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**53% of Pharma Companies Achieve Advanced Quality Systems While One in Four Risk Regulatory Exposure, NSF Study Warns**

*Despite progress, uneven quality system maturity poses compliance risks as Annex 1 and regulatory pressures intensify; full findings to be revealed at NSF Pharma Biotech Conference, October 23 in London.*

**OXFORD, UK** (**Sept 29, 2025)** — [NSF](http://www.nsf.org/), a global leader in pharmaceutical quality and regulatory consulting, today released new research revealing a significant maturity gap in European pharmaceutical quality systems. While 53% of companies report advanced, risk-based approaches, nearly a quarter (23%) remain at basic compliance levels.

This disparity creates substantial regulatory risk as authorities intensify scrutiny across the E.U. and U.K. NSF will unveil the complete findings from its 2025 EU & UK Pharma & Biotech Quality and Compliance Study at the [NSF Pharma Biotech Conference](https://www.nsf.org/knowledge-library/nsf-pharma-biotech-conference-2025?utm_source=pr&utm_medium=pr&utm_campaign=2025_NSF_EU_UK_Survey) on Oct. 23 in London.

The research comes at a critical time for European pharmaceutical manufacturers, as regulatory authorities across the UK and EU intensify focus on data integrity, contamination control, and supply chain resilience. With inspectors increasingly emphasising quality culture during site visits, the maturity gap identified in NSF's research highlights both risk and opportunity for organisations navigating this evolving landscape.

“Our research reveals a fundamental shift in how quality maturity develops,” said Dr Peter Gough, Vice President, Pharmaceutical Services at NSF. “The most resilient organisations are those balancing human and digital transformation, building quality culture while strategically deploying technology. This integrated approach is becoming essential as regulatory expectations evolve beyond basic compliance toward sustained quality performance.”

The comprehensive research, conducted in partnership with Opinium, surveyed senior quality and regulatory leaders across leading pharmaceutical and biotech companies in the UK and Europe. Key findings include:

* EU Annex 1 remains the top regulatory challenge (37%), driving investment in training, cross-functional teams, and quality management system (QMS) redesign.
* Quality culture initiatives (33%) significantly outperform technical controls alone (22%) for long-term data integrity, despite growing technology investment.
* Data integration across multiple systems is the biggest pain point for 58% of companies, hampering compliance efforts.
* Nearly half (46%) report increased technology investment over the past three years, with biotech firms leading the digital transformation.
* Raw material and component sourcing and authentication (32%) are the most critical supply chain integrity vulnerabilities.
* 84% of firms now embed sustainability into QMS, linking metrics like energy efficiency and carbon reduction to inspection readiness.

These findings will shape the agenda at the NSF Pharma Biotech Conference, where experts will explore how emerging technologies, including artificial intelligence, machine learning, advanced analytics, and integrated QMS platforms, are reshaping compliance strategies and driving long-term quality maturity.

“Our research shows 37% of leaders cite compliance to Annex 1 as their top challenge, and it’s driving real change: more training (55%), more cross-functional task forces (54%), and redesigned quality systems (46%),” said Dr Kay Hukin, Executive Director, NSF. “This is compliance pressure turning into performance advantage, and it’s reshaping how the industry thinks about risk and readiness.”

Limited spaces remain at NSF’s Pharma Biotech Conference at the Royal Society of Chemistry in London. The one-day conference will provide critical updates, real-world guidance, expert panels, and exclusive networking opportunities. For more information or to register, [visit www.nsf.org.](https://www.nsf.org/knowledge-library/nsf-pharma-biotech-conference-2025?utm_source=pr&utm_medium=pr&utm_campaign=2025_NSF_EU_UK_Survey)

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*\*Full findings and practical implementation frameworks will be unveiled at the NSF Pharma Biotech Conference on 23 October in London.*

***Notes to editors***

**About NSF**

[NSF](http://www.nsf.org/) is an independent, global services organisation dedicated to improving human and planet health for more than 80 years by developing public health standards and providing world-class testing, inspection, certification, advisory services and digital solutions to the food, nutrition, water, life sciences and consumer goods industries. NSF has 40,000 clients in 110 countries and is a World Health Organisation (WHO) Collaborating Centre on Food Safety, Water Quality and Medical Device Safety.

**Research methodology**

The findings referenced in this release are based on an independent survey conducted by [Opinium](https://www.opinium.com/us/home/) on behalf of NSF. The research was carried out between 20 and 26 August 2025 and gathered responses from 100 senior quality and regulatory leaders across pharmaceutical and biotechnology organisations in Europe and the UK. Respondents represented a mix of company sizes and roles, ensuring a balanced view of industry practices.