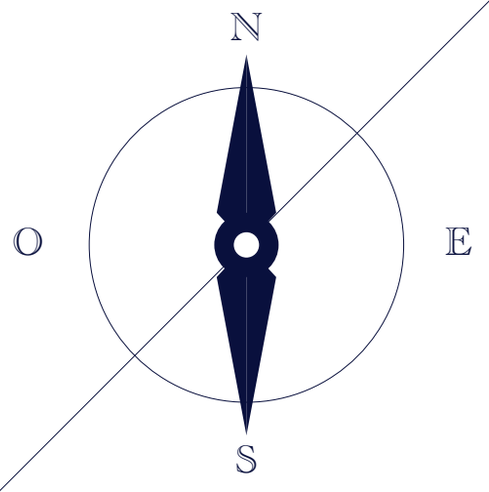
Implementing Risk-Based Approaches to Computerized System Validation

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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

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“In a landscape of complexity, a risk-based CSV stands as a beacon of efficiency,

directing our focus where it matters most for quality and compliance.”

Meet the expert behind the talk

Joseph Turton

The Knowlogy

Joseph began his regulatory career as an Apprentice Lab Technician in 2011, earning distinctions as the "Chemical Sciences" Apprentice of the Year and "Advanced Apprentice of the Year" for Yorkshire and Humber due to his exceptional work. Over the last 12 years, Joe has been deeply involved in various regulatory projects such as:

- Leadership in environmental risk assessment studies and the supervision of customized regulatory initiatives and facilities.
- Specialization in Computerised Systems Validation (CSV), marked by the introduction of inventive methodologies, including the life-cycle approach to CSV.
- Proficiency in CSV across various instruments, from spectrophotometers to complex systems such as radio-labeled chromatography (HPLC, GCMS, LCMS) and LIMS.

Currently, as the QA Manager CSV Specialist at The Knowlogy, Joe provides consultancy, manages projects, conducts GxP audits, and develops training programs.

Key Takeaways

Challenges in Risk-Based CSV

Resistance to Change

Human Nature

Concerns over disrupting established processes duced rigor

Misalignment between IT, Quality Teams and Operations

Potential communication barriers and varied priorities

Need for cross-functional collaboration

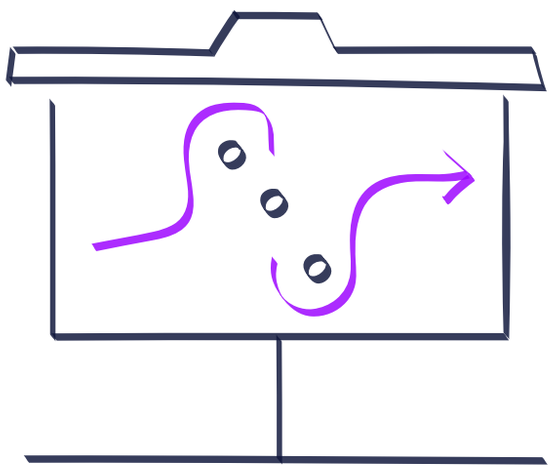
The perception that Risk-based Means Less Rigorous

Misconceptions about risk-based approaches being shortcuts

Ensuring stakeholders understand that risk-based is about focused rigor, not reduced rigor

Key Takeaways

Overcoming the challenges



Educate stakeholders on the Value of Regulatory Acceptance

- Workshops, seminars and training sessions
- Showcase real-world examples and case studies
- Highlight regulatory endorsements of risk-based approach

Foster collaboration between **IT** and **Quality Teams**

Highlight the **Adaptability** and **Responsiveness** of the Approach

Key Takeaways

Essential Insights

The Shift to Risk-based:

Modern complexities demand a departure from traditional methods to the more dynamic risk-based CSV.

Resource Optimization:

Organisations can allocate resources more efficiently by focusing on high-risk areas.

Enhanced Compliance:

Tailored validation strategies ensure rigorous examination of critical components, aligning with regulatory requirements.

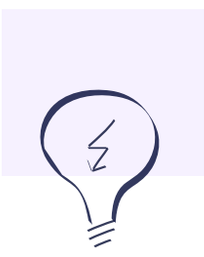
Continuous Improvement:

Risk-based CSV promotes regular reassessments, fostering a culture of ongoing enhancement and vigilance.

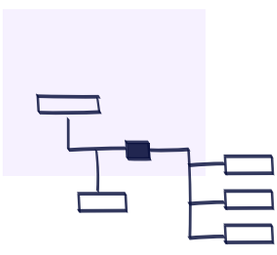
Practical Steps
to Implementing Risk-Based CSV

Requirements

Produce **detailed** and **unambiguous requirements**



Think about how you would **define failure** for the **specific system** and process



Think about the **whole process**, not just the technical requirements of the system

System Classification

Critical

Directly affects product quality, patient safety or study outcome

Non-Critical

Indirectly affects product quality without immediate patient, product or study impact

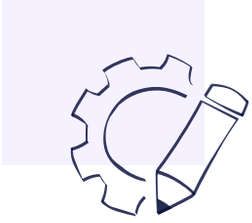
Non-GxP

Outside the realm of regulated processes, there is no direct impact on product quality or patient safety of the system

Practical Steps
to Implementing Risk-Based CSV

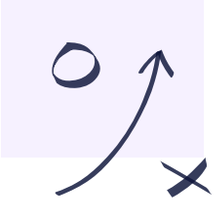
Risk-Assessment

Evaluating systems against their potential to influence **product quality** and **patient well-being**

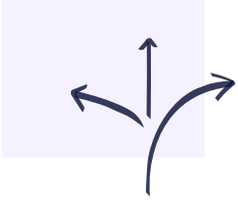


Prioritization **methodology**, considering the severity of **potential failure** and its implications on end-users

Plan and Strategy



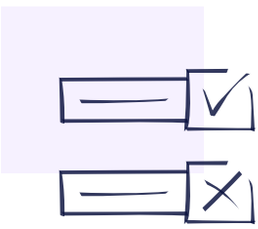
Crafting a **customized validation strategy** rooted in the outcomes of the risk assessment



Be **flexible, adaptable** and **scalable**

Practical Steps
to Implementing Risk-Based CSV

Execution

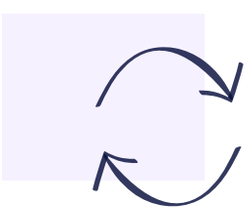


Implementation of the **validation tests**

Focus on the areas flagged as **higher risk**, ensuring robustness in **critical areas**

Review and Monitor

Ongoing **risk reassessment** to stray on top of changes



Persistent system surveillance to detect and manage **merging risks**

Embracing a risk-based approach to Computerized System Validation (CSV)

it's a transformative journey that optimizes resources and ensures the highest quality.

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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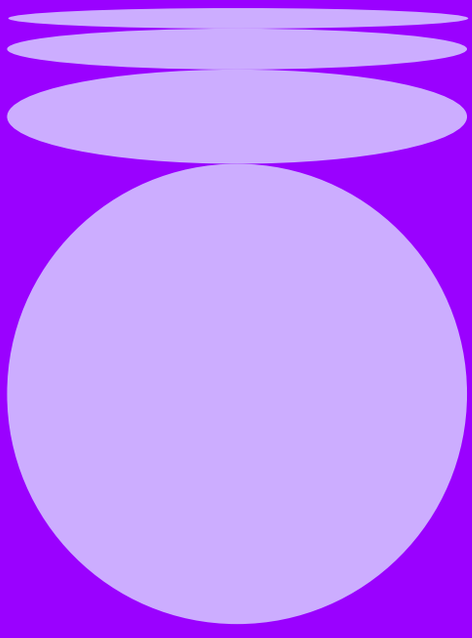

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