

14 NOV |
VIRTUAL EVENT

Scilife



Smart quality Summit **2024**



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In sync for quality: humans and technology leading the way

Today's fast-moving world is facing tremendous societal challenges, and the quality community must ensure this is matched by new ideas and evolutions about how people and organizations think about and apply quality.

Solely embracing digital technology is not enough. Now the world's leading businesses are looking at the bigger picture. While customers remain a priority, the perspective has broadened to include employee engagement and sustainability in all its dimensions.

Quality 5.0 is on the horizon.

What is Quality 5.0?

Quality 5.0 takes a step further by combining human intelligence with advanced technologies to revolutionize quality management.

By augmenting human capabilities with digital tools, it enhances decision-making, fosters innovation, and boosts job satisfaction and creativity among quality professionals, all while supporting higher quality standards and more sustainable practices.

Scilife



Artificial intelligence
is powerless without
the human heart.

Manish Kohli

smart quality summit **2024**



14 NOV

12:00 CET

06:00 EST

Lars de Nul

Industry 5.0 as a North Star

Explore the vision of Industry 5.0, a future-proof approach that prioritizes sustainability, resilience, and agility through flexible and adaptable technologies. Discover how Industry 5.0 invests in skills, promoting talent, diversity, and empowerment. Understand the role of industry in achieving societal goals beyond jobs and growth.

13:00 CET

07:00 EST

Rudolf Wagner

DigitalHealth, AI and Software—lean regulatory market access now and in future

Explore the impact of digital health, AI, and software on modern healthcare, and the regulatory frameworks that govern them, including FDA, EU MDR/IVDR, IMDRF, and the EU AI Act. We will discuss future regulatory trends, enforcement challenges, strategies for efficient market access, and showcase case studies for successful approaches.

14:00 CET

08:00 EST

Christy Mazzarisi

Cultivating a living quality culture in life sciences: Excellence in action

Are you an asset or gatekeeper in your organization? This workshop will help you assess your quality maturity and explore how Quality aligns with your organization's mission. We'll use three performance pillars and a 4-step approach to build a strong quality culture, including identifying key influencers and creating alignment.



15:00 CET

09:00 EST

Jennifer Mascioli-Tudor

Innovating the Future: Key MedTech Trends Shaping Medical Device Industry

Explore the latest trends in MedTech and their impact on medical device regulations, including FDA's QMSR and new cybersecurity requirements. Understand evolving regulations for Laboratory Developed Tests (LDTs) and the role of AI in medical devices. Gain insights to ensure compliance and navigate the changing regulatory landscape.

16:00 CET

10:00 EST

Karen Taylor

Harsh Thakkar

Lesley Worthington

From Industry 4.0 to Industry 5.0: Europe's Path to Human-Centric, Sustainable, and Resilient Life Sciences

Join us for a roundtable on Europe's transition from Industry 4.0 to 5.0, focusing on sustainability and human-centric technology. Explore how life science companies can redesign value chains using AI, enhance resilience, and adopt regenerative models. Don't miss this opportunity to lead the shift towards a more resilient economy.

17:00 CET

11:00 EST

Roundtable discussion: How Scilife puts people at the center

Discover how Scilife's eQMS is transforming quality management in life sciences. Join our roundtable to explore how to enhance collaboration and job satisfaction through technology, lead with sustainability, ensure compliance, and adapt to evolving regulations while strengthening resilience.

Scilife



Innovate
with
technology.

Lead with
humanity.

Thrive with
quality.

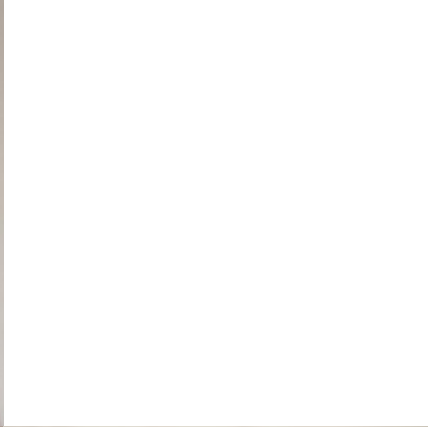
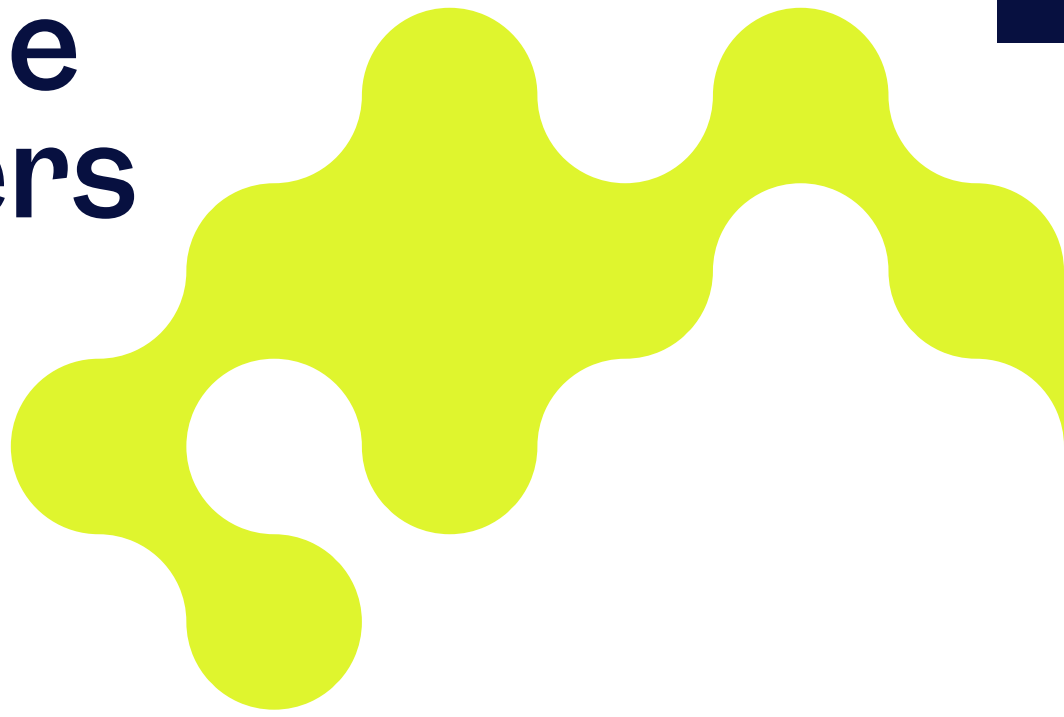
Get a certificate of attendance

2024

**Certification
of Attendance**
Smart Quality Summit

Whether you join one or all of our sessions at Smart Quality Summit 2024, you will receive a certificate of attendance that you can share with your online community on social media!

Meet the Speakers





Lars de Nul

Deputy Head of Unit Industry 5.0
and Artificial Intelligence in Science

Linkedin



Bio

Lars De Nul serves as deputy head of the "Industry 5.0 and AI in Science" unit in the European Commission's Directorate-General for Research & Innovation.

His work focuses on developing sustainable, resilient, and human-centric industry (Industry 5.0), as well as AI and digital technologies in the science domain. Lars holds master's degrees in Artificial Intelligence and Applied Computer Science, as well as a PhD in Philosophy.



Jennifer Mascioli-Tudor

Founder and CEO, JMT compliance consulting

Linkedin



Bio

Jennifer Mascioli-Tudor brings 20+ years of pharmaceutical and medical device industry experience and has excelled in implementing robust quality systems at major healthcare companies.

Now CEO of JMT Compliance Consulting, she helps med-tech firms improve business and regulatory strategies. Jennifer holds degrees from Eastern Michigan University and University of Phoenix, and teaches regulatory affairs at UC San Diego.



Christy Mazzarisi

Principal Consultant

Linkedin



Bio

Christy Mazzarisi is a senior Quality Systems Professional, with 20 years of experience in pharmaceutical and laboratory sciences.

She specializes in R&D and commercial manufacturing, focusing on sterile and non-sterile environments. Christy has led major initiatives across GxPs, including PQS transformation, SOP optimization, and QMS audits. She is an advocate for continuous improvement in life sciences.



Karen Taylor

Head of the centre for Health Solutions

Linkedin



Bio

Karen established Deloitte UK's Centre for Health Solutions in 2011, providing research and insights on trends and challenges in life sciences and healthcare.

She authors reports on AI in biopharma, pharmaceutical innovation, and sustainability, while also managing a health blog and podcast. Karen has served as a Non-Executive Director for NHS Trusts since 2011 and she was the Health Value for Money Audit Director at the National Audit Office.



Harsh Thakkar

CEO and Founder at Qualtivate

LinkedIn



Bio

Harsh Thakkar is CEO of Qualtivate, a consultancy enhancing quality management in life sciences. With 15 years of experience, he specializes in QMS strategy, GxP compliance, and fostering quality culture.

Harsh advocates for AI/ML and automation in quality operations across biopharma and MedTech. He holds ASQ certifications in Quality Auditing and Quality / Organizational Excellence, an M.S. in Regulatory Affairs and Quality Assurance, and a B.Sc. in Pharmaceutical Sciences.



Astrid Thorissen

Global Healthcare Quality Manager

LinkedIn



Bio

Astrid is the Global Healthcare Quality Manager at Yusen Logistics, where she integrates her expertise in pharmaceutical manufacturing with logistics services.

A pharmacist by training, she also serves as a Dutch Delegate for the European Industrial Pharmacists Group. As part of the professional competencies working group, she ensures that Industrial Pharmacy subjects are properly represented in European Pharmacy Curricula.



Rudolf Wagner

CEO, ADHOCON

Linkedin



Bio

Rudolf Wagner is a Quality and Regulatory expert with over 15 years of experience in Pharma, Medical Devices, and Digital Health, including SaMD and AI.

He has successfully led global quality and regulatory teams, managed complex projects involving AI-integrated solutions, and facilitated medical device registrations in 132 countries. Rudolf's expertise spans strategic planning, cross-functional leadership, and operational excellence.



Lesley Worthington

Communication and leadership coach

Linkedin



Bio

Lesley has 20 years of quality and regulatory experience, coupled with university degrees in psychology and law. Her background includes thousands of hours of teaching and coaching.

As a trained executive coach, Lesley equips her clients with essential skills, techniques, and insights. Her approach boosts their confidence, enhances their communication abilities, and empowers them to make a positive impact within their organizations.

Quality 5.0 needs YOU.

Join us at Smart
Quality Summit 2024
and become the
changemaker in
quality management.

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Meet our partners





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SUMMIT

2024