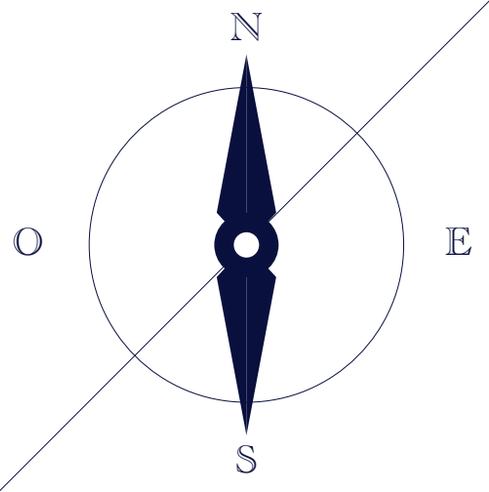
CAPAs, events, and change control: Unlocking the potential for continuous quality improvement

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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

“Impact along with risk can help drive your decisions for where to place resources toward **continuous improvements.**”

Meet the expert behind the talk

Scilife

Ricki A. Chase

RChase Consulting LLC

Ricki is a quality compliance professional with over 30 years of experience in regulatory enforcement roles and quality consulting leadership. She has worked in multiple jurisdictions, including 20 years of federal service. Here is a brief summary of her career journey:

- She worked at the US Food and Drug Administration as an Investigator in the Office of Regulatory Affairs where she was responsible for assessing all regulated commodities.
- She was a Supervisory Investigator and Director of Investigations where she led offices and programs as well as developing enforcement cases and working with industry partners.
- As Vice President at Lachman Consultant Services, Inc., she spearheaded the development of the medical device/combination products business line.

As President of RChase Consulting LLC, Ms. Chase works with industry, academia and non-profits within the life sciences to develop, support and grow successful people, products and companies.

Key Takeaways

Data, data, data

Results and continuous quality improvement are only as good as the data you rely on:

- Identify quality data
- Define how you will analyze the data
- Ensure appropriate and timely reaction to the data

Analyzing the data

Don’t define a “trend”:

- use data to build a historical norm
- look for movement away from the norm

Choose useful tools:

- Show how your data may be interrelated
- Demonstrate data are quality indicating

Key Takeaways

Bring it together

Risk management plan should be a living document.

Quality data should be used to update the risk management plan based on analysis.

Some risks will be greater:

- Update the risk management plan
- Use resources to monitor the risk and drive change to reduce it

Some risks will be reduced as learnings are gained and there are continuous QMS improvements.

Risk management plans should be product focused, process focused and systemically focused.

Leverage data to create a program of **continuous quality improvement**

The Quality System Regulation (devices) identify quality data as...

"Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming proudct, or other quality problems."

Anything you **SHOULD** have hbeen analyzing but **were not**

While pharma regulations are not specific...

it is recognized as best practice that quality organizations identify and respond to **quality signals.**

Pitfalls of Data

Yin and Yang

Yin

Too many

Can't analyze them all or see the interconnections

Not granular enough: lacks specifics, only generalizations

Lack of acceptance criteria: not knowing when the data shows a response in required

Yang

Too few

Not enough information to base improvements

Too granular: miss the bigger or systematic level signals

Acceptance criteria not based on risk or historical performance: too much work or not enough

Analyzing data

Data, data, data

Describe by procedure how you will analyze the data	→	Many data points - tools to “see” patterns and interconnectivity
Strong statistical techniques	→	Analysis of variance or covariance to identify interrelated events and outcomes
Defensible method	→	Demonstrate the tool/analysis was not chosen to deliver the desired outcome

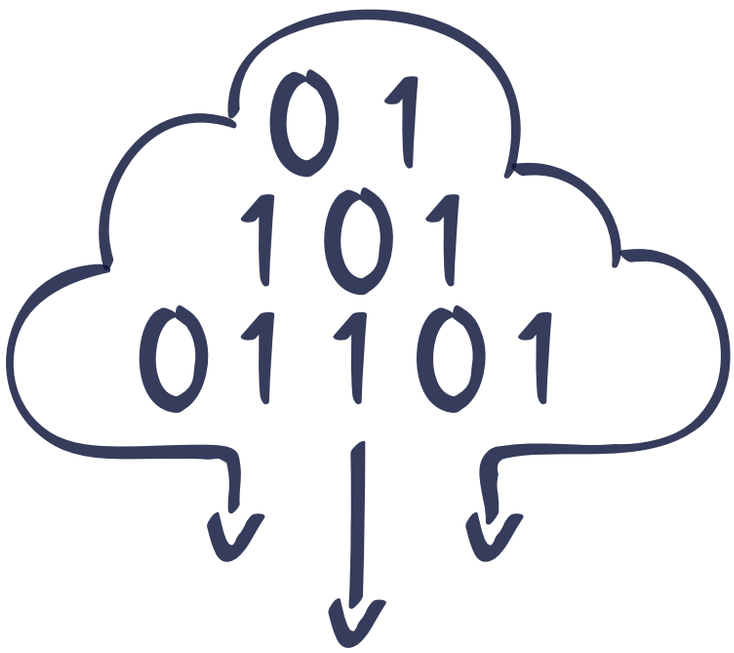
* No need for action

Common mistake!

Only considering data as discrete data points may lead to a failure in identifying potential problems, resulting in a **lack of continuous improvement.**

Responding to data

Data, data, data



Knowing **when to respond** to data signals is key to **taking early action**.

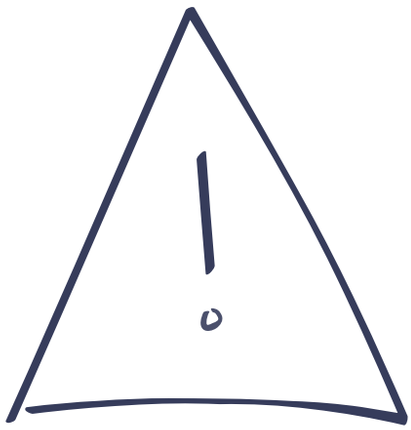
- Responding late:
  - Early signals not identified
  - Event/non-conformance investigation brings the problem forward.

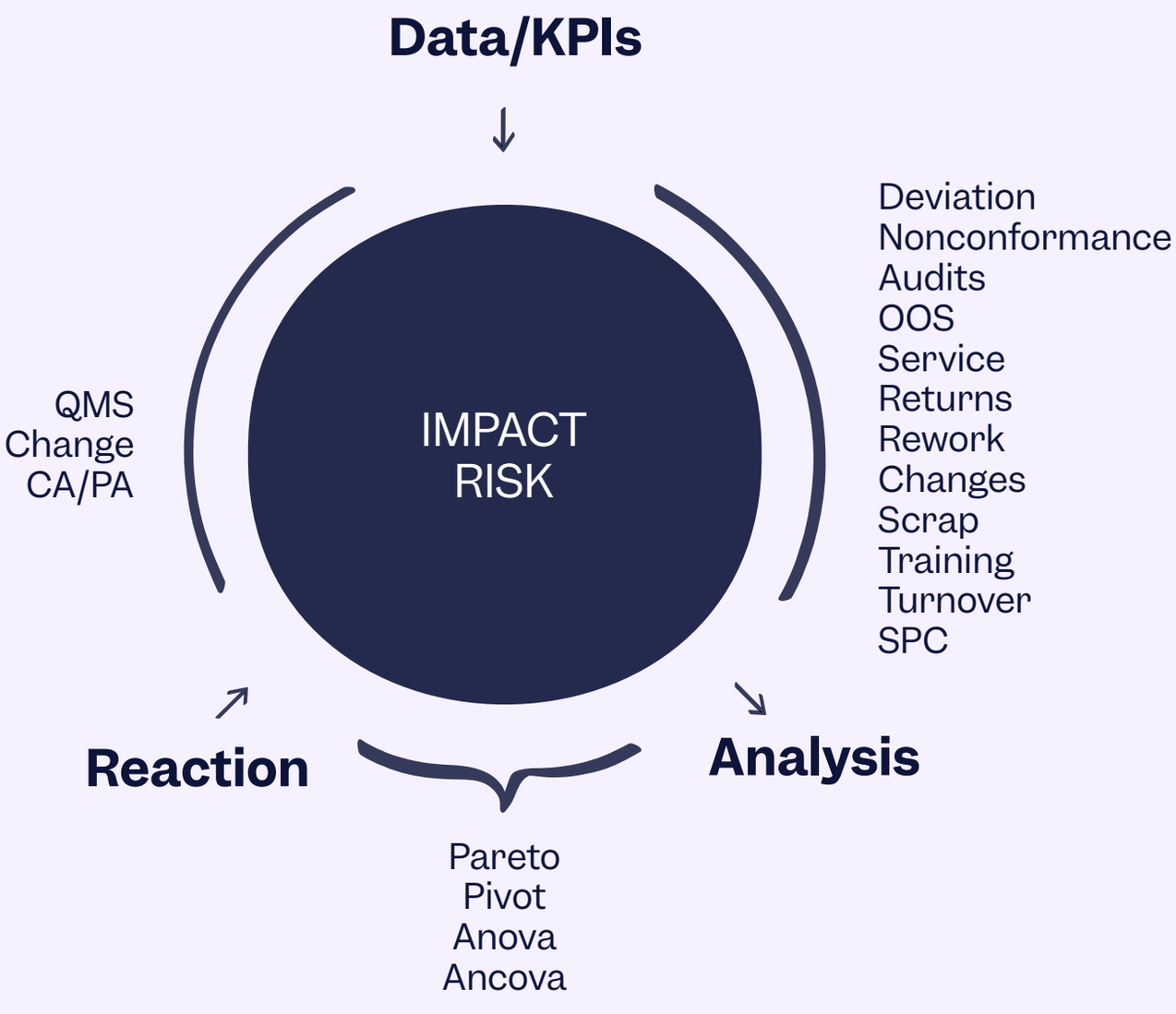
Clear rules for when and how to respond to data signals, described **by procedure.**

- Over reaction → overburdening your CAPA system.
- Under reaction → complex or system-wide changes consuming time and resources.

Continuous Improvement

Data, data, data





Realizing the true potential of quality lies in strategically balancing risk with impact.

It's about making informed decisions on resource allocation to foster continuous improvement.

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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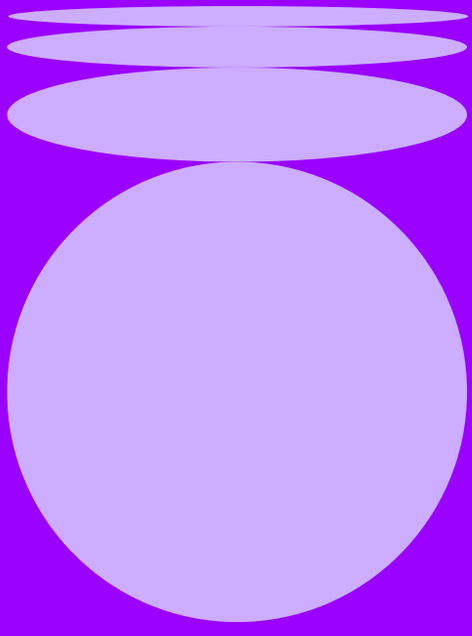

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