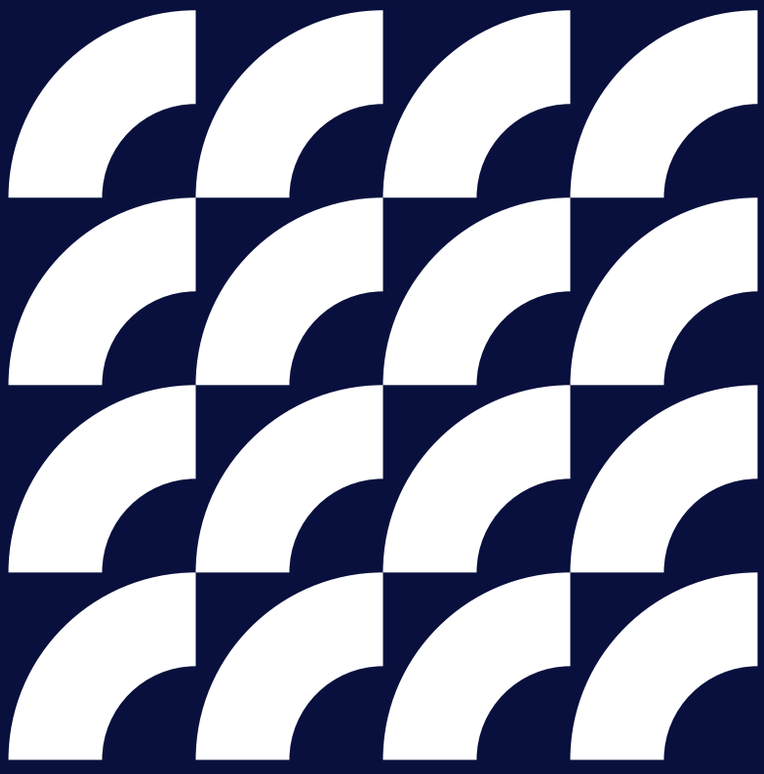
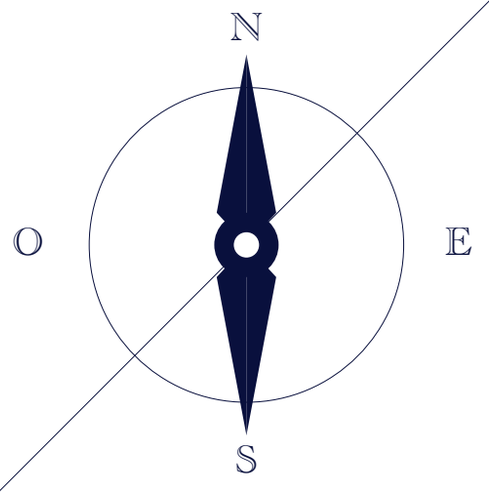


Managing Quality Risks in Life Sciences. Case Study: Switch from paper based to electronic QMS

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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

“The transition to smart quality is only feasible with the **right mindset**;

without it, success remains unlikely.”

Meet the expert behind the talk

Bodo Brocks

Coriolis Pharma

Bodo has 25 years of experience in biotechnology and held positions as Director Analytical Development, Head of QC and Director QA at the German biotech company MorphoSys AG. Since October 2021, he has headed the Quality Unit at Coriolis Pharma in Germany, an outstanding global service provider in the field of biopharmaceutical formulation development and analytics. He is dedicated to:

- Supporting therapeutic product development with scientific excellence.
- Advancing novel immunotherapies for diseases like cancer, ensuring that quality in medical products directly translates to benefiting patients.
- Functional and physico-chemical analytics, understanding that robust analytical data forms the cornerstone for informed decision-making.

Bodo receives great satisfaction from bringing benefits to patients and being responsible for the quality of medical products.

Key Takeaways

QRM as a promoter of a Smart Quality culture

Promote a culture of risk awareness instead of risk aversion

Bring multifunctional teams together

Foster rational decision process

Smart Quality assurance: Focus resources for root cause investigation and CAPA

Avoid the “death by CAPA” by following a risk-based approach

Consider probability and consequences of recurrence of a non-conformity

Utilize smart electronic systems to gather information on non-conformities with similar root cause

Introduction: QRM

Some misconceptions about QRM

"We use common sense, why having a formal QRM process?"

"We follow all applicable guidelines, what risks should we face?"

"Risk assessment is fine, but a formal risk control and risk review process is a bureaucratic overkill"

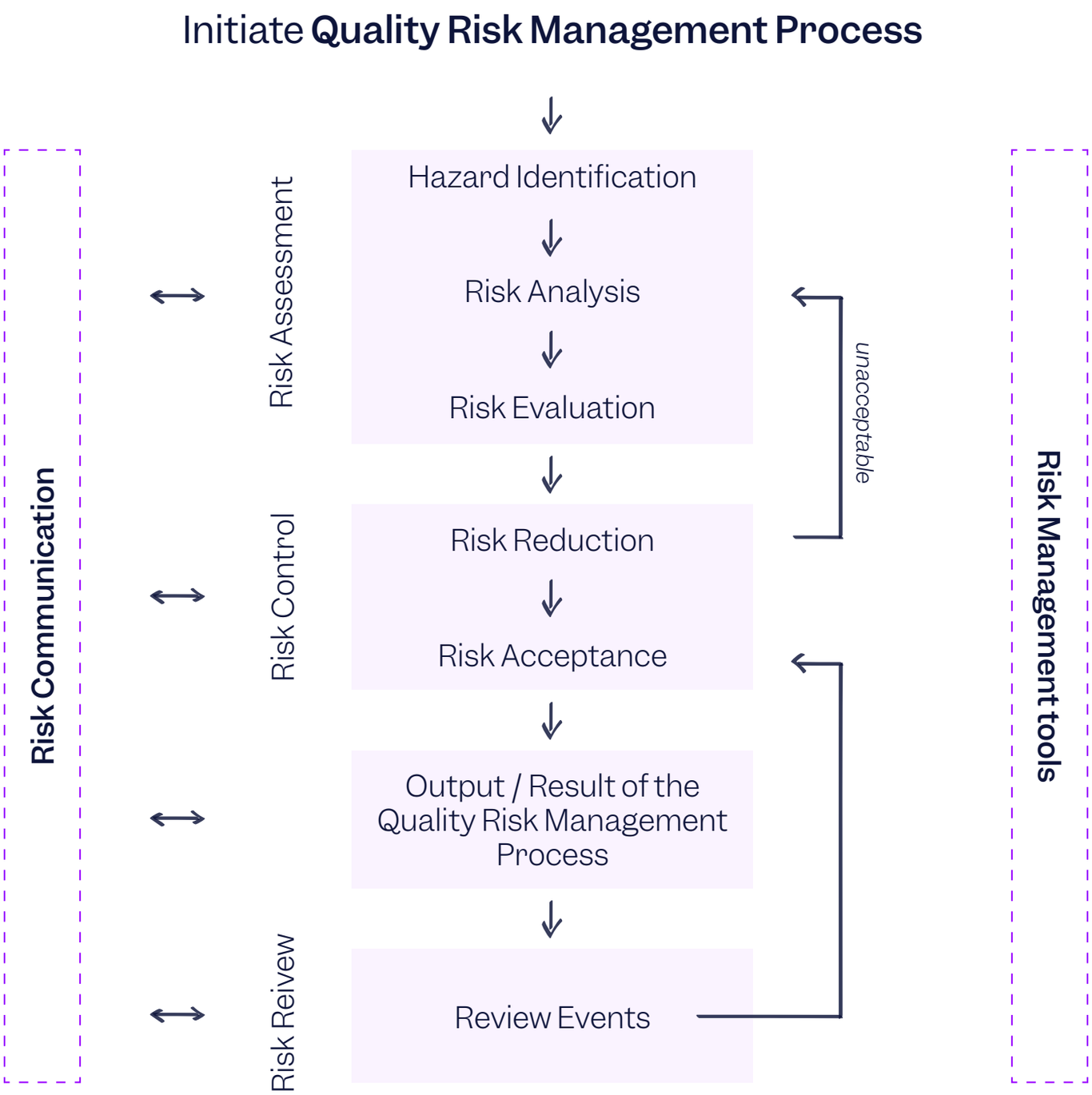
"QRM interferes with our lean management approach"

"We have outsourced all activities to CMOs. They are responsible to manage the associated risks"

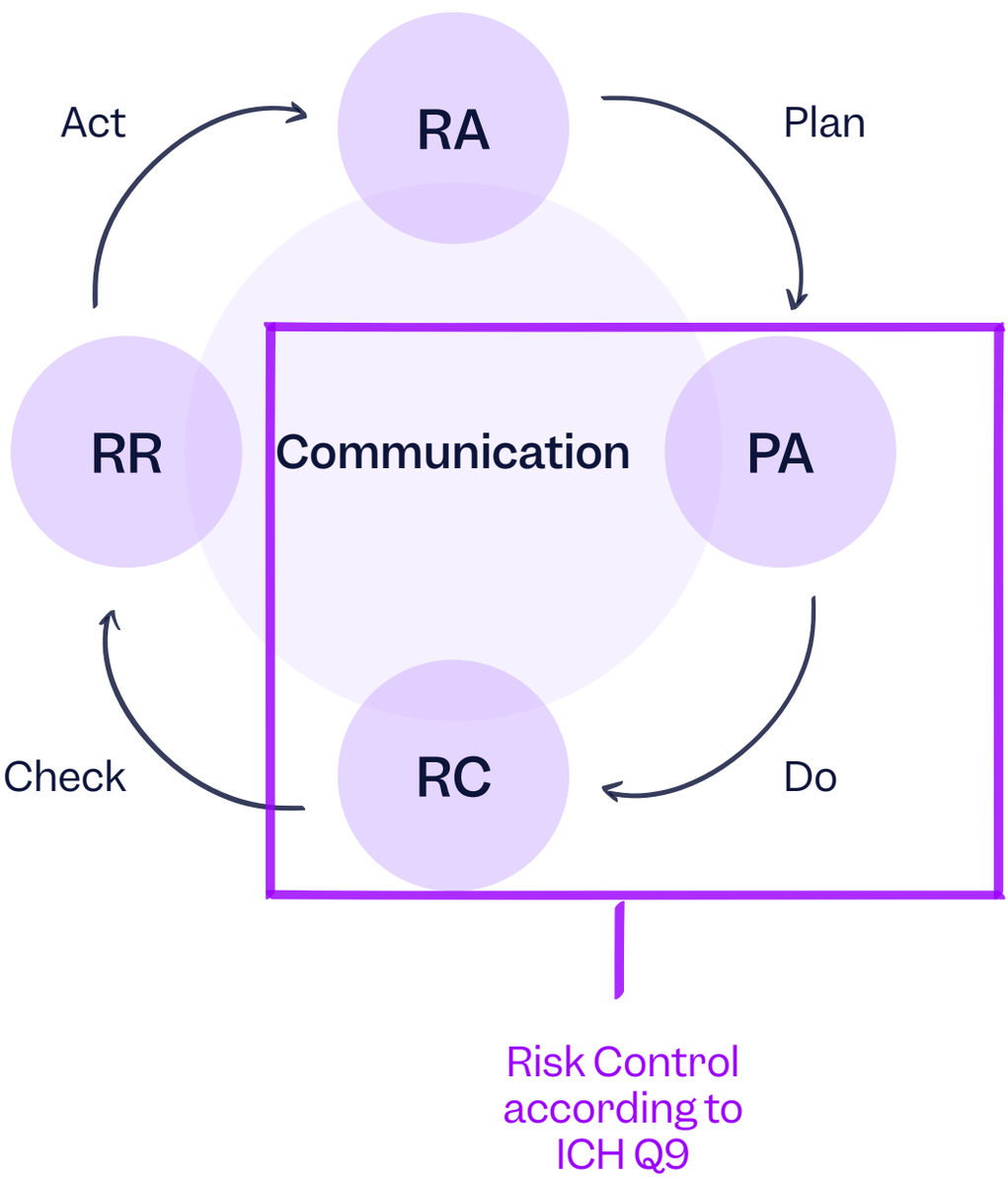
"We asses risks as part of our change control and deviation management. What else should we do?"

Introduction: QRM

QRM Process according to ICH Q9



QRM as PDCA process



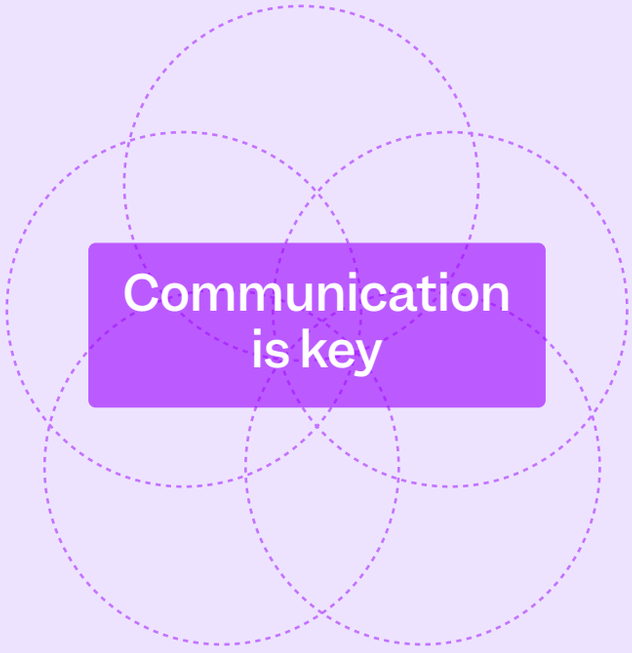
RA: Risk Assessment **PA:** Preventive Actions **RC:** Risk Control **RR:** Risk Review

Introduction: QRM

Risk Communication

Openly **discurss risks** in **multidisciplinary teams**

Regular agenda point in Quality Management Reviews



Be transparent: Do not hide risk reports in a QA silo

Management **approval** for acceptance of business-critical risks

Openly **discurss risks** in **multidisciplinary teams**

ICH Q9 (R1): What's new?

ICH Q9 (R1) 26 Jul 2023

New text on subjectivity in QRM prcesses	Subjectivity to be controlled by proper use of tools and source of knowledge
Clarification on the formality of QRM processes	Focus resources based on complexity and risk level. The more important a risk-based decision is, the higher the level of formality
Term "Risk Identification" exchanged by "Hazard Identification"	
Product availability risk	GMP compliance issues may lead to product shortages Non-availability of product must also be considered as quality risk
Risk-based decision making	Informed decisions in a multitude of areas Risk-based allocation of resources

ICH Q9 (R1): What's new?

A practical approach to formality in QRM

Formality	Risk affecting…	Example	RA Tools
Degree I	Certain parts of a system or process steps	▪ Simple changes ▪ Quality events	Qualitative with simple classification
Degree II	Less complex or well-established systems or processes	▪ "Off-the-shelf" equipment or software	Risk ranking list with simple classification
Degree III	▪ Complex systems and processes *and/or* ▪ High degree of uncertainty *and/or* ▪ Business critical systems or processes	▪ Production process ▪ Supply chain for new product ▪ Business critical computerized system	FMEA or comparable (more than one may be required)

RA: Risk Assessment **RC:** Risk Control **RC:** Risk Control

Embracing change in life sciences means transforming risks into gateways for innovation.

It's a narrative of confronting challenges and leveraging them to unify our quality processes.

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 >>

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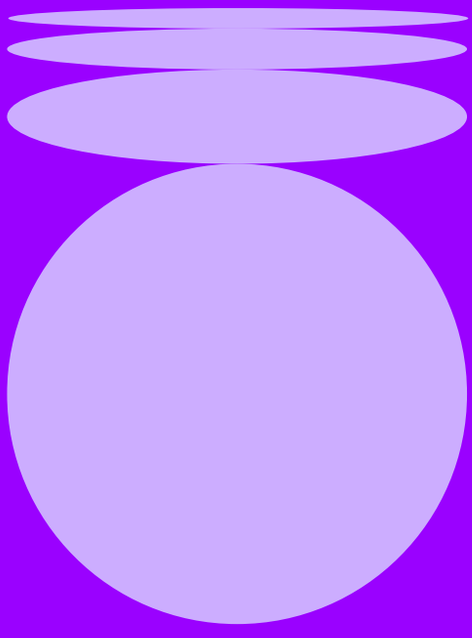

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