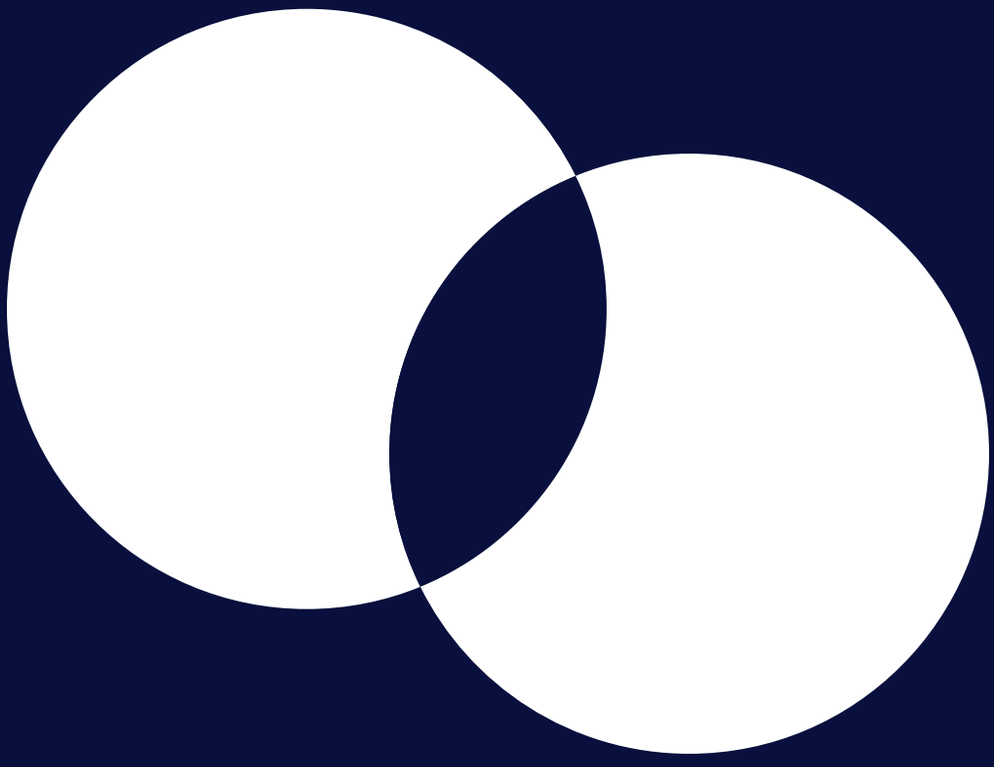
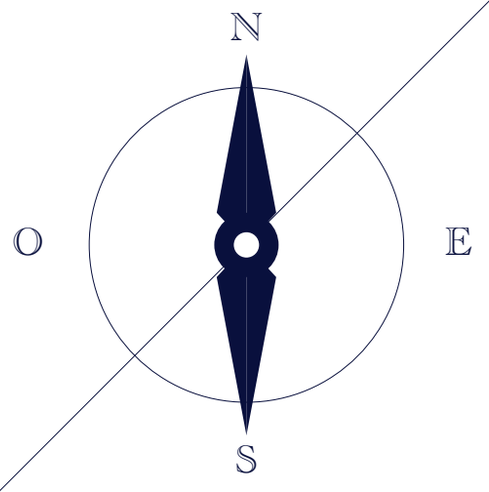


Practical strategies to boost your QMS document compliance

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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.

Scilife

Contents

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

“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

Dr. Kathy Walsh

Quality Systems Now

Kathy has over 25 years' experience working in the pharmaceutical and medical device industries, as well as biotech, distribution and wholesaling, compounding, and clinical / R&D organisations. She has extensive expertise in helping clients:

- Achieve accreditation or licensing to GMP or ISO standards.
- Develop and transform Quality Management Systems (QMS) for startups, growing small to medium sized companies, and assisting large corporations trying to simplify their large QMSs.
- Develop Plain Language writing skills with trainees.

Kathy has a proven track-record in leading quality systems, documentation, compliance and training programs to deliver high-profile site Quality, technical and QMS projects. In addition to her scientific qualifications (PhD), she is a qualified project manager, trainer, technical writer and author.

Key Takeaways

Compliance problems are rooted in **behaviors** —understand the behavior, improve the problem.

Learn to communicate with different demographics in the business — **business language** with Top Management, OpEx language with Production, regulatory language with QA.

Company size/age is often related to **quality maturity**. Different document compliance issues occur as the company matures and grows.

Teach people how to **write** – don't expect them to know from university.

Common QMS Problems Related to Company Size

Startup

Manual systems

Team not compliance experienced - R&D

Product focused

Technical specialists write documents

Scaling

1st eQMS - migrating to workflows

1-2 compliance experienced

Business focused

QA police/write documents

Large

Integration & automtion

Compliance maturity across the company

Compliance focused

Tech writers write procedures

what we **can see**

what we **can't see**

Owner/inventor/ investors driving activities

Role sharing

Time pressures to commercialization

QMS a “bolt on”, not intrinsic to activities

CEO driving activities

QA Mgr holding QMS together

Business pressures to make sales

QMS still a “bolt on”, starting to integrate

Top Mgmt engaged

QMS integrated within all operations

Efficient & compliant operations

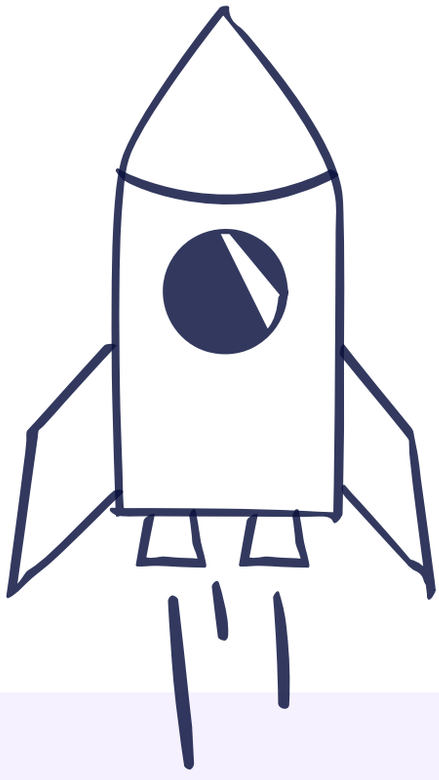
The QMS is the business

What's really going on when an auditor says

"Missing Procedure"?

What's the real root cause?

Startup



*

Behaviours and culture
have a huge influence on compliance

Culture is **not QMS focused**

Processes **not fully defined** or mapped

Procedure is in someone's head

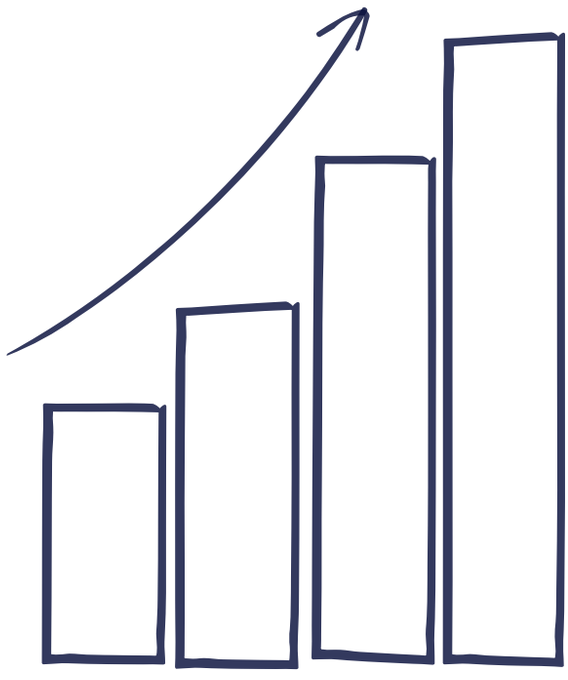
Procedure is high level info only. **Not detailed enough**

Inconsistent staff training

SOP **not enforced**

What's the real root cause?

Scaling



*

Behaviours and culture
have a huge influence on compliance

QA Mgr trying to **influence culture**

Staff trained but pockets of **"resistance"** - QA/Ops

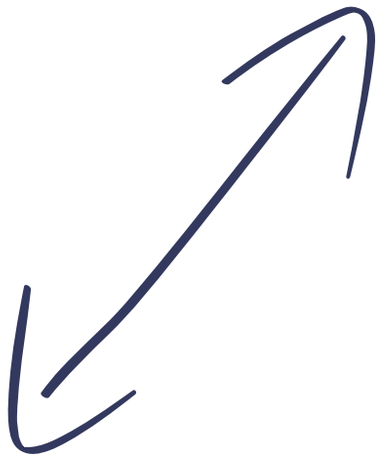
QA Mgr "fixes" everything for next audit

Processes **not consistently executed** & records **not consistently documented**

Documentation still considered **"paperwork"**

What's the real root cause?

Large



*

Behaviours and culture
have a huge influence on compliance

Culture is **compliance focused**

New staff/turnover - **responsabilities** well understood

Procedures **well documented & communicated**

Periodic review/change control may lag & cause **issues**

Temporary change/planned dev may not be well executed

SOPs enforced by line mgrs

What's the common denominator? The People Piece.

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.

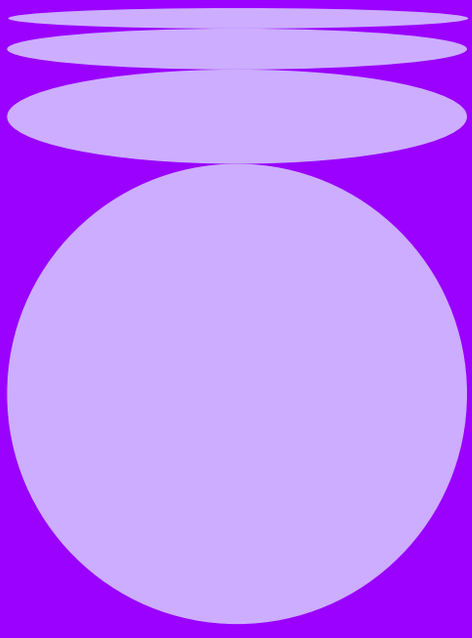
Ready to unlock new skills and capabilities?

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

SUMMIT 2023