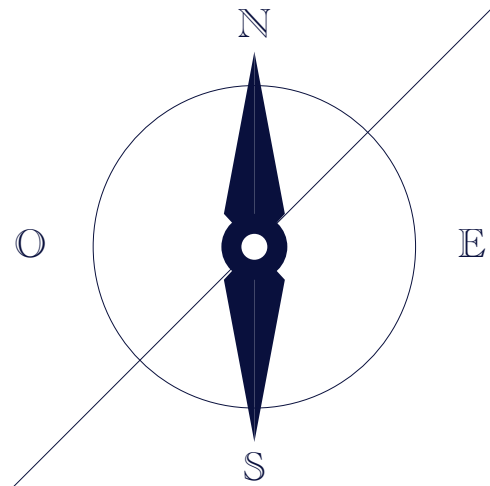


Leverage your audits towards
digital transformation

Navigating the Future of Quality in Life Sciences



From creating 100% paperless workflows to automating data to leverage meaningful insights, digital technologies are opening up limitless opportunities. However, most organizations are using these digital tools to solely reduce directly identifiable costs and manage quality-compliance budgets. **Their mindset remains unchanged - they still view quality compliance as a burden cost of doing business.**

At Scilife, we believe **that there is a missed opportunity in the life sciences industry.** The traditional reactive quality mindset obstructs organizations from fully leveraging speed, data, and connectivity to enhance product quality, ensure process reliability, and, most importantly, advance efficacy and patient safety.

It's slowing down their business. It's driving up costs. It's a scatter-shot approach that's no longer effective. **By sticking to how they've "always done it", organizations are setting themselves up for failure** in meeting the demands of Industry 4.0. So, what's the solution?

Smart quality. A new quality model that **empowers life sciences organizations to transform quality into a key catalyst of value creation.** Adopting new technologies is just the first step. The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working. But with the right approach, you can **take quality beyond compliance.**

Going down an unfamiliar path can be daunting, but don't worry, we're here to guide you every step of the way.

Unlock your competitive edge



If you want to turn quality into your competitive advantage in the life sciences and reap the benefits of a truly robust QMS system, then you're in the right place.

Smart quality offers a unique opportunity to integrate compliance into your regular operations and embed quality into every aspect of your organization. The results? **Reduced compliance, heightened peak performance and an enhanced patient experience**, just to name a few advantages.

Held annually, our **Smart Quality Summit** gathers the industry's brightest minds to share the latest trends, insights, and innovations in quality. In our 2023 edition, we went beyond redefining quality; the focus was on providing **practical strategies for organizations to move beyond the 'compliance only' mindset and cultivate a strong quality culture.**

However, this magazine is not merely a recap of the event—it stands as **the most powerful resource** we've created to date, designed to empower you on your continuous learning journey.

Within these pages, we've extracted the highlights shared by one of our experts, offering a comprehensive guide to **enhancing your organization's competitiveness through smart quality.**

Ready to embrace change and step out of your comfort zone? **Join us** on a journey to discover the transformative power when quality surpasses regulatory compliance.

Contents

This document is interactive, you can navigate through the contents by clicking on titles.

Meet the expert behind the talk	5
Key Takeaways	7
Solutions integrating: Machine Learning and Artificial Intelligence, why?	9
Change of paradigm of supply change management	11
Thank you	13

“A QMS is integrated with all business activities & operations. It is not a “bolt on” system. It is not “set and forget”.

It is your business.



Meet the expert behind the talk



Carla Peraferrer

Qualifyze

Carla, a dedicated pharmacist, has been captivated by supplier qualification since 2015 and is committed to ensuring the highest standards of quality and compliance. Here are some of her key achievements:

- As the VP of Quality at Qualifyze, she played a key role in establishing the internal Quality Management System (QMS)
- She remarkably grew the Quality team at Qualifyze from a single member to a force of over 20 individuals within just three years
- She has supervised and conducted over 300 audits during her career

With a rich background spanning over 15 years, Carla has engaged with various stakeholders across the pharmaceutical supply chain, including community and hospital pharmacies, compounding laboratories, and third-party auditing service providers.

Meet the expert behind the talk



Cesc Muñoz

Qualifyze

With a background as a pharmaceutical chemist, **Cesc** has been immersed in the world of GxP audits since 2015, undertaking the responsibility of over 200 audits. Here are some notable highlights of his professional journey:

- Having completed his degree in Medicinal and Pharmaceutical Chemistry he has previously worked as a pharmaceutical chemist
- He is an experienced GxP auditor with expertise in large-scale assessments, always bringing a meticulous and analytical approach to his work
- His commitment to collaboration and finding innovative solutions has been a driving force throughout his career.

As the Head of Quality at Qualifyze, Cesc is dedicated to maintaining high standards in the industry.

Key Takeaways



A **thorough audit** encompasses the auditor's profile, meticulous preparation, efficient execution, and insightful reporting & follow up.

Data compilation involves gathering information from a variety of sources, each playing a valuable role in the overall assessment.

The **integration of machine learning** and **artificial intelligence** holds significant potential for bolstering supply chain control, improving efficiency, and increasing effectiveness.

What do we need to use tools



**to put it
all together?**

Solutions integrating Machine Learning and Artificial Intelligence,

Why?

How are your suppliers **envolving** and **benchmarking** with the others?

Can I **anticipate problems** with my suppliers?

Can I improve my **supplier risk management** with the **available data**?

Can I visualize my **suppliers' compliance** in **real time**?

Solutions integrating Machine Learning and Artificial Intelligence,

Why?

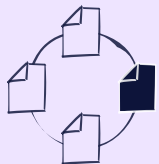
Software to manage



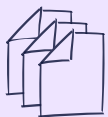
Audits



Data



CAPAs

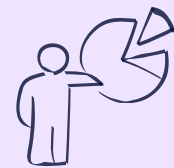


Documents

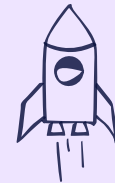


Supplier risk

Data insights to understand



What happened?
Descriptive



What action to take?
Prescriptive



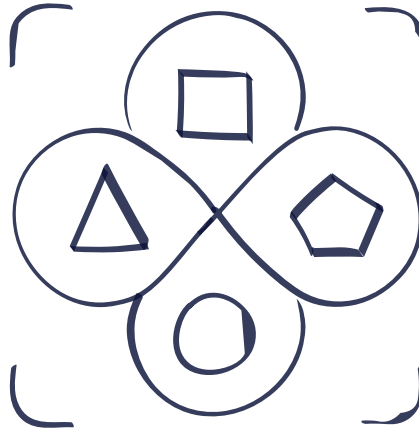
Why did it happen?
Diagnostic



What will happen?
Predictive

More software usage results in more **data insights**, which in turn encourages **greater software usage**

Change of paradigm of supply change management



Old approach

- Discrete snapshots of a single supplier
- Non-integrated data
- Compliance as a “binary” concept

Digital transformation

- Continuous monitoring of the complete supply chain
- Integration of data from various sources for best decision making
- Compliance / Maturity Metrics, evaluation of trends, anticipating problems

***** **Safer** and more **reliable** supply chains!

Auditing is no longer just about ticking boxes; it's an opportunity to not only streamline operations but also transform your data collection processes.

This approach opens a gateway to unprecedented efficiency and insights, helping your organization **navigate the complexities** of today's digital world with precision and foresight.



[Link to masterclass >>>](#)

A thank you to those who shape the future

The life sciences industry is undergoing rapid evolution, presenting numerous challenges on the horizon. Preparation is paramount. The future demands both resilience and a proactive approach. Recognizing this, Smart Quality Summit 2023 had a clear mission: **equip today's professionals with all the tools and knowledge they need to excel tomorrow**. It is safe to say that we passed with flying colors.

However, this would have not been possible without the invaluable contributions of our **exceptional panel of 11 industry-leading experts and the speakers who lead our round table discussion**. You successfully disrupted, inspired and reinvented everybody's perception of quality during our two-day event on November 8-9.

Your engagement created an enriching atmosphere for learning, enabling participants to gain practical strategies to enhance their quality management processes. We are confident that **your insights will empower industry professionals to apply the smart quality approach** and make significant strides in driving progress within their organizations.

Finally, we would like to express our sincere gratitude to our **event partners and attendees**. Without your support, we wouldn't be here, collectively shaping a future where innovation, collaboration, and continuous improvement stand as pillars of quality excellence.

Thank you for being an integral part of this meaningful journey.

Scilife

Take the leap to Smart Quality with Scilife

Future-proof your organization by making quality your key differentiator in the dynamic life sciences industry.

We're here, ready to guide your transformation journey, where quality is intentionally integrated into processes, fosters resilience, agility, and your competitive advantage.

Ready to unlock new skills and capabilities?

[Get in touch >>](#)

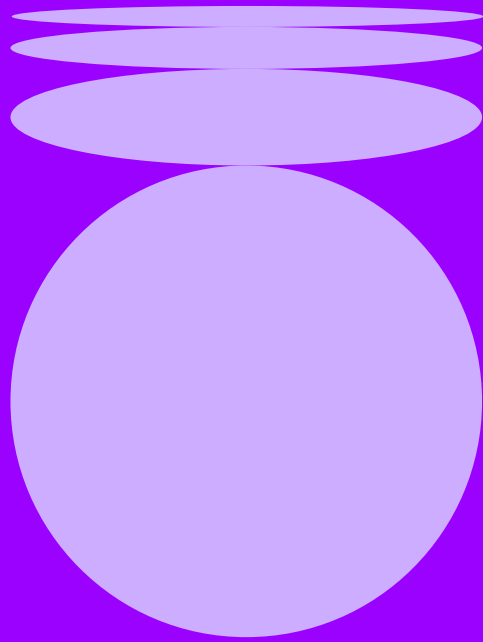
EMEA Office

Groenenborgerlaan 16
2610 Antwerpen
Belgium

US Office

Scilife Inc.
228 E 45th St. RM 9E
New York, NY 10017

Scilife



Scilife

S U M M I T

2023