28TH FEBRUARY 2026

Quality Quotient

EDITION #19

28TH FEBRUARY 2026 | WWW.RIVERARK.COM | YOUR GLOBAL QA PARTNER

Industry & Regulatory Highlights

FDA approves targeted lung cancer therapy under accelerated review pathway

The U.S. FDA granted approval for a targeted therapy for a rare genetic form of non-small cell lung cancer through an accelerated review programme designed to prioritise serious conditions affecting small patient populations. Such compressed development and review timelines do not reduce regulatory expectations; instead, they place greater reliance on robust clinical documentation, reliable data integrity, and well-controlled CMC development, meaning quality oversight must be inspection-ready much earlier in the product lifecycle.

FDA proposes new approval framework for personalised gene therapies

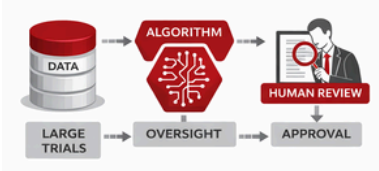
The FDA introduced a framework intended to speed approvals of individualized genetic medicines for rare diseases, potentially allowing developers to rely on smaller, well-controlled clinical studies when large trials are impractical. With less statistical redundancy, regulators depend more heavily on the credibility of trial conduct and traceability of data, increasing the importance of protocol compliance, contemporaneous documentation, and clear oversight of study execution.

EMA backs combined flu–COVID vaccine for older adults

European regulators issued a positive recommendation for a combination influenza and COVID-19 vaccine for adults aged 50 and above. Combination products bring added complexity to manufacturing comparability, stability testing, and pharmacovigilance reporting, requiring integrated quality systems that connect clinical development, manufacturing control, and post-market safety surveillance rather than treating them as separate functions.

Drugmakers increasingly using AI to accelerate clinical trials and submissions

Pharmaceutical and biotechnology companies are adopting artificial intelligence tools to identify trial participants, optimise site selection, and assist with regulatory submissions. As AI becomes embedded in regulated processes, quality oversight is shifting away from simply reviewing outputs toward validating intended use, ensuring data provenance, and maintaining documented human oversight — areas regulators are beginning to examine closely during inspections.



UK regulator cracks down on illegal medicines distribution

Regulators in the UK recently seized large quantities of illegally manufactured medicines and associated production equipment as part of enforcement operations targeting criminal supply chains. The action highlights the growing regulatory focus on product authenticity, supplier qualification, and GDP controls, reinforcing that quality assurance responsibilities now extend beyond manufacturing to include distribution oversight and supply chain security.

Quality assurance is evolving alongside scientific progress—today, regulators look beyond procedures to whether organisations can clearly demonstrate oversight, sound judgement, and control while advancing innovation in an uncertain environment.

RiverArk® Quality Delivered

RiverArk voice:

Ananya Nadgouda

Project and Process Analyst

What Working in Biotech Taught Me About Uncertainty

Biotech teaches you very quickly that certainty is a luxury.

When I first started working in this field, I thought that strong data and smart people would be enough. If the preclinical results looked solid, if the hypothesis made sense, if the team was experienced and motivated surely that meant we were on the right path.
But biotech doesn't work that way.

You can have:

- Strong preclinical data
- A thoughtful, well-supported hypothesis
- A brilliant, committed team

...and still fail.

That was one of the hardest lessons to learn. Not because failure is common, but because it's often unpredictable. Biology is complex. What works beautifully in early studies may fall apart in later stages. Signals shift. Variability shows up.

Unexpected safety findings appear. The story you thought you were telling changes.

Over time, I realized that uncertainty isn't a sign that something is wrong. It's the starting point and that adaptability is not weakness. It is scientific maturity.

One of the biggest lessons biotech taught me is that data evolves and your decisions must evolve with it. Early results are just the beginning of the conversation. As more information comes in, the picture becomes clearer or sometimes more complicated. You learn not to fall in love with your original idea. You learn to follow the evidence, even when it challenges your assumptions.

.. Continued on next page

28TH FEBRUARY 2026

Quality Quotient

EDITION #19

28TH FEBRUARY 2026 | WWW.RIVERARK.COM | YOUR GLOBAL QA PARTNER

Industry & Regulatory Highlights

Obesity drug competition intensifies as manufacturers scale production

Major pharmaceutical manufacturers are rapidly expanding production capacity and launching new delivery devices to meet demand for weight-loss therapies. Rapid scale-up introduces heightened risks around process validation, equipment qualification, change control, and supplier management, making proactive quality planning essential to prevent inspection findings and product shortages.

Mixed late-stage trial results highlight challenges in genetic disorder therapies

A late-stage study of a therapy for a rare genetic disorder produced promising but inconsistent results, illustrating the ongoing complexity of developing treatments for small and heterogeneous patient populations. Rare-disease trials often depend on novel endpoints and adaptive designs, increasing regulatory reliance on protocol adherence, data traceability, and clear documentation of decision-making during clinical conduct.

Regulatory changes continue in clinical trial frameworks

Regulators updated clinical trial application requirements and submission processes in several jurisdictions, including revised forms and transitional provisions. These procedural changes frequently lead to inspection observations when organisations do not promptly update SOPs, training programmes, and operational processes, highlighting the importance of active regulatory intelligence within the quality system.

Biotech sector investment continues in AI-driven drug discovery

An AI-focused biotechnology company recently debuted on the public market, demonstrating continued investment in computational drug discovery despite broader market uncertainty. As algorithm-driven development expands, quality systems must adapt to govern new data types and modelling approaches, including validation of algorithms and documentation of decision-support tools.

Global policy shifts could affect pharmaceutical supply chains

Recent international policy changes affecting health cooperation may create new vulnerabilities in pharmaceutical logistics and research collaboration networks. In response, quality assurance is increasingly expected to address supplier and distribution risk management alongside traditional manufacturing oversight, particularly for organisations operating across multiple regions.

Closing Remarks – A Quality Outlook

Looking across this month's developments, a pattern emerges. Innovation in the life sciences is accelerating, but regulatory expectations are not relaxing — they are maturing.

Accelerated approvals rely on credible evidence rather than lengthy timelines. Gene therapies rely on traceability rather than population size. AI-assisted development relies on oversight rather than automation alone. Global supply chains rely on visibility rather than assumption. In each case, the focus shifts away from how much documentation exists and toward how well an organisation understands and controls its own decisions.

For quality professionals, this signals an important transition. The role of QA is no longer limited to verifying compliance after activities occur. Increasingly, quality functions must help shape how decisions are made in the first place — guiding risk discussions, ensuring transparency, and maintaining organisational awareness of regulatory intent.

Ananya Nadgouda's reflection reinforces this idea. Biotechnology does not eliminate uncertainty; it teaches organisations how to operate responsibly within it. The same is true of modern quality systems. The strongest quality organisations are not those that attempt to predict every outcome, but those that create environments where evidence can be questioned, assumptions can be challenged, and actions can be justified. As we move further into 2026, quality assurance will continue to act as the stabilising force between scientific innovation and patient safety. The challenge is not to add more procedures, but to ensure that existing systems truly support informed, transparent decision-making. We hope this edition provides perspective and practical reflection as you navigate the months ahead.

Click here to see where we will be in 2026!

RiverArk® Quality Delivered

RiverArk voice:

Ananya Nadgouda

Project and Process Analyst

... Continued

I also learned that risk isn't a flaw in innovation it's the baseline. If you're trying to develop something new, especially something that could impact patients' lives, you are stepping into the unknown. The goal isn't to eliminate risk completely. That's impossible. The goal is to understand it, manage it thoughtfully, and communicate it transparently.

Progress in biotech rarely looks dramatic from the inside. It looks like careful discussions. It looks like revising protocols. It looks like asking uncomfortable questions in meetings. It looks like deciding to pause when momentum says, "push forward." Sometimes, it even looks like shutting down a project to protect patient safety or scientific integrity.

Biotech professionals don't eliminate uncertainty. They work with it. They build systems around quality frameworks, cross-functional reviews, regulatory checkpoints, so that decisions are responsible and patient-centred.

The real skill isn't predicting outcomes perfectly. It's knowing when to move forward, when to pause, and when to pivot without compromising safety or integrity.

That mindset doesn't stay at work. It changes how you think about problems in general. It teaches you humility. It teaches you resilience. And most of all, it teaches you that moving forward thoughtfully even without guarantees, is sometimes the most responsible thing you can do.

VISIT OUR WEBSITE FOR CASE STUDIES