~\$15.2 billion in 2025, growing ~19% annually (to \$72.6b in 2034) with AI/IoT as key drivers. In practice, such digital twins have begun integrating with process analytical technology to create environments where compliance information can be stored and validated, underscoring their regulatory potential.

Altogether, these trends suggest AI tools are tightening quality (and sustainability) in pharma, even as companies must invest in new skills and data integrity measures.

Hot takes

India mandates global GMP by January 2026

India’s regulator has ordered all domestic drug plants to meet WHO-recommended manufacturing standards by Jan. 1, 2026. This urgent deadline follows a scandal in which contaminated cough syrups were linked to over 140 child deaths abroad, prompting “global outrage” and pressure to raise quality norms. Regulators refused industry calls for delay, warning that non-compliant facilities will face closure. Small manufacturers warn that the expensive upgrades risk bankrupting some firms and driving up drug prices. The move highlights that even low-cost generics must adhere to strict QA rules to protect patients and the reputation of the “pharmacy of the world”.

FDA to examine AI-driven mental health apps

In the U.S., the FDA’s Digital Health Advisory Committee will convene on Nov. 6, 2025 to scrutinise the rise of generative AI in Med Devices. The meeting will focus on “generative artificial intelligence-enabled digital mental health devices,” weighing their potential benefits against safety risks. Experts will advise on what pre-market evidence and post-market monitoring are needed for smartphone apps and chatbots that use AI to diagnose or treat anxiety, depression, etc. This signals that regulators are taking an active role in guiding how novel AI algorithms can be safely integrated into healthcare.



RiverArk voice:

Amy King



Project Coordinator

From Project Administrator to Project Coordinator: My Journey at RiverArk

When I joined RiverArk just over two years ago, I came from a strong administrative background but had limited experience in the QA and Pharma industries. It was a completely new challenge but one I was eager to take on. I knew RiverArk was a place where I could grow, learn, and make an impact.

Starting as a Project Administrator, my role focused on supporting the Project Management team to ensure the smooth delivery of audits and consulting projects. This involved scheduling meetings, sending reminders for key deliverable deadlines, and maintaining progress trackers throughout each audit to make sure everything stayed on schedule. This gave me a solid foundation for my progression into my role as a Project Coordinator. I was also able to get valuable insight into how the business operates and how every detail contributes to a successful project outcome. The role also helped me develop a better understanding of client expectations within such a regulated industry.

After my first year at RiverArk, I naturally began to take on more responsibility and ownership of projects.

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Hot industry news

Paper prescribing info stays

The U.S. Congress has barred the FDA from requiring electronic-only drug labels. A section in the FY2026 Agriculture FDA appropriations forbids use of funds to mandate e-labeling (e.g. barcode- or app-based leaflets), effectively forcing companies to continue providing printed package inserts. Supporters say this preserves patient access to medication info; critics say it delays the transition to digital packaging.

New QMS rules ahead (US)

On Oct. 27, 2025 the FDA released draft guidance detailing the QMS information expected in medical device PMA submissions. This precedes the forthcoming QMS Regulation (effective Feb. 2, 2026), which replaces the legacy U.S. Quality System Regulation with an ISO 13485-aligned framework. Under the new regime, PMA and HDE applications (and their inspections) will be evaluated against ISO 13485:2016 standards, requiring firms to map procedures to ISO clauses to ensure compliance. Companies are advised to conduct gap analyses and update documentation before the 2026 deadline, since applications lacking ISO-based QMS data could be denied.

Medical device cybersecurity

The FDA finalised guidance in June 2025 on “Cybersecurity in Medical Devices: Quality System Considerations.” This document adds new recommendations under section 524B of the Food, Drug, & Cosmetic Act, reflecting the 2023 Omnibus law on device cybersecurity. Manufacturers must now explicitly include cyber risk management in their design controls and QMS, and provide security documentation in premarket filings. The update underscores that protecting devices from hacking or malware is becoming a core part of quality assurance.

Brazil slashes device backlog

Brazil’s ANVISA reports major progress in medical device regulation under its 2025 Modernisation Plan. The agency has cut the post-registration backlog by ~40% and accelerated review times for biologics, clinical trials, and radiopharmaceuticals. ANVISA invested R\$25 million in AI tools and added 102 reviewers (its largest staff boost since 2014). As a result, device approval queues are expected to halve within months, improving predictability for manufacturers in one of Latin America’s biggest markets.

New drug-safety biomarker

The FDA qualified a novel biomarker for drug-induced liver injury (DILI), expanding tools for assessing liver toxicity in clinical trials. This biomarker can help detect early signs of liver damage from an investigational compound before traditional lab tests flag a problem. While implementation will require broad validation, the qualification is a step toward more sensitive safety monitoring. Regulators hope such biomarkers can make trials safer by predicting adverse reactions earlier, potentially speeding development of safer drugs.



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Project Coordinator

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I started leading client accounts and managing audits from start to finish, including scheduling, preparing, overseeing deliverables, and ensuring projects met deadlines and high standards. This led me to my current role as Project Coordinator, managing multiple projects independently with a focus on client satisfaction.

Over the past two years, my understanding of QA and Pharma has grown greatly. When I joined, I didn’t know what GxP meant, and many terms were unfamiliar. Now, I’m confident applying technical knowledge throughout projects and client discussions.

Looking ahead to 2026, I’m excited to continue delivering successful projects, maintaining strong client relationships, and taking on new challenges as I transition into a Project Manager role.

I’ve grown a lot at RiverArk. Taking on unfamiliar responsibilities was intimidating but pushed me to develop skills and confidence. I particularly value RiverArk’s culture of support and collaboration, where everyone is encouraged to grow, share knowledge, and take ownership—this has made all the difference in my journey.

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