# Life Sciences

Fact sheet

## About NSF

NSF 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 operates in 180 countries and is a World Health Organization (WHO) Collaborating Center on Food Safety, Water Quality and Medical Device Safety.

## Our Mission in Life Sciences

NSF provides world-class services and solutions across the product lifecycle for clients in the pharmaceutical, biotech, clinical trial, medical device, in vitro diagnostic and combination product industries. Our team of experts ensure drugs and devices meet high safety and quality standards, with ex-regulators verifying compliance to assure consumers and industry of product integrity. We work hand-in-hand with companies across the world to navigate an ever-evolving matrix of regulations and deliver lifesaving and life-changing medical products and pharmaceuticals to patients.

**NSF Life Sciences has 1,500+ clients in 68 countries around the world and 25 market approvals.**

**We work with 12 of the world's top 15 dietary supplement companies, 18 of the world's top pharmaceutical companies and 18 of the world's top medical device companies.**

## Milestones

**1990** NSF launches Qualified Person training program.

**2009** NSF launches medical device training and its first pharmaceutical training course in the United States.

**2011** IRCA certifies our Pharmaceutical QMS Auditor/Lead Auditor course.

**2019** NSF expands its offerings in Germany to include Medical Device/In Vitro Diagnostic Consulting.

**2020** NSF-certified Qualified Person qualifies the first vaccine for COVID-19 in the UK.

**More than 230 team members across the globe support the Life Sciences division at NSF.**

## Our Services

- **Pharmaceutical/Biotech Consulting:** Leveraging our extensive industry expertise and a solid reputation of ex-regulators, we specialise in delivering consulting, training, and auditing services and solutions to the world's largest and most dynamic companies in the pharma/biotech industry. Our solutions span industry audit preparation and mock inspections, post-inspection response and support, regulatory submission strategy, quality system consulting, remediation projects, trainings and data integrity support.
- **Medical Device/In Vitro Diagnostic Consulting:** NSF's range of consulting, training and auditing services for medical device, IVD and combination product manufacturers are called upon by companies globally. Our ability to navigate the maze of ever-changing regulations enables us to deliver consistent outcomes for client companies. Mitigate risk, ensure compliance with international and FDA regulations and standards, and apply effective quality systems with expert advice from NSF that range from quality management solutions and regulatory services to post-inspection and post-market response and inspection readiness.
- **Clinical Research:** NSF's clinical research arm supports clients as they bring new drugs to market. This group of experts has conducted over 400 clinical trials and received more than 25 market approvals.

## Life Sciences Accreditations

ANAB ANSI National Accreditation Board · USDA Food Safety and Inspection Service · MHRA · CQI · IRCA APPROVED TRAINING PARTNER

## Key Divisional Figures

NSF provides unparalleled expertise in the life sciences industry. Our team of experts can provide insights on a wealth of topics.

**James Howe**
Vice President, Life Sciences

**Ann Gates**
Director, Medical Device/IVD Consulting

**Michael Hidock**
Director, Pharmaceutical/Biotech Consulting

**Kush Dhody**
Senior Vice President, Clinical Research

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# NSF Pharma Biotech Conference 2025

**Date:** Thursday, October 23, 2025
**Venue:** The Royal Society of Chemistry, Burlington House, Piccadilly, London, UK

## About the event

Now in its third year, this conference has become a key fixture for professionals working in pharmaceutical quality and regulatory affairs across Europe. The 2025 edition focuses on one of the most critical challenges facing the industry today: maintaining compliance in an increasingly complex and regulated environment.

## Theme: Quality and Regulatory Compliance for European Companies

With regulatory expectations evolving rapidly, pharmaceutical companies must take a proactive approach to managing quality systems, ensuring inspection readiness, and strengthening supply chain integrity.

This one-day conference brings together expert voices from regulators, industry leaders, and consultants to explore how companies can adapt and thrive in this shifting landscape.

## What to expect

This full-day event will deliver a dynamic mix of presentations, panel discussions, case studies, and networking sessions. Attendees will gain practical insights and actionable strategies from leading voices in regulatory affairs, industry operations, and compliance.

Speakers represent global pharmaceutical manufacturers, European and UK regulators, major trade associations, and NSF's senior pharmaceutical consultants.

Notable contributors include professionals from Bristol Myers Squibb, NHS Manufacturing, West Pharmaceutical Services, and the Ethical Medicines Industry Group.

| Time | Session title | Speaker/Details |
|---|---|---|
| 09:00 | Registration and networking | |
| 10:00 | Setting the Scene | Dr Peter Gough, NSF/Global Shifts in Pharmaceutical Regulation: What's New and What's Next |
| 10:30 | AI 2025 Briefing | Sarah Chan, TOPRA AI and Digital Steering Committee Lead and ex-Director, Regulatory Affairs International, Business Strategy & Operations at MSD. AI in Action: Driving Innovation Across the Pharma Industry |
| 11:00 | Live Panel: Where Are We Now? | Featuring Speakers 1–3<br>Perspectives from a regulatory, industry body, and industry perspective |
| 11:30 | Networking Break | |
| 12:00 | Report Launch | NSF will unveil its upcoming industry report on quality and regulatory challenges in pharma and biotech at the event. Commissioned by NSF and conducted by leading research firm Opinium, the report explores key issues facing decision-makers across Europe. Presenter: Molly Maclean, Associate Director, Opinium |
| 12:30 | Roundtable Discussion and Q&A | We will take a deep dive into the report findings and host a facilitated discussion. This will also give delegates the opportunity to comment and pose questions to the panel. Panel: Michael Hidock (Confirmed), Catherine Kay (Confirmed), Kay Hukin (Confirmed), (Panel members will receive a copy of the report in advance of publication) |
| 13:00 | Networking Lunch | |
| 14:00 | Transatlantic Pressures: The FDA Perspective | Dr Julia Marré, NSF/Regulatory Expectations from the U.S.: What European Firms Must Know and Do |
| 14:25 | Case Study Spotlight: West Pharma | Niamh Bissett, Director Business Transformation, West Pharma<br>How One Manufacturer is Effectively Handling Consistent Regulatory Changes |
| 14:50 | Networking Break | |
| 15:20 | Leadership Under Pressure | Dr Kay Hukin, NSF/From the Top: How Strong Leadership Transforms Regulatory and Operational Challenges |
| 15:45 | Challenges in Supply Chain -Existing and New Challenges | Newaj Khan, Associate Director, BMS / Challenges in the Supply Chain post-Brexit & New Tariff Challenges Facing the Pharma Sector |
| 16:10 | Case Study: How the NHS is Meeting the Challenge | Adam Walker and/or Marc Sutton, NHS Manufacturing<br>Resilience, Innovation, and Impact: How NHS Manufacturing is Meeting Patient Needs |
| 16:35 | Panel:Transformation in Action | Speakers 4–8<br>Practical Lessons from Industry, Manufacturing, and Leadership Frontlines |
| 16:50 | Closing Reflections | James Howe, VP of NSF in EMEA |
| 17:00 | Event Close | |

# Key Spokespeople

## At the NSF Pharma Biotech Conference 2025

**Dr Peter Gough**
Vice President, Pharmaceutical Services

Gough brings over 50 years of experience in pharmaceutical manufacturing, control, and quality management. A chemist with a master's in analytical chemistry, Peter has held senior roles including Senior Quality Consultant at Eli Lilly and partner at David Begg Associates. He is a Fellow of both the Royal Society of Chemistry and the Chartered Quality Institute.

Gough's team supports pharmaceutical organisations with expert auditing, training, and consulting services focused on GMP, quality risk management, and statistical process control. Through his work at NSF, he has helped companies strengthen global quality systems, improve compliance, and adopt Quality by Design principles across solid dosage and API manufacturing.

**Key interview topics:**

- Artificial intelligence (AI)
- Decentralised manufacturing
- EU reform of Human Medicines Legislation

**Dr Kay Hukin, NSF**
Executive Director

Hukin leads NSF's pharmaceutical quality and compliance programs. With over 20 years of industry experience, she is a PhD microbiologist, a member of the Royal Society of Biology, and eligible to act as a Qualified Person under the permanent provisions. Hukin's expertise spans manufacturing, packaging, and testing of commercial and investigational medicinal products across solid, liquid, and sterile dosage forms.

Her team delivers trusted auditing, training, and consulting services to pharmaceutical organisations, supporting quality management, regulatory compliance, and operational efficiency. Through her work at NSF, Hukin has helped companies strengthen their supply chains, improve right-first-time performance, and meet global regulatory standards across the UK, Europe, and India.

**Key interview topics:**

- The role of senior leadership and the PQS,
- Quality Culture,
- Quality Management Maturity

**Dr Julia Marré, NSF**
Principal Program Lead Pharma Biotech

Marré is an expert in pharmaceutical and biologic manufacturing and FDA regulatory compliance. She brings senior-level experience as a manufacturing reviewer at the U.S. Food and Drug Administration (FDA) and as the regulatory and compliance lead for drugs, biologics, and combination products. She has a proven track record of leading industry-regulator interactions, leveraging deep regulatory knowledge to drive successful outcomes. With experience as both a senior FDA manufacturing reviewer and industry expert, she serves as a trusted advisor in navigating complex regulatory landscapes.

**Michael Hidock**
Director Pharma and Biotech Consulting

Hidock has over 20 years of industry experience in pharmaceutical quality. He has served various manufacturers as director of quality where he was responsible for championing quality culture, streamlining processes, enhancing and developing foundational quality management systems.

Notably, Hidock has led efforts to remove FDA warning letter status in several global companies leading to successful regulatory compliance. As an industry consultant, he has worked with many small to large sized pharma and biotech companies implementing "right sized" quality management systems, lead inspection readiness efforts, supported regulatory inspections, performed internal and due diligence audits, conducted collaborative gap assessments, implemented CAPA in response to regulatory and internal findings, and led large scale remediation projects leading to a successful regulatory pathway.

# Press release

## 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, 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 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.

**---ENDS---**

## Notes to editors

**About NSF**
NSF 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 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.

**Contact:** Steven MacEwan, media@nsf.org

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