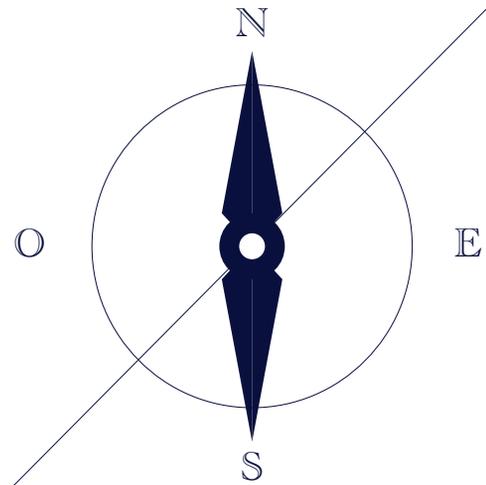


How quality in MedTech became  
a driver of financial performance

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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

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

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“Quality has  
become a strategic  
**differentiator**  
when it comes to  
stock market  
**performance.**”

”

## Meet the expert behind the talk



Drawing from his experience in the pharmaceutical industry and contributions to a pharmaceutical start-up, Florian, educated as a chemist, brings substantial expertise gained from both operational and strategic roles. His passion centers around:

- Developing user-centric and value-adding Quality Management
- Systems and embracing the principles of Quality 4.0.
- A deep commitment to quality management and quality culture. Pursuing innovative solutions to overcome regulatory hurdles with a transformation mindset.

**Florian** is dedicated to reshaping regulatory approaches and fostering smarter, more dynamic quality practices. He currently works as the Senior Manager in Deloitte Risk Advisory's Life Science Practice and spearheads Regulatory Transformation for clients, transitioning from a compliance-driven to a smart and risk-driven Quality Management System.

### Dr. Florian Zischka

Senior Manager at Deloitte

## Key Takeaways

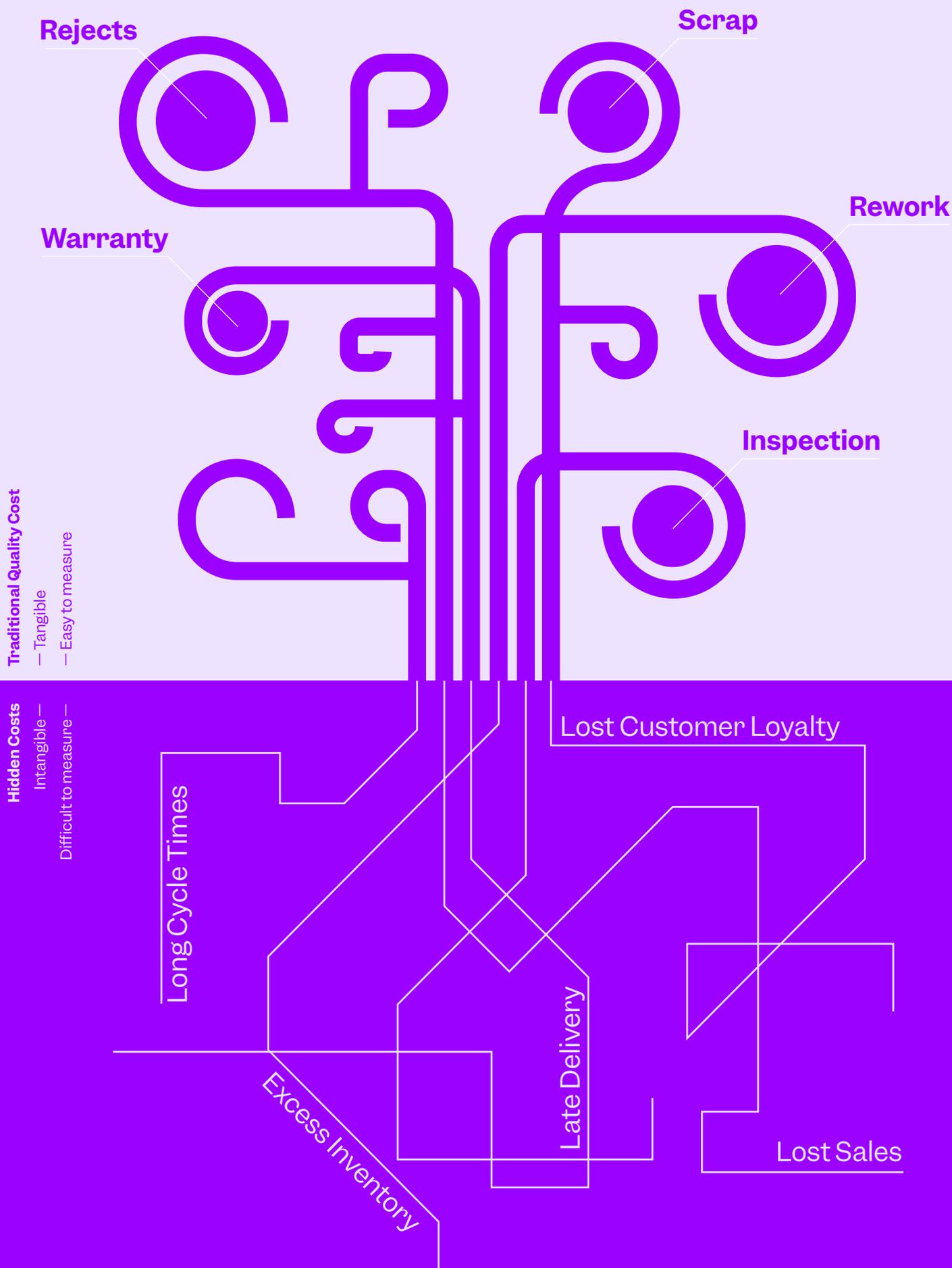


**Low quality performance** has a severe impact on stock market performance.

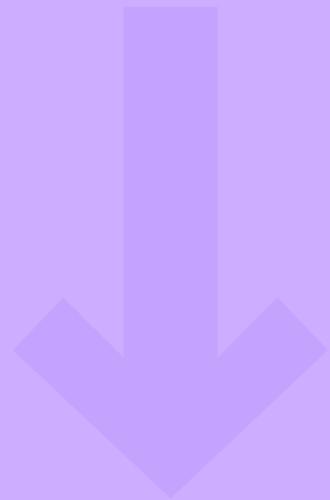
Monitoring Quality Systems like CAPA provides **early warning signs for bad quality performance**.

**Risk and non-compliance** should be the key design principle for quality management.

# The Situation: Cost of **poor Quality**



“The cost of poor quality are tangible, and their effect will cost you money, customers, and ultimately

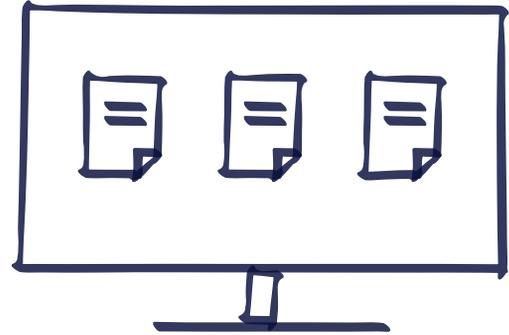


**the success  
of your business”**

Subir Chowdhury

## The Trends

# From documents to data and automated workflows



### Ambitions:

**Get rid** of documents

**Embrace** procedures as processes

**Leverage** workflow automation

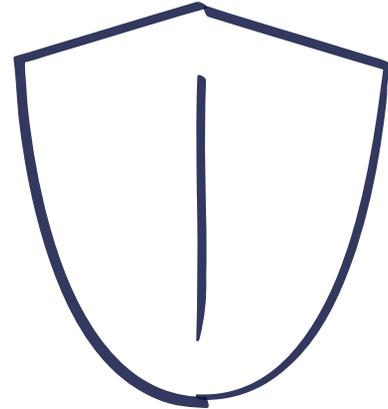
### Lessons learned:

PDFs in a DMS are **not data**

Choice of '**best in class components**' versus '**unified platform**' can be painful

## The Trends

# Moving from reactive to preventive quality



### Ambitions:

Be more impactful by **preventing non conformities** before they can occur

From retrospective snapshots **to accurate predictions**

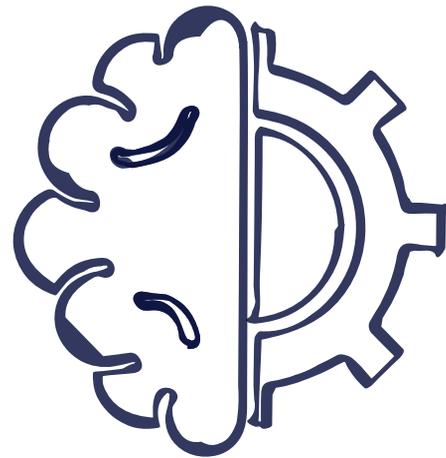
### Lessons learned:

**Inified data platform** is key foundation

**Cross-functional collaboration** and information flow need to be established

## The Trends

# Validate AI for use in GxP regulated processes



### Ambitions:

Unlock the potential of **AI for use in GxP** regulated processes

**Leverage trustworthy and controlled GenAI models** to accelerate compliant processes

### Lessons learned:

**Validation of training data** is a key component of **AI Validation**

**Lacking scalability** - only very few AI projects grow beyond MVP status in GxP

## The Trends

# Risk-based QMS and “quality by design”



### Ambitions:

Establish a culture of **preventive quality**

**Optimize** the use of QA resources by focusing on “**what really matters**”

Build quality systematically into **products and processes**

### Lessons learned:

**Capture quality risks** systematically in the QMS (e.g. in the procedures)

**Risk-based mindset can increase reputation** of QA function in the business

## The Trends

# Balancing local and global governance



### Ambitions:

Establish a **“one QMS”** approach globally

Create a culture of **end-to-end thinking**

**Reduce silos and enhance global oversight**

### Lessons learned:

**Significant monetary savings** can be achieved through global/local QMS alignment

**Balancing** the need for global oversight with the need for local empowerment **is difficult**

## The Trends

# Increasing the agility and speed of controlled changes



### Ambitions:

**Embrace agility and regulatory speed** as drivers of competitive advantage

**Simplify** the monitoring and implementation of **regulatory changes**

### Lessons learned:

**Transparent** linkage of regulations to QMS procedures can **speed up** change impact analysis and implementation

**GenAI**, text mining and automation have **huge efficiency potential**

**“Quality professionals achieve success by delivering products of the highest quality, ensuring the safety and well-being of patients.”**



[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 >>](#)

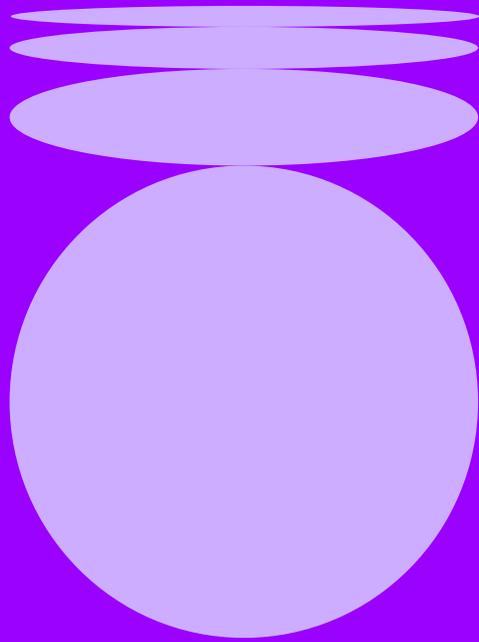
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2023