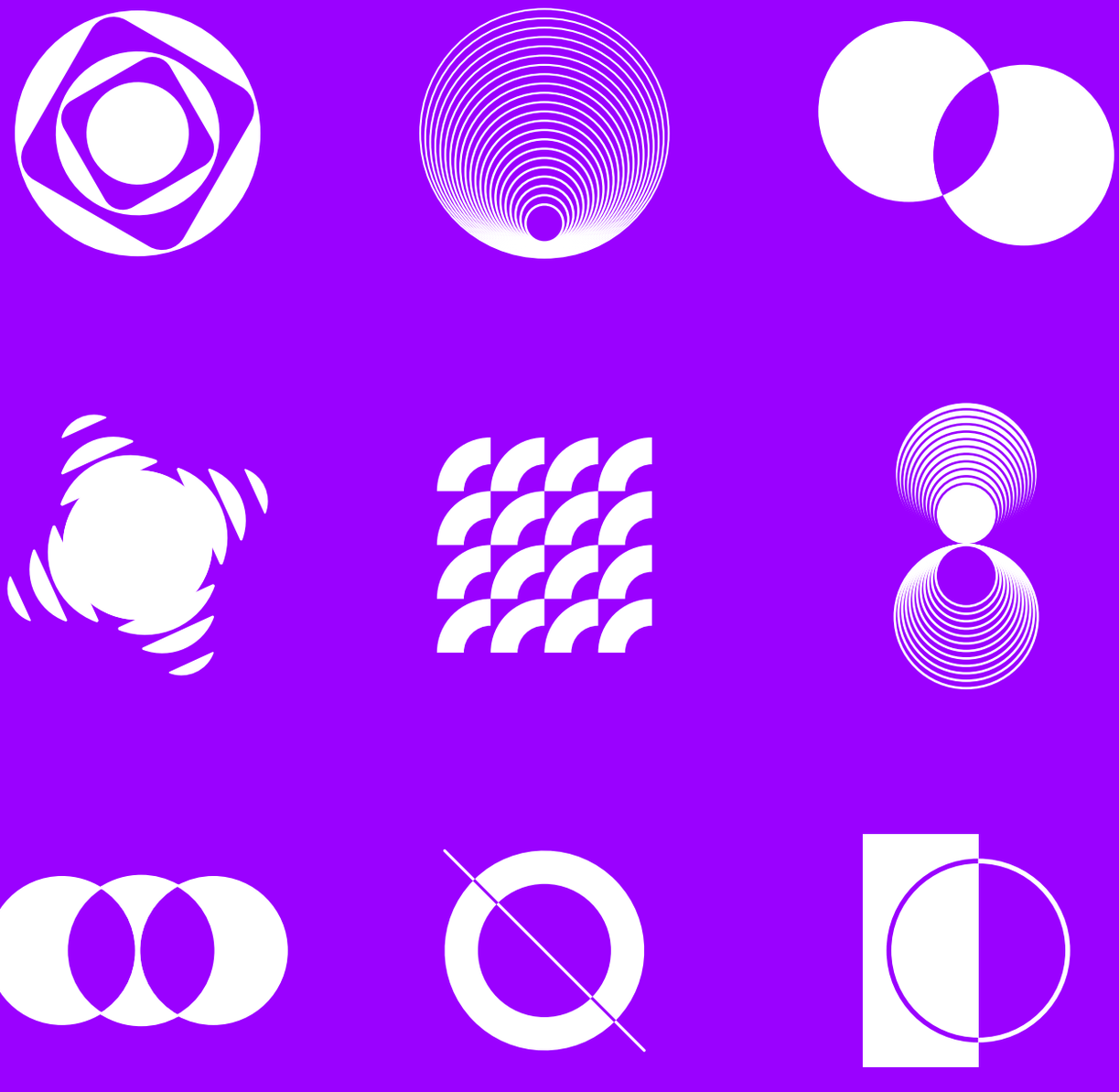
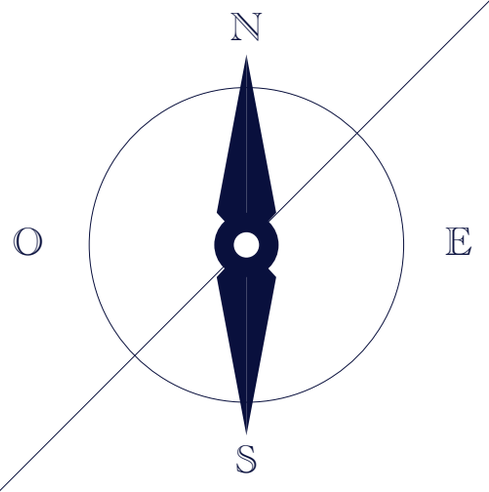
Scilife



Smart Quality Summit 2023

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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

GAMP: From theory to action in compliance management

Scilife

Contents

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

Lean documentation as part of smart quality is the way to reduce errors, effort and cost, while maintaining a high level of quality.

Meet the expert behind the talk

Angela Bazigos

Touchstone Technologies

With 40 years of experience in life sciences, **Angela** is the CEO of Touchstone Technologies, Inc., and has led the company since its inception in 2001. Under her guidance, the company expanded to Silicon Valley, driven by her patent expediting computer systems validation.

Some of her key accomplishments include:

- Co-authored & prototyped 21 CFR 11 guidance with FDA and work with FDA on Data Integrity Regulations.
- Co-authored Computerized Systems in Clinical Research with the FDA & DIA
- Quoted in Wall Street Journal for using training to bring regulatory compliance to the boardroom

Angela is also the Former President and Vice President of Pacific Regional Chapter of Society of Quality Assurance (PRCSQA) and specializes in many fields including remote, on-site, and hybrid audit services, covering GLP, GCP, Data Integrity, CLIA, and CAP.

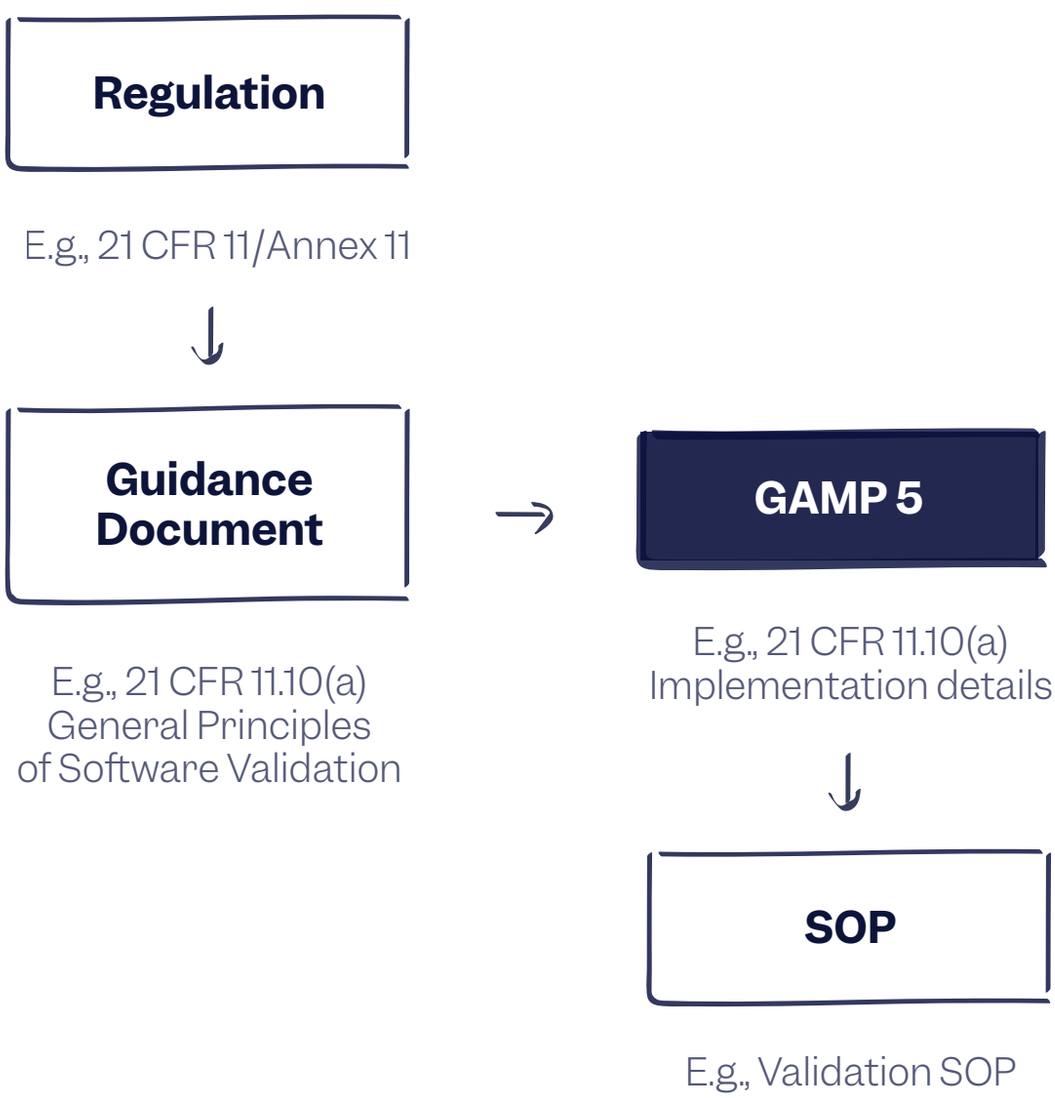
Key Takeaways

GaMP 5 deliverables are designed to ensure that **regulatory authorities** are all looking at the same thing when **inspecting a company**. They are mandatory because regulatory authorities do not have the time to understand each company's processes for every inspection.

The way that GaMP 5 deliverables are created is **decided by the company.**

Lean Documentation is one way to implement **Smart Quality.**

From Regulation to SOP Predicate Rules

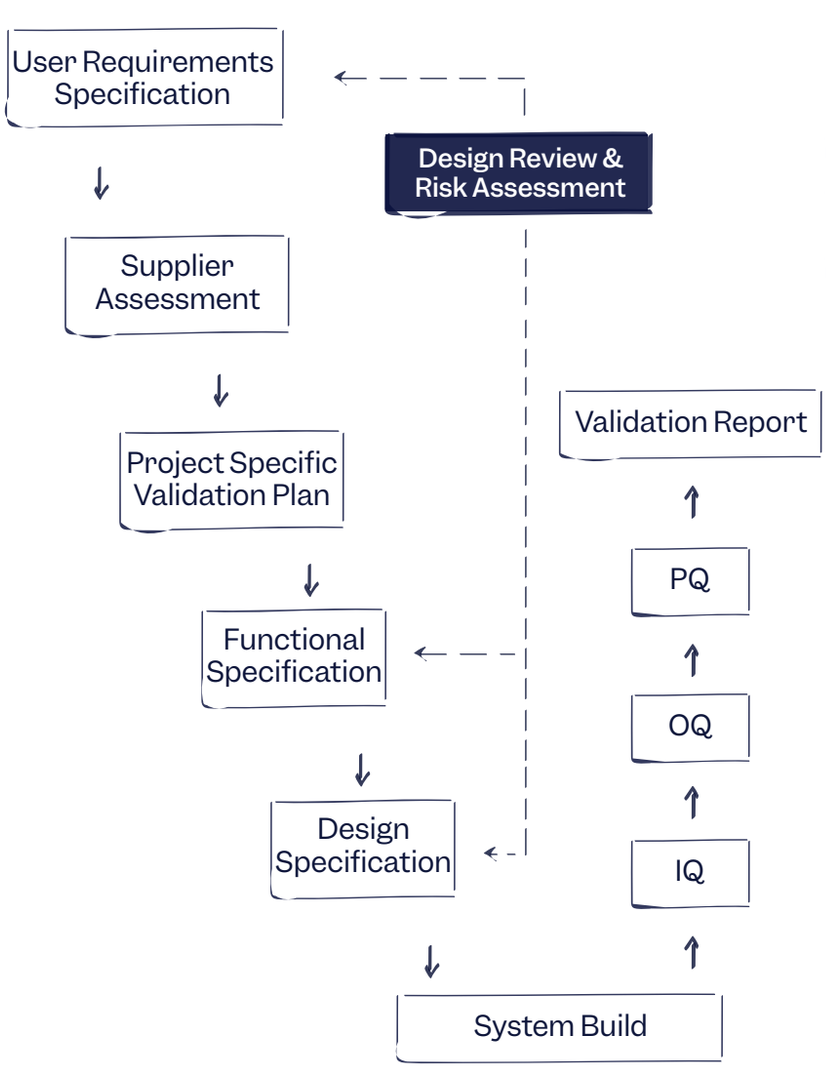


GAMP 5 Implementation

Validation Deliverables Formally...

Sections of **Validation Plan**

- Introduction and Scope
- Organizational Structure
- GxP Critically Assessment
- Validation Strategy
- Validation
- Acceptance Criteria
- Change Control
- SOPs and Training
- Documentation Management
- Maintaining the Validated State
- Glossary



Sections of **Validation Report**

Phase by Phase

- Introduction and Scope
- Summary of Results
- Details of Execution
- Deviation Reporting and Resolution
- Validation Status
- Training
- Maintaining the Validated State
- Glossary
- Appendices

GAMP **Planning/Reporting** Relationship

GAMP 5 Implementation

Validation Deliverables in IT Speak...

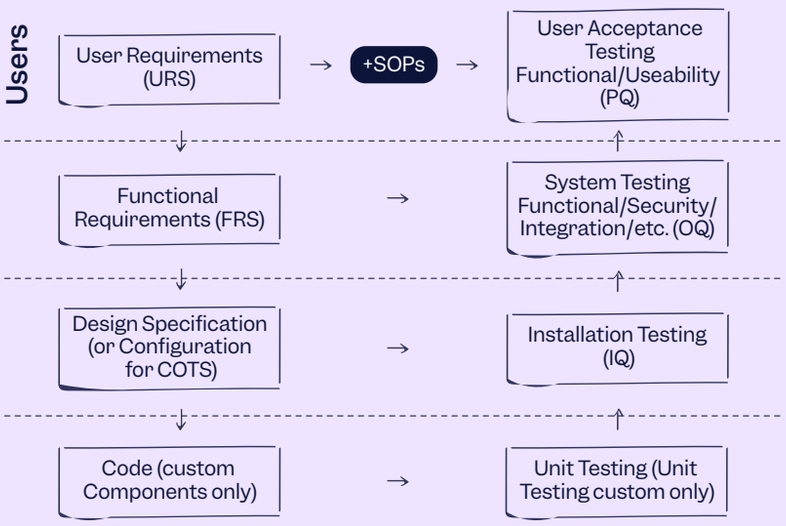
Hazard Analysis / Risk Assessment

Software Development Lifecycle - CUSTOM & COTS

Software Development Plan

(Validation Protocol)

- Overall Strategy and test lists (can even include this diagram)
- Attach Test Scripts as appendices
- Attach Trace Matrix as a appendix



Test Summary

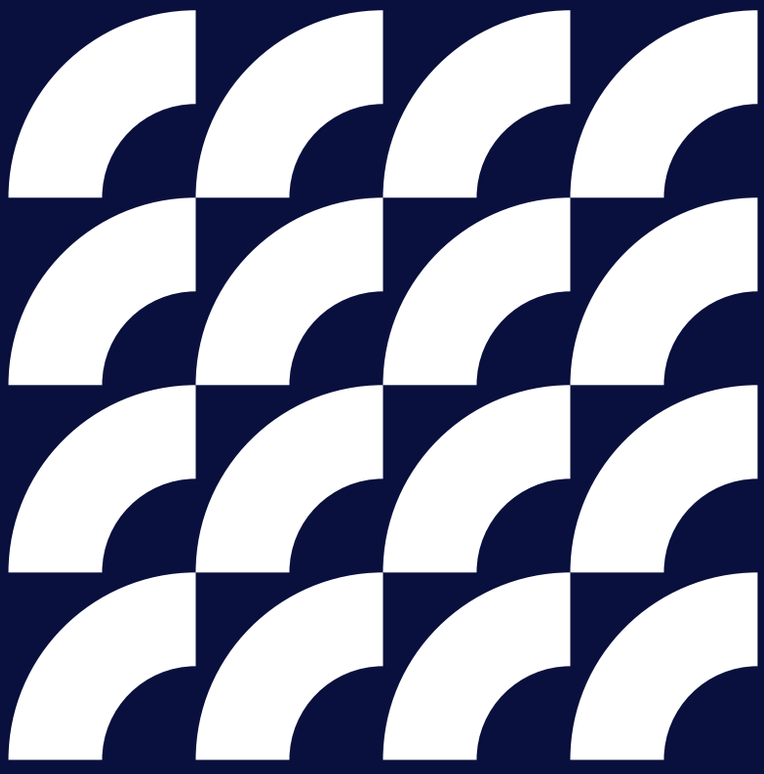
(Validation Summary Report)

- Test Results Evaluation
- Deviations
- Open Issues (for release notes)

Traceability Matrix

GAMP isn't just about knowing the rules; it's about integrating them seamlessly into the fabric of your operations. It helps us navigate the complexities of automated systems with a clear focus on risk management and product quality.

Link to masterclass >>>



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

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"

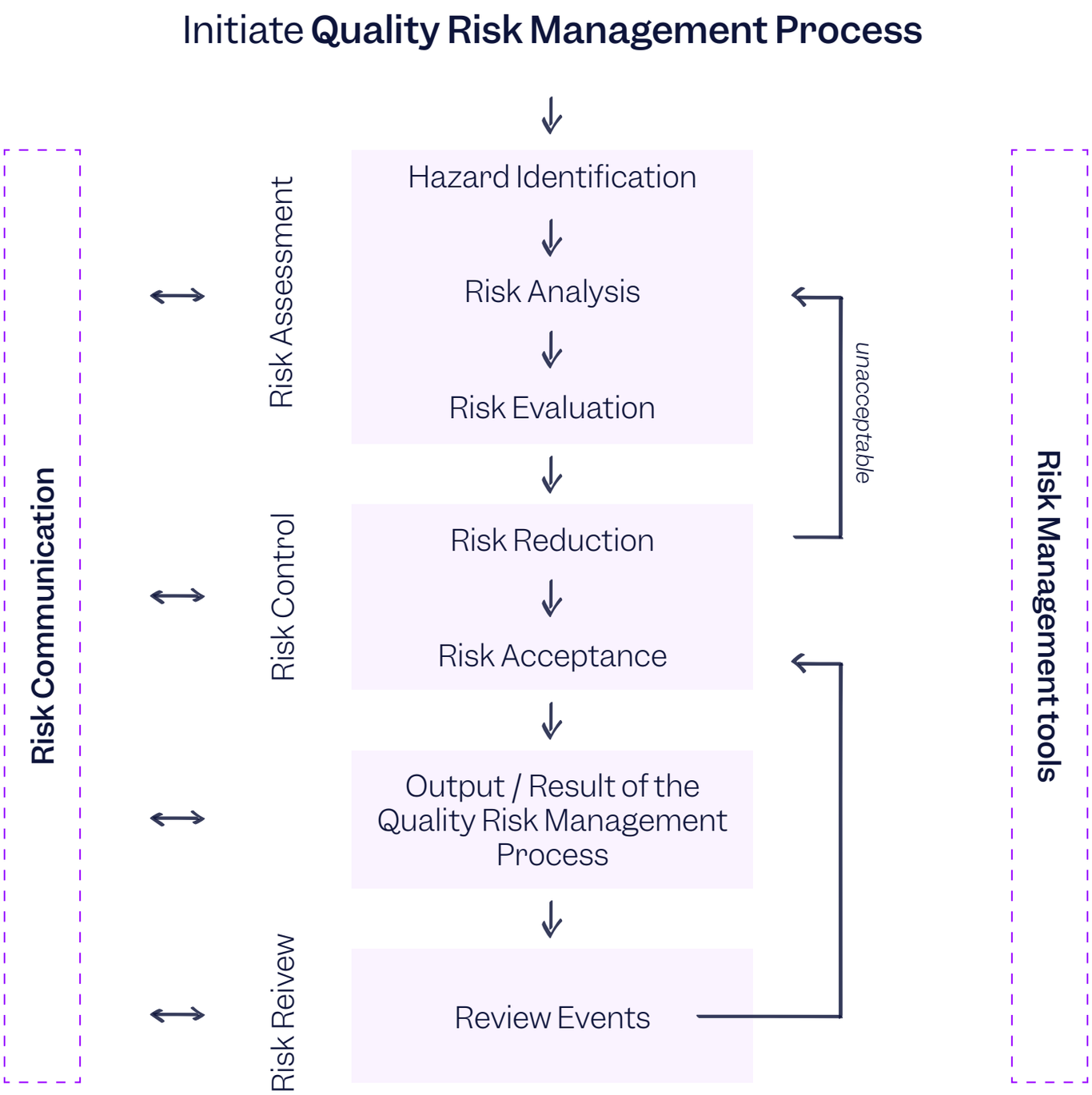
"QRM interferes with our lean management approach"

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

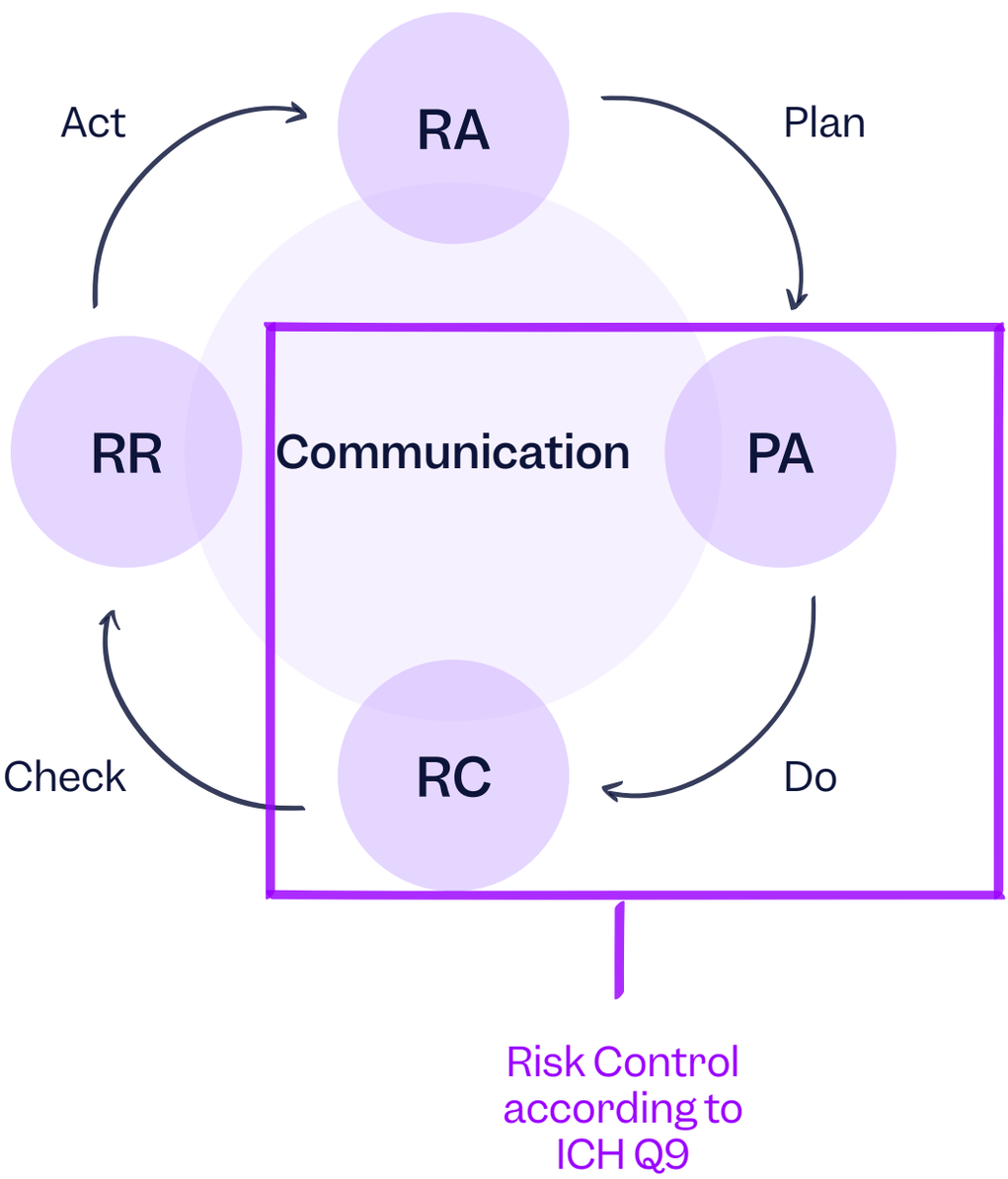
"We asses risks as part of our change control and deviation management. What else should we do?"

Introduction: QRM

QRM Process according to ICH Q9



QRM as PDCA process

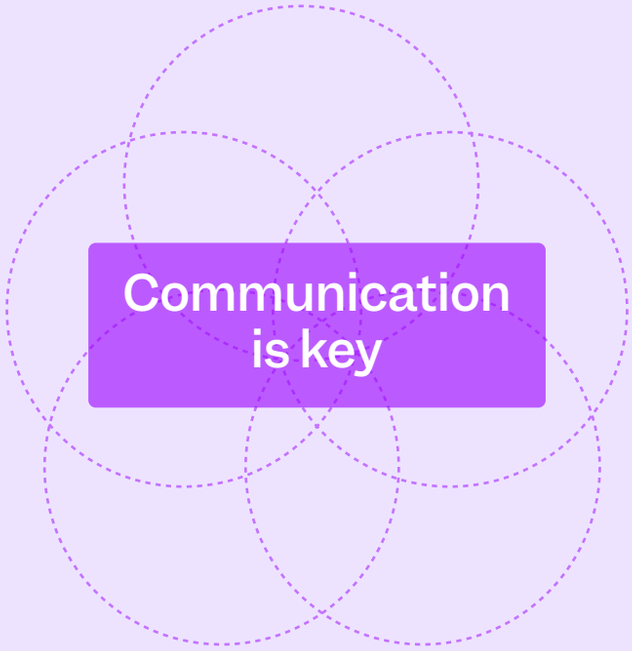


RA: Risk Assessment **PA:** Preventive Actions **RC:** Risk Control **RR:** Risk Review

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
Clari˜ication 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 Identi˜ication" exchanged by "Hazard Identi˜ication"	
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

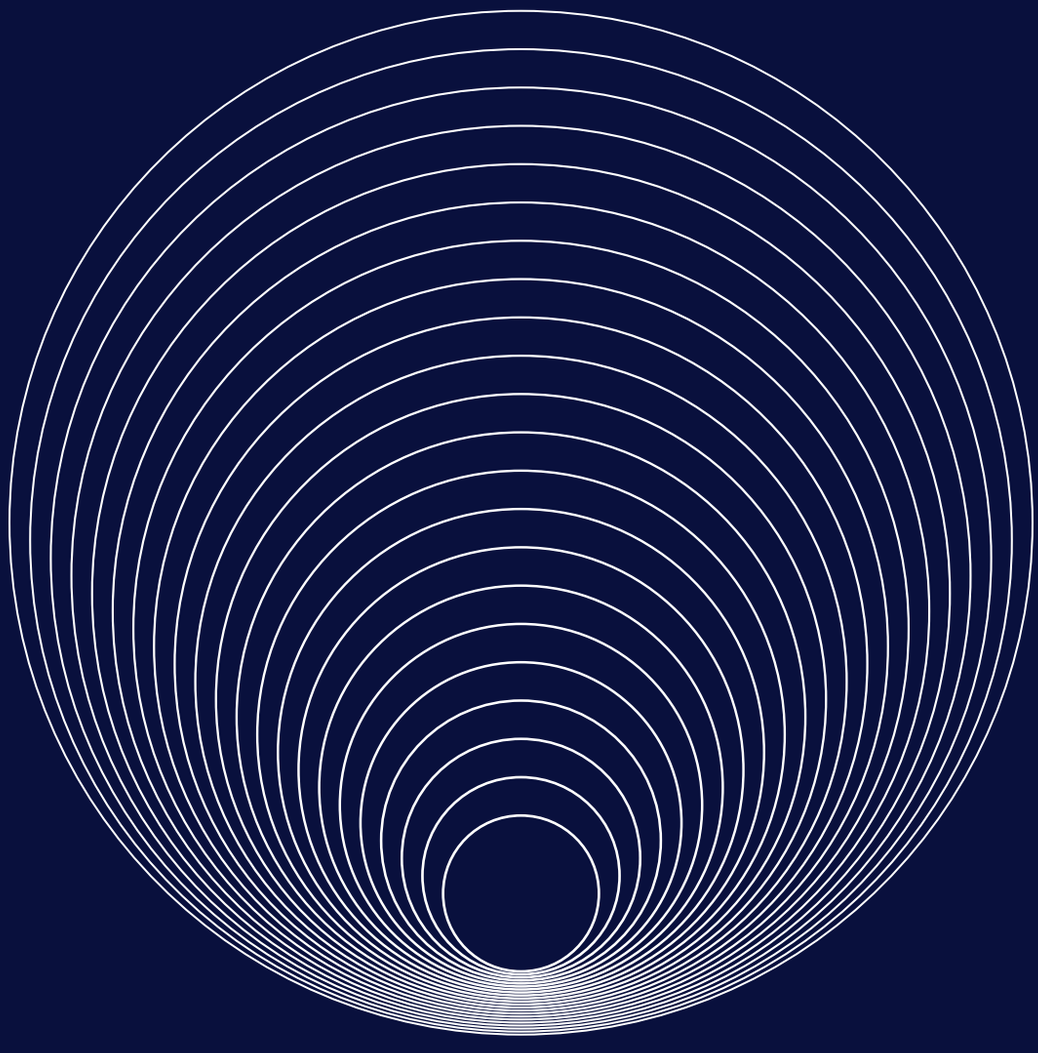
Formality	Risk a° ecting...	Example	RA Tools
Degree I	Certain parts of a system or process steps	▪ Simple changes ▪ Quality events	Qualitative with simple classification
Degree II	Less complex or well-established systems or processes	▪ "Off-the-shelf" equipment or software	Risk ranking list with simple 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 >>>



How quality in MedTech became a driver of financial performance

Contents

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

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

Meet the expert behind the talk

Scilife

Dr. Florian Zischka

Senior Manager at Deloitte

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.

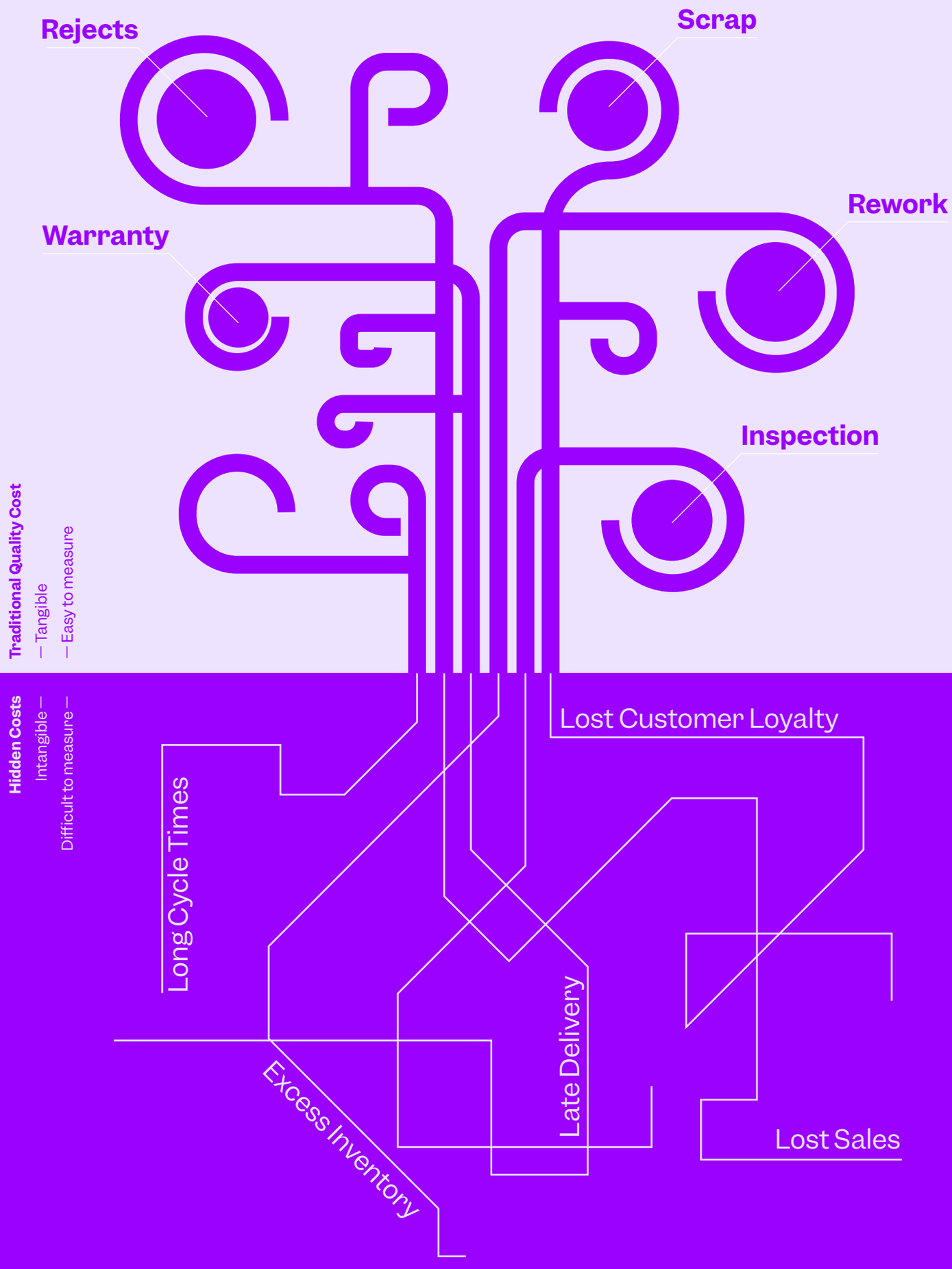
Key Takeaways

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**



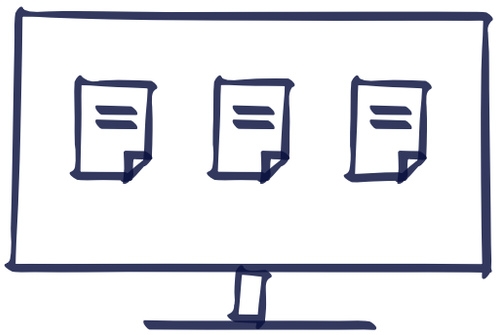
“The cost of poor quality are tangible, and their effect will cost you money, customers, and ultimately

the success of your business”

Subir Chowdhury

The Trends

From documents to data and automated work˜lows



Ambitions:

Get rid of documents

Embrace procedures as processes

Leverage workflow automation

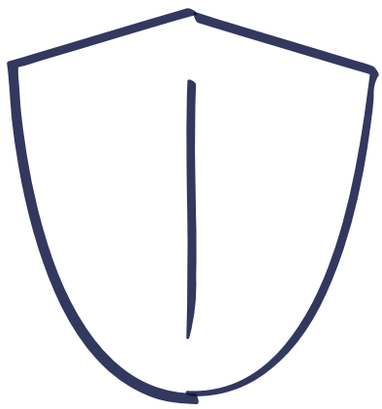
Lessons learned:

PDFs in a DMS are **not data**

Choice of **'best in class components'** versus **'uni˜ied platform'** can be painful

The Trends

Moving from reactive to preventive quality



Ambitions:

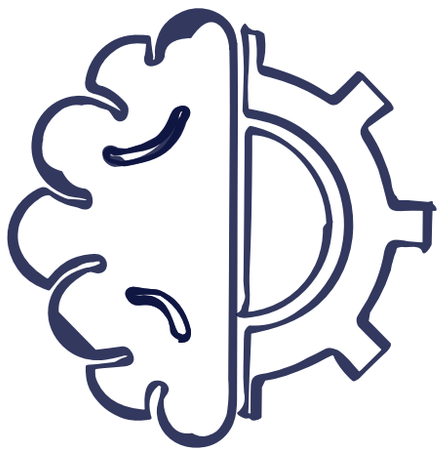
- Be more impacful by **preventing non conformities** before they can occur
- From retrospective snapshots **to accurate predictions**

Lessons learned:

- **Ini˜ied 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 quiality**
- **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

Balacing local and global governance

Ambitions:

- Establish a **“one QMS”** approach globally
- Create a culture of **end-to-end thinking**
- **Reduce silos and enhance globa loversight**

Lessons learned:

- **Signi˜icant monetary savings** can be achieved through global/local QMS alignment
- **Balancing** the need for global oversight with the need for local empowerment **is di° icult**

The Trends

Increasing the agility and speed of controlled changes

Ambitions:

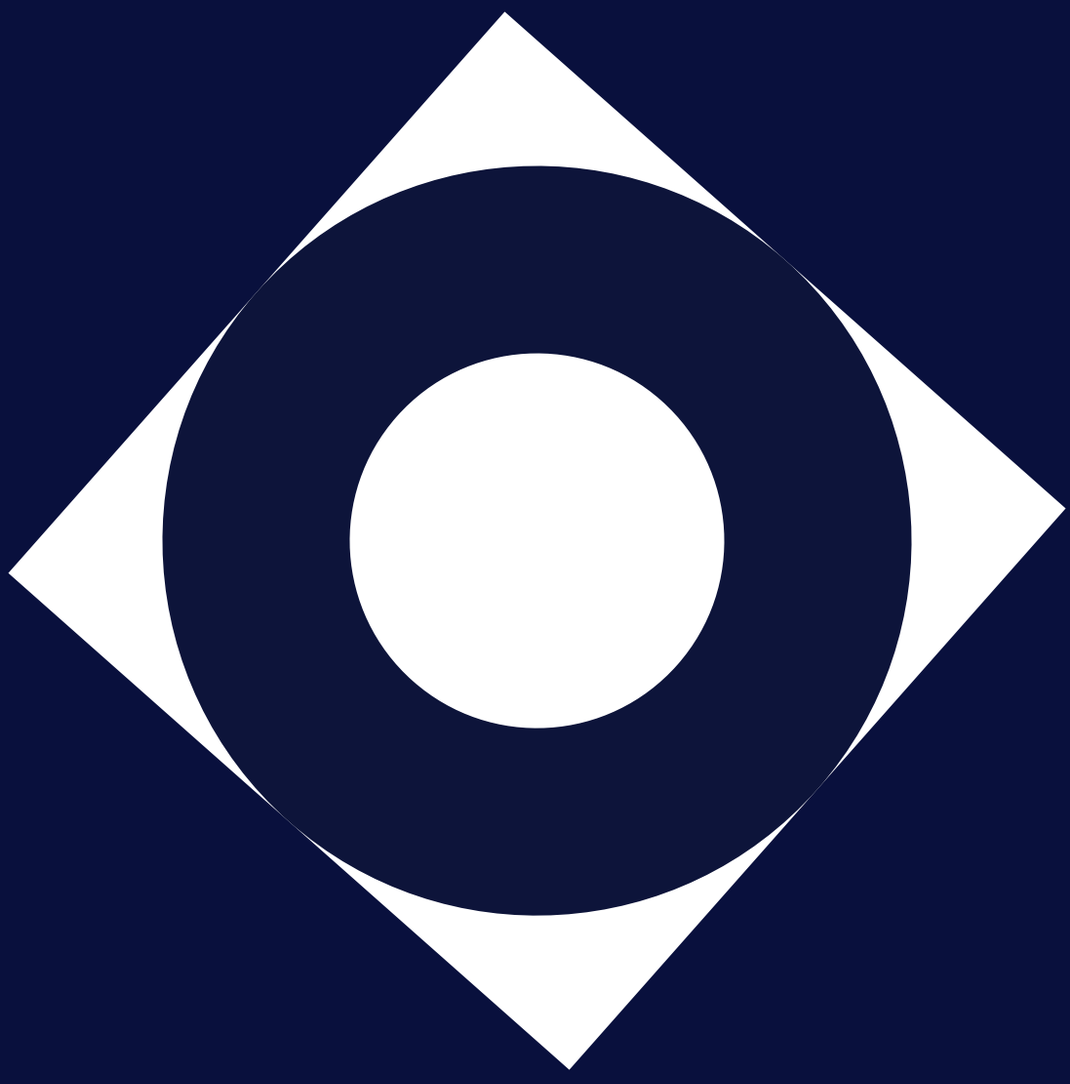
- **Embrace agility and regulatory speed** as drivers of competitive advantage
- **Simplify** the monitoring and implementation of **regulatory changes**

Lessons learned:

- **Transparent** linkage of regulations to QMS procedures can **speed up** change impact analysis and implementation
- **GenAI**, text mining and automation have **huge e° iciency potential**

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

Link to masterclass >>>



Integrity of Quality and the Quality of Data Integrity

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

Scilife

Galit Lisaey

Gal.IT
Data Integrity Consulting

Galit boasts over 20 years of dual expertise as a Data Integrity consultant and Information Technology Project Manager. She is dedicated to assisting organizations in ensuring compliance with regulatory requirements for robust data management. Here are some key strengths that define her:

- Developer of the CPF-Data Integrity methodology, underscoring her commitment to innovation and excellence in the field.
- Expertise spanning quality management, compliance, business analysis, business processes, Computer System Validation, customer support, and professional services.
- Holds an MSc. degree and a decade-long tenure as an R&D team member.

Galit's overarching goal is to provide customized solutions for implementing data integrity processes, drawing from her profound experience in regulatory environments.

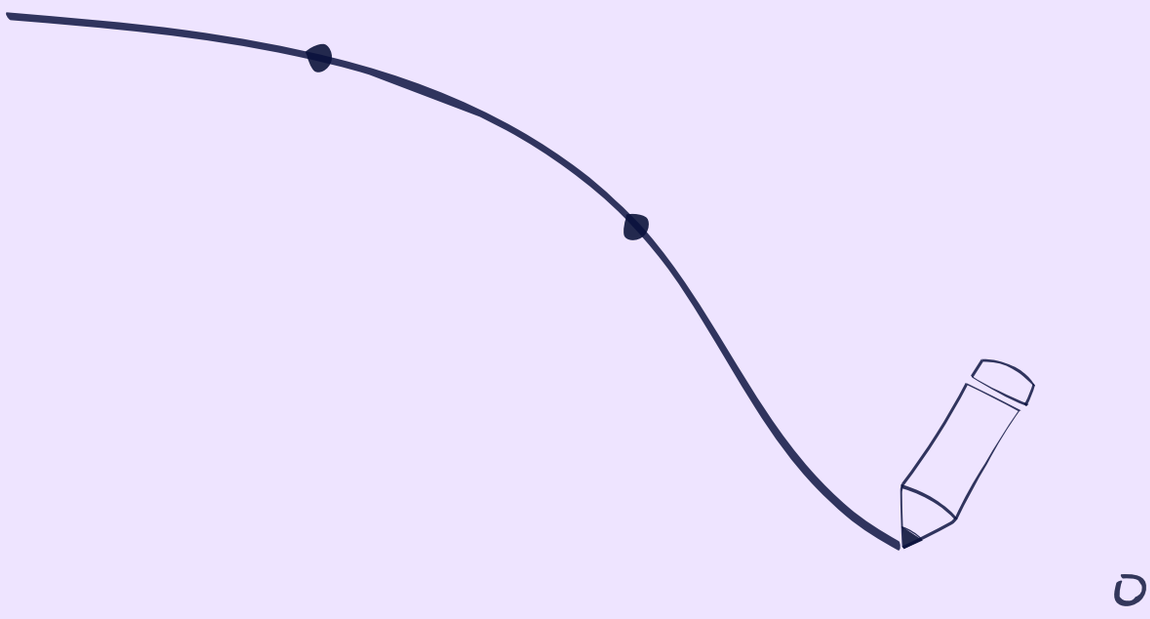
Key Takeaways

Data Integrity requires **determination, attention**, and **ongoing e˜ ort**. Stopping or slowing down could result in setbacks or regression.

The **golden triangle** is everything related to **data management**.

To understand how to protect data and ensure it's complete and reliable, we need to **understand the risks** we are taking within the product's lifecycle and their correlation to data management.

Connecting the dots; **it's all about control**

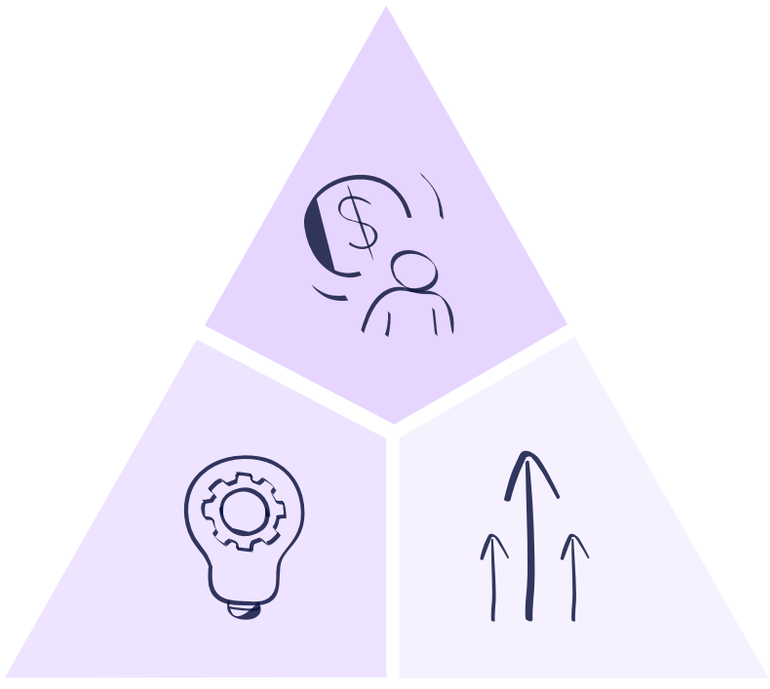


The 'Connecting the Dots' game

In the game, the denser and closer the dots are to one another, the fewer mistakes might occur, and the more accurate and smoother the picture. This same concept applies to an organization. The data moves between different points within the organization.

Therefore, regulators have a similar understanding of this process. If the image is compromised, it could jeopardize the safety of the product.

The Golden Triangle and Segregation of Duties



Golden Triangle

It's everything related to data management. To meet the requirement for managing reliable data, we need to adhere to the five principles in the acronym of ALCOA.

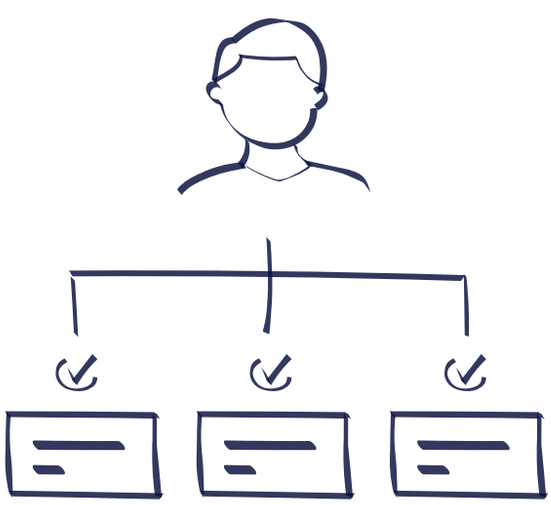
The best approach is to work together, embodying the Golden Triangle principle, not only ensuring teamwork but also a system of checks and balances.

Everyone must understand their role, their value, and their part in protecting the organization. The business, whose goal is to progress, profit and, of course, add value to the world is one vertex. On the other vertex, it's important to meet the requirements for information security and privacy.

The Golden Triangle is aligned with the requirement of segregation of duties.

Everyone needs to know their roles, and therefore the access to data should be aligned accordingly.

All of these are tailored to the technology connectivity embedded in the organization, but everyone must understand the role of the quality manager who's sitting in the third vertex; they are the gatekeepers.



“Data Integrity is a **fundamental requirement** for an effective Pharmaceutical Quality System which ensures that medicines are of the required quality. Poor data integrity practices and vulnerabilities undermine the quality of records and evidence and may ultimately undermine the quality of medicinal products.”

Data Integrity and **Smart Quality**

Smart Quality

Focusing on **compliance-only topics** is **not enough**

Smart Quality focus on higher-value tasks: avoid repetitive actions, save resources, pay attention to added-value tasks, based on data and insights.

Quality Culture: Engaging everyone in Quality

Optimization and **continuous improvement**

In the realm of quality management, data integrity is the guiding star.

It silently steers our journey towards excellence, making certain that every piece of information we utilize is accurate, reliable, and trustworthy.

Link to masterclass >>>

Implementing Risk-Based Approaches to Computerized System Validation

Scilife

Contents

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

“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

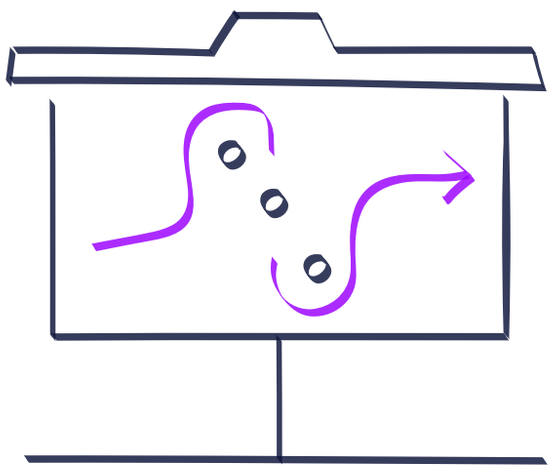
The perception that Risk-based Means Less Rigorous

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.

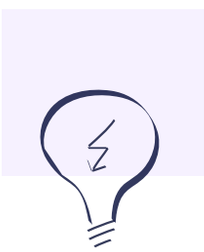
Continuous Improvement:

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

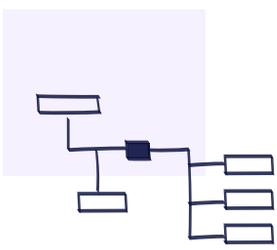
Practical Steps
to Implementing Risk-Based CSV

Requirements

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



Think about how you would **de˜ine failure** for the **speci˜ic system** and process



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

System Classi˜ication

Critical

Directly affects product quality, patient safety or study outcome

Non-Critical

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

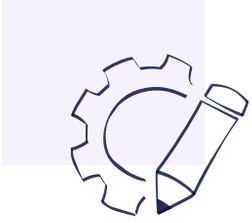
Non-GxP

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

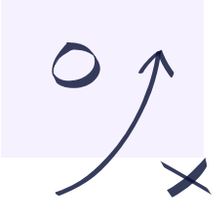
Risk-Assessment

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

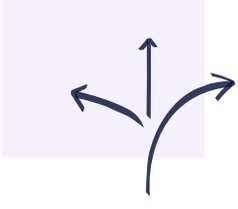


Prioritization **methodology**, considering the severity of **potential failure** and its implications on end-users

Plan and Strategy



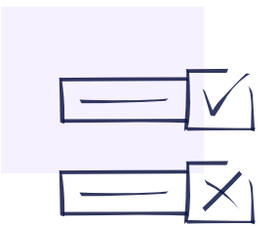
Crafting a **customized validation strategy** rooted in the outcomes of the risk assessment



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

Practical Steps
to Implementing Risk-Based CSV

Execution

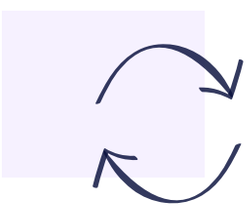


Implementation of the **validation tests**

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

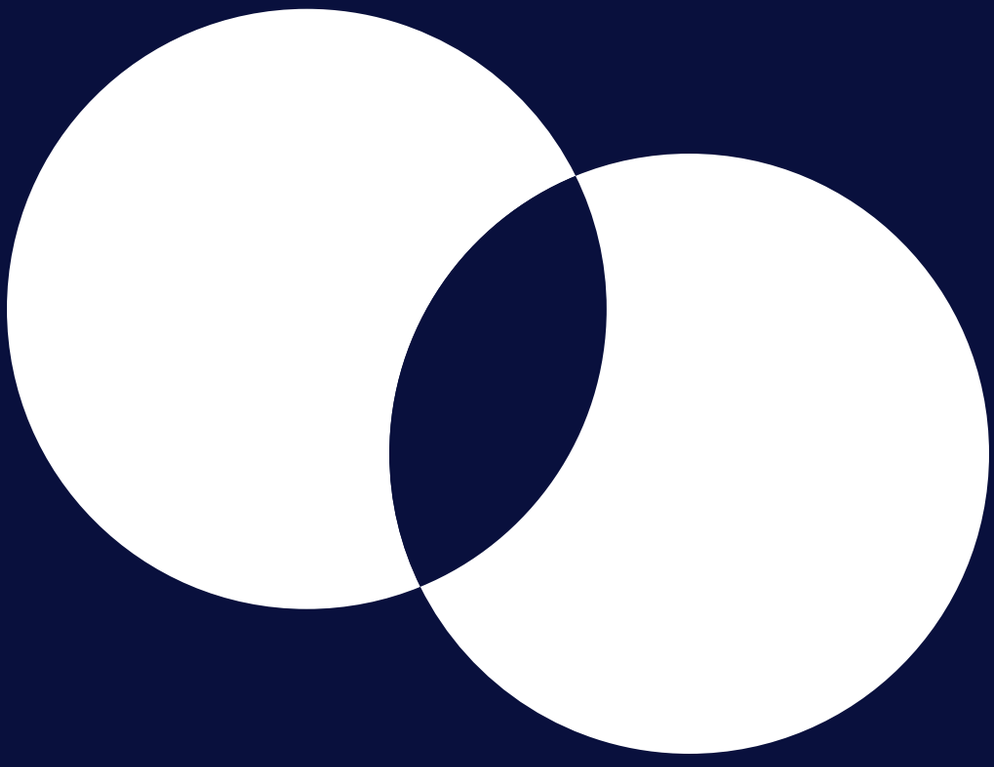


Persistent system surveillance to detect and manage **merging risks**

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 >>>



Practical strategies to boost your QMS document compliance

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

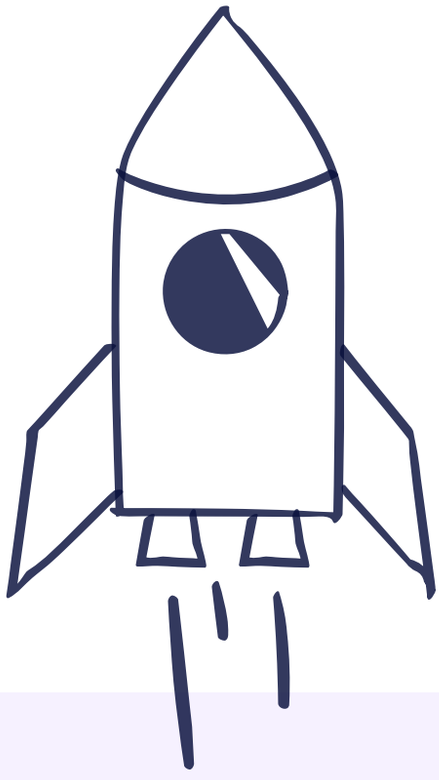
The QMS is the business

What's really going on when an auditor says

"Missing Procedure"?

What's the real root cause?

Startup



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Behaviours and culture
have a huge influence on compliance

Culture is **not QMS focused**

Processes **not fully de˜ined** or mapped

Procedure is in someone's head

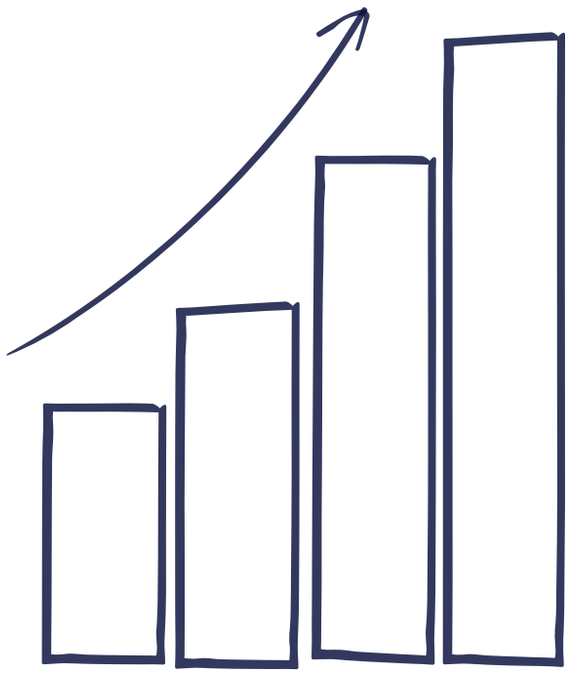
Procedure is high level info only. **Not detailed enough**

Inconsistent staff training

SOP **not enforced**

What's the real root cause?

Scaling



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Behaviours and culture
have a huge influence on compliance

QA Mgr trying to **in˜luence culture**

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

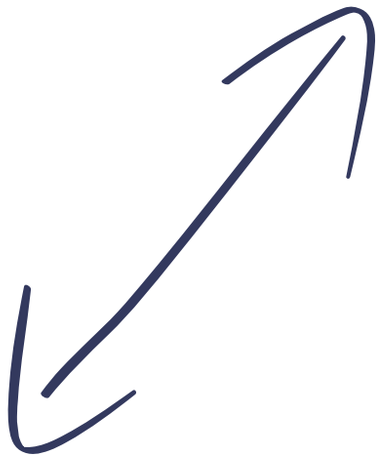
QA Mgr "fixes" everything for next audit

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

Documentation still considered **"paperwork"**

What's the real root cause?

Large



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Behaviours and culture
have a huge influence on compliance

Culture is **compliance focused**

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

Procedures **well documented & communicated**

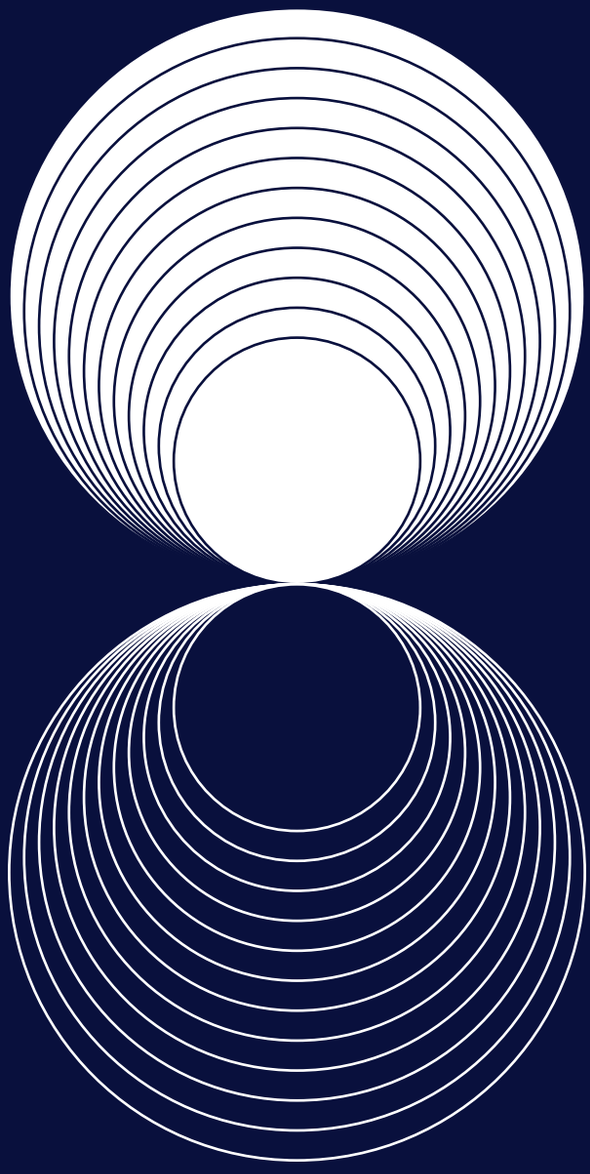
Periodic review/change control may lag & cause **issues**

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 >>>



Driving Quality Culture: The Power of Your People

Contents

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

"I believe that business success always comes down to the people piece. And the people piece always comes down to how well we communicate.

If we can improve our communication and build good relationships, anything is possible."

Meet the expert behind the talk

Lesley Worthington

Leadership Coac and Consultant

Lesley combines 20 years of quality and regulatory experience, university degrees in both psychology and law, thousands of hours of teaching and coaching, and her training as an executive coach. She works with:

- Anyone who feels like their people skills and communication skills might be standing in their way.
- Quality professionals that are frustrated in their mission to get everyone on board with quality.
- Established and emerging leaders looking for a trained executive coach to help them get to the other side of their roadblocks and challenges.

She is passionate about providing her clients with the skills, techniques, insights, and mindset that raise their confidence, take their communication skills to the next level, and allow them to have a positive impact in their organizations.

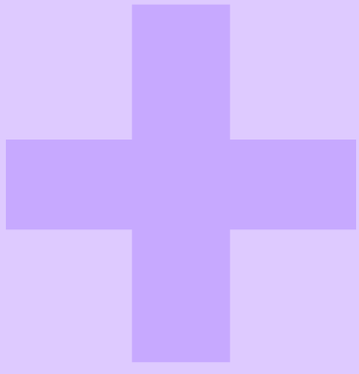
Key Takeaways

The key to building a Quality Culture is to **keep things simple and relevant.**

A Quality Culture is only possible where **business objectives and quality objectives are aligned.**

Good communication skills are the foundation of clarity and trust. And **clarity and trust are the foundation of a Quality Culture.**

Think fo what your listener needs to know,



say it in **words they know,** and leave it at that.

A **Quality Culture** is...

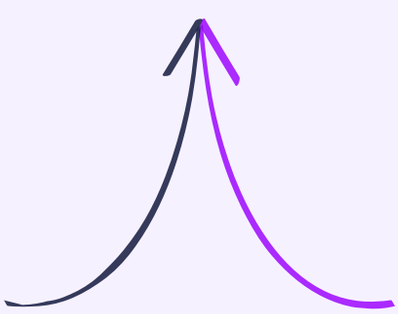
a culture where there is a shared set of values, beliefs, attitudes, and practices that guide how people think and act about the importance of quality in their roles.

Compliance mindset
vs.
Quality mindset

Compliance helps us meet standards and regulations.

Compliance
mindset

But a **quality mindset** or a quality culture helps us exceed them. It's a competitive advantage and is the difference between an ordinary organization and an extraordinary one.



Quality
mindset

How to build a **Quality Culture**

Clarity

Taking a step back and remembering our purpose:

What's the purpose of our organization?

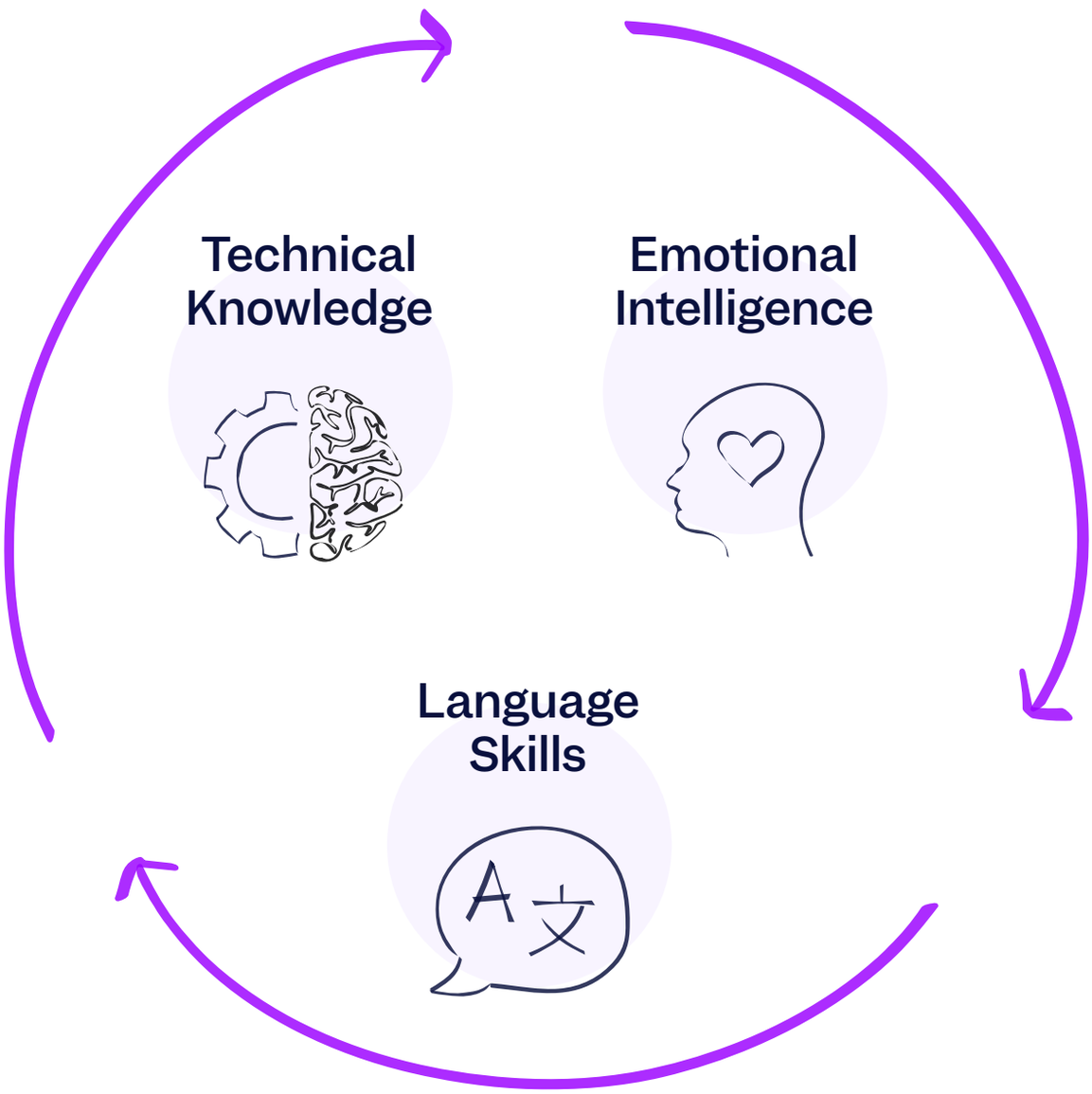
Why do we do what we do?

Trust

People need to feel like they belong and that their opinions matter.

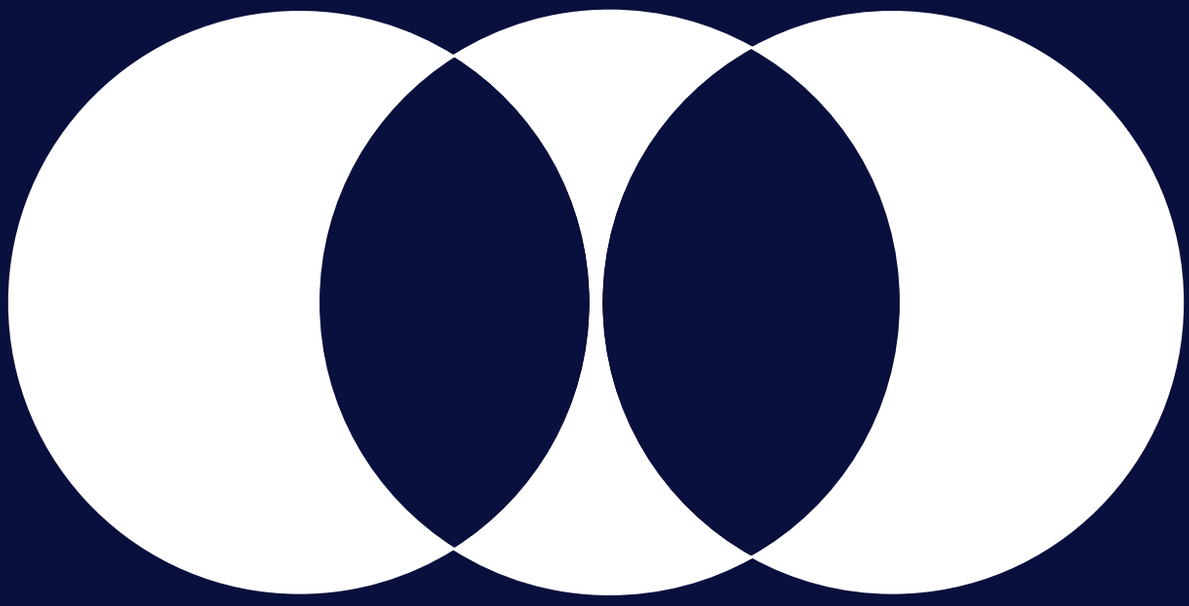
How to build a **Quality Culture**

Required skills



In the pursuit of a true Quality Culture, the key lies not in systems or processes, but in the power of your people.

Link to masterclass >>>



Leverage your audits towards digital transformation

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

Carla Peraferrer

Qualifyze

Carla, a dedicated pharmacist, has been captivated by supplier qualification since 2015 and is committed to ensuring the highest standards of quality and compliance. Here are some of her key achievements:

- As the VP of Quality at Qualifyze, she played a key role in establishing the internal Quality Management System (QMS)
- She remarkably grew the Quality team at Qualifyze from a single member to a force of over 20 individuals within just three years
- She has supervised and conducted over 300 audits during her career

With a rich background spanning over 15 years, Carla has engaged with various stakeholders across the pharmaceutical supply chain, including community and hospital pharmacies, compounding laboratories, and third-party auditing service providers.

Meet the expert behind the talk

Cesc Muñoz

Qualifyze

With a background as a pharmaceutical chemist, **Cesc** has been immersed in the world of GxP audits since 2015, undertaking the responsibility of over 200 audits. Here are some notable highlights of his professional journey:

- Having completed his degree in Medicinal and Pharmaceutical Chemistry he has previously worked as a pharmaceutical chemist
- He is an experienced GxP auditor with expertise in large-scale assessments, always bringing a meticulous and analytical approach to his work
- His commitment to collaboration and finding innovative solutions has been a driving force throughout his career.

As the Head of Quality at Qualifyze, Cesc is dedicated to maintaining high standards in the industry.

Key Takeaways

A **thorough audit** encompasses the auditor's profile, meticulous preparation, efficient execution, and insightful reporting & follow up.

Data compilation involves gathering information from a variety of sources, each playing a valuable role in the overall assessment.

The **integration** of **machine learning** and **artiﬁcial intelligence** holds significant potential for bolstering supply chain control, improving efficiency, and increasing effectiveness.

What do we need to use tools

to put it all together?

Solutions integrating **Machine Learning** and **Arti˜ical Intelligence**,

Why?

How are your suppliers **envolving** and **benchmarking** with the others?

Can I **anticipate problems** with my suppliers?

Can I improve my **supplier risk management** with the **available data?**

Can I visualize my **suppliers' compliance** in **real time?**

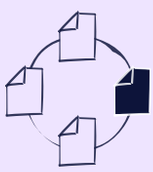
Solutions integrating
Machine Learning and **Arti˜ical Intelligence,**

Why?

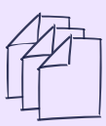
Software to manage

Audits

Data



CAPAs



Documents

Supplier risk

More software usage results in more **data insights**, which in turn encourages **greater software usage**

Data insights to understand

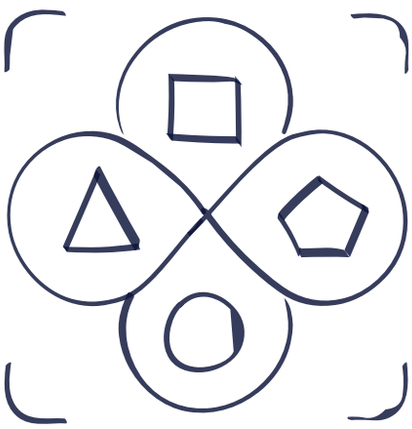
What happened?
Descriptive

What action to take?
Prespective

Why did it happen?
Diagnostic

What will happen?
Predictive

Change of paradigm of **supply change management**



Old approach	Digital transformation
Discrete snapshots of a single supplier	Continuous monitoring of the complete supply chain
Non-integrated data	Integration of data from various sources for best decision making
Compliance as a “binary” concept	Compliance / Maturity Metrics, evaluation of trends, anticipating problems
	* **Safer** and more **reliable** supply chains!

Auditing is no longer just about ticking boxes; it's an opportunity to not only streamline operations but also transform your data collection processes.

This approach opens a gateway to unprecedented e° iciency and insights, helping your organization navigate the complexities of today's digital world with precision and foresight.

Link to masterclass >>>

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

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

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

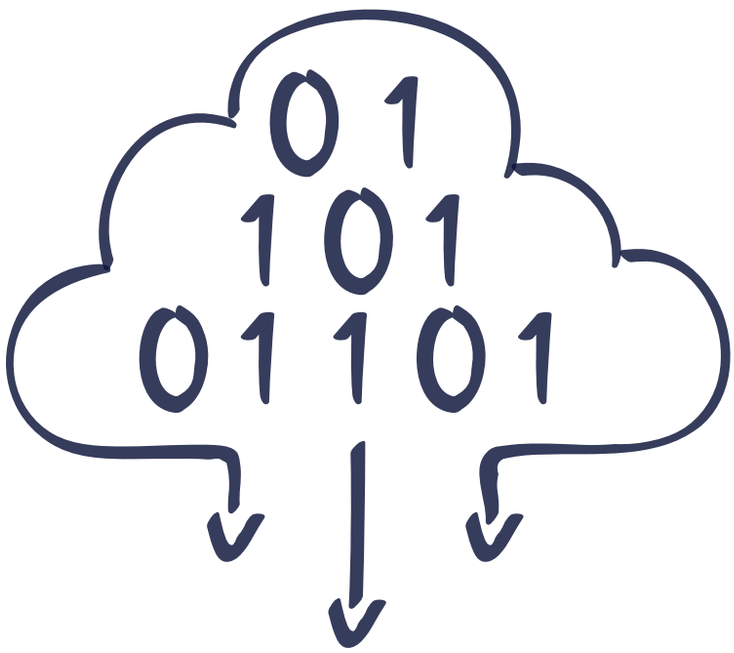
* No need for action

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**.

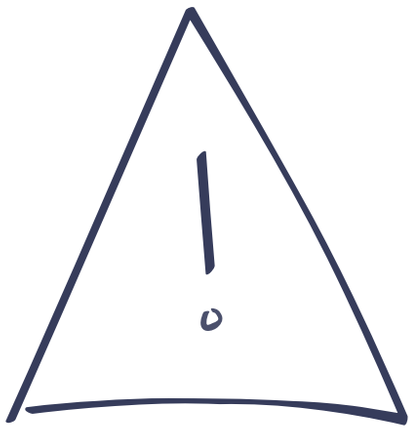
- Responding late:
  - Early signals not identified
  - Event/non-conformance investigation brings the problem forward.

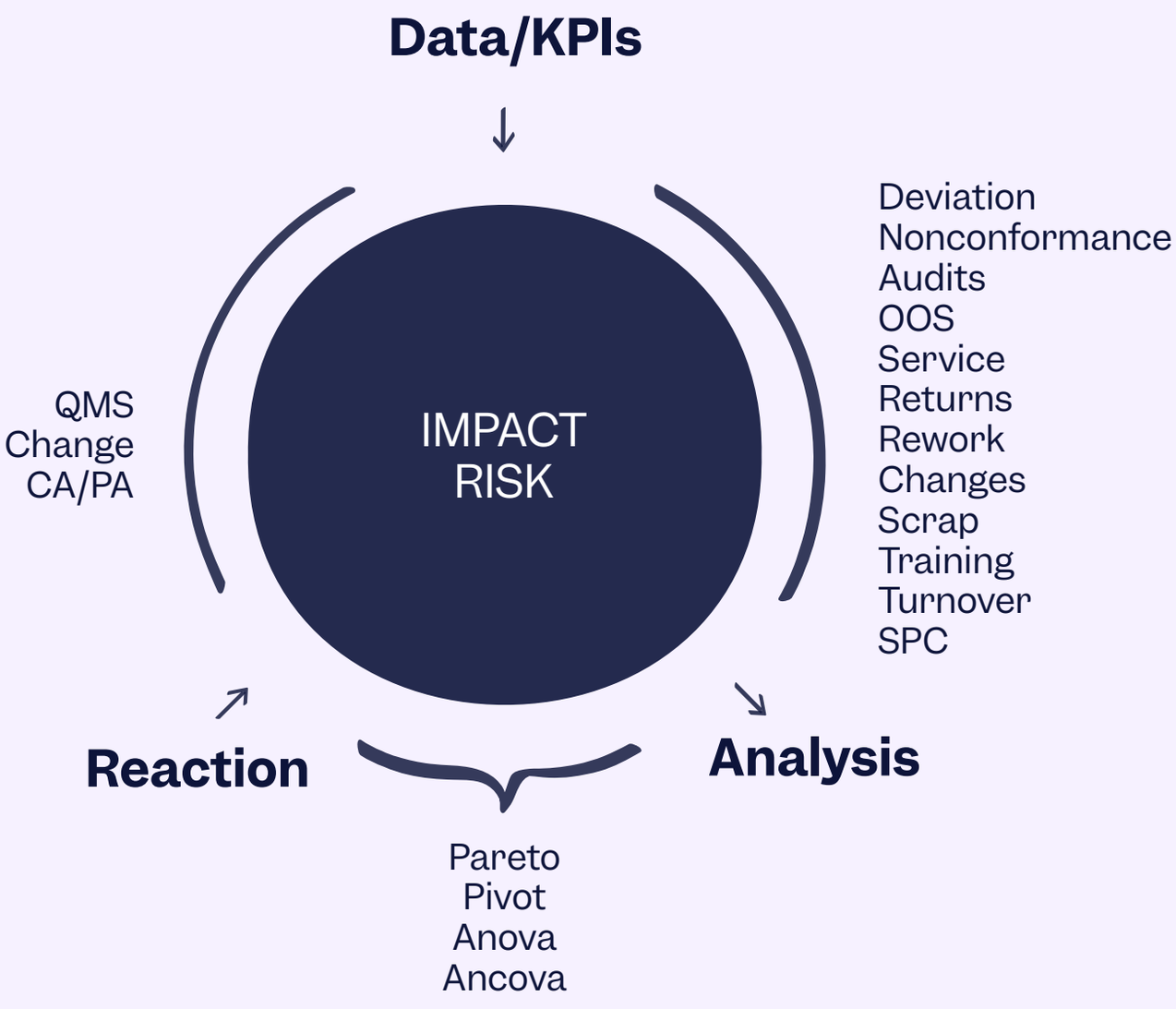
Clear rules for when and how to respond to data signals, described **by procedure.**

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

Continuous Improvement

Data, data, data

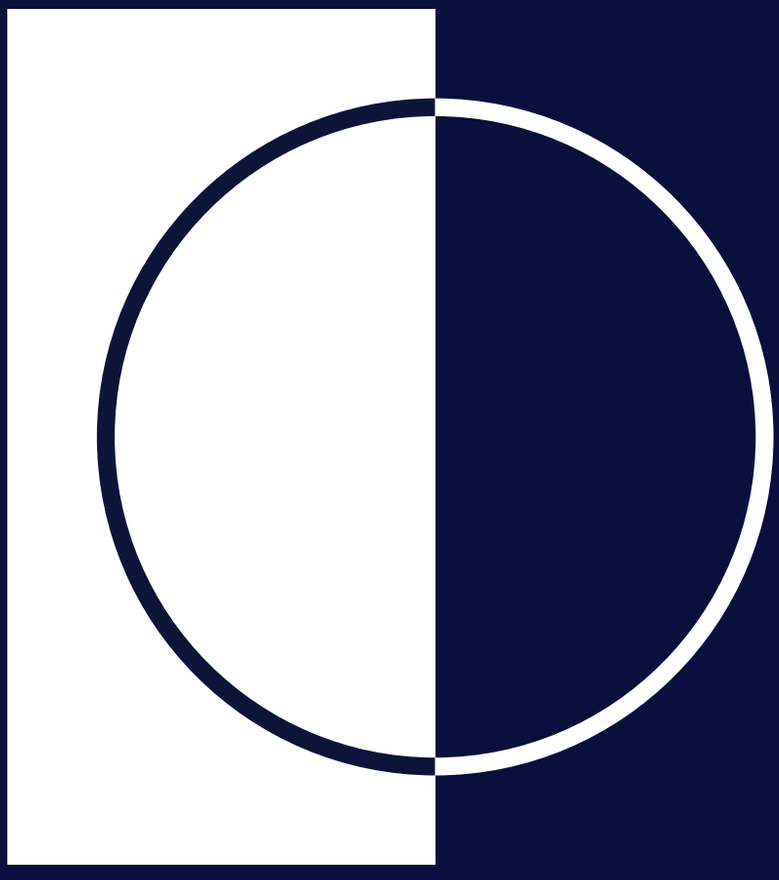




Realizing the true potential of quality lies in strategically balancing risk with impact.

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

Link to masterclass >>>



Round table: Best practices in Quality Management that will impact your business

Contents

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

Meet the expert behind

Tinne Bockx

Quality Manager
at Inovet

With a robust 18-year tenure in the pharmaceutical industry, **Tinne Bockx** has become a linchpin in the realm of Quality Assurance.

Beginning her journey at Inovet in the Quality Control department, Tinne has spent over a decade dedicated to Quality Assurance. Her expertise is not just in maintaining standards but elevating them, as she adeptly navigates the intricate landscape of pharmaceutical regulations and quality norms.

Tinne's approach is deeply rooted in a commitment to precision and excellence, where she blends analytical acumen with a strategic mindset. Her leadership is marked by a collaborative spirit, guiding her team with clarity and fostering an environment where quality is not just a requirement but a continuous pursuit.

Insider

Bridging teams and transforming quality

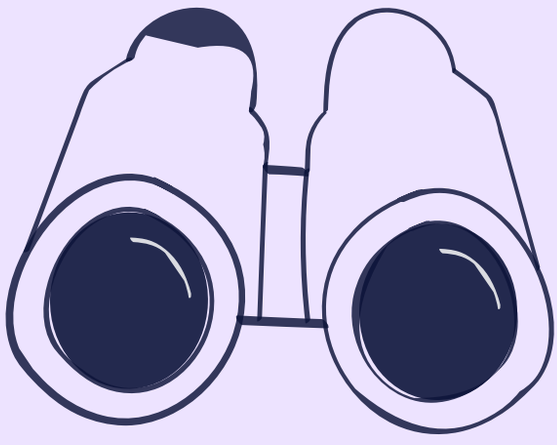
Tinne Bockx makes regular visits to the production floor, ensuring she's there at least once every week. During these visits, she actively engages with her team, inquiring about their challenges and encouraging their input. These interactions are highly effective, fostering a **culture of inclusivity** where every team member feels heard and valued. This approach has been instrumental in enhancing their processes.

By transforming **quality management** from a basic requirement into a powerful tool for **continuous improvement** and **innovation**, Tinne Bockx's collaborative efforts have become a cornerstone of their success.

Scilife's POV

To elevate our quality standards, we need to shift our **focus** from a strict compliance-centric mindset to embracing a **quality culture-driven ethos**.

It's time to move beyond the confines of traditional policy thinking, embracing a more dynamic and **inclusive approach to quality** within our organization. This reimagined culture is not just limited to the written policies but is actively embodied in every aspect of our daily operations. By living and breathing this culture, we foster an environment ripe for **continuous improvement** and **internal innovation**. This is the heart of Scilife's commitment to not just maintaining, but elevating, **quality** in every facet of our work.



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To elevate our quality standards, we need to shift our focus from a strict compliance-centric mindset to embracing a quality culture-driven ethos.

Meet the expert behind

Rupert Sedlmayr

Quality Manager
at EvidentIQ

With a master's in biology and a diverse 9-year background in clinical data management and project management, **Rupert Sedlmayr** is a seasoned professional in the pharmaceutical sector.

His journey includes significant roles at various Clinical Research Organizations and at EvidentIQ Germany, followed by a strategic shift to business development, where he excelled as Executive Director BD for EMEA & APAC at EvidentIQ Group.

In 2021, Rupert pivoted his career towards Quality Management. He brings to this role an expansive process knowledge, now focusing on overseeing the quality systems of all four international companies within the EvidentIQ Group. As part of an expert team, he ensures that quality is not just a standard but a culture deeply ingrained in the organization's DNA.

Insider

The art of breaking silos and harmonizing processes

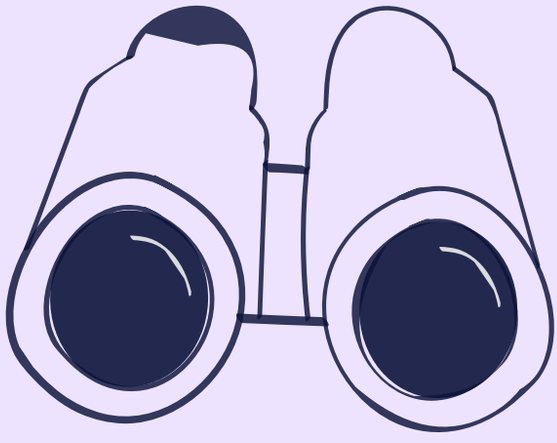
In his discussions with top management regarding the need for organizational change, **Rupert Sedlmayr** prioritizes discussions around efficiency and harmonization over the elusive hard numbers of ROI, particularly in the quality domain. Given the ongoing mergers and acquisitions in their environment, he identifies **e˜ iciency** as a critical factor. Rupert points out the inefficiencies that arise when software development teams operate in silos, leading to friction and reduced productivity.

His strategy revolves around creating a **'best of all worlds' scenario** through **harmonization**. Rupert advocates for departments, such as different software development teams, to work **collaboratively** towards a **uni°ied approach**. This strategy not only mitigates internal friction but also significantly improves the work environment.

Scilife's POV

At Scilife, we recognize the profound impact of fostering a **collaborative spirit**, as exemplified by Rupert Sedlmayr's approach.

We firmly believe that **true change** is cultivated **from within**, rather than being imposed from the outside. This philosophy has been pivotal in not only enhancing the quality of our work but also in establishing a **strong culture of quality** throughout our organization. By encouraging departments to understand and address each other's unique needs, we create a **uni°ied front**, aligning all teams towards a shared objective.



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We °irmaly believe that true change is cultivated from within, rather than being imposed from the ouside.

Meet the expert behind

Àngel Buendia

Knowledge Manager
at Scilife

With 20+ years of experience shaping quality within pharmaceuticals, **Àngel** bridges QC & QA expertise in Life Sciences.

His passion for continuous learning, combined with his role as a Smart Quality advocate, drives his dedication to instilling a Quality Culture, guiding teams with collaborative leadership, and fostering excellence as a cornerstone.

He navigates complex regulations, and is driven by upholding high standards and fueling innovation.

Insider

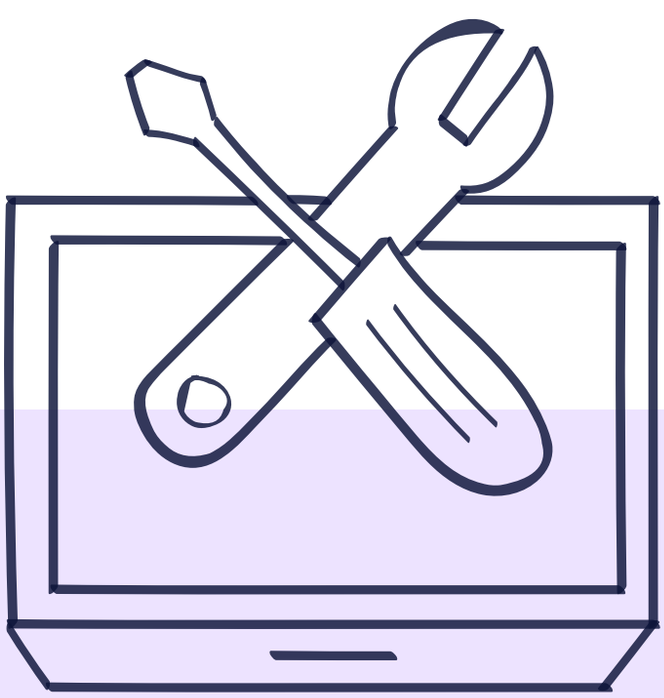
Getting people together in the digitalization boat

In today's rapidly evolving digital landscape, the significant leap in **digitalization** has proven to be a game-changer, especially with **collaborative tools.** These tools become crucial when working across different locations, allowing for seamless access to unified documents within a Quality Management System (QMS).

Traditional paper or **semi-paper-based systems**, in contrast, lead to substantial **ine˜ iciencies**. On average, employees in paper-based environments waste approximately two and a half to five hours weekly just searching for and collecting documents. These are valuable hours lost, contributing nothing to the enhancement of our processes. Therefore, the shift towards **digitalization** isn't a future aspiration; it's an immediate **necessity**.

A turning point

The pandemic served as a stark wake-up call, hastening our transition to **digital solutions**. Initially, there was skepticism — concerns about system failures and the unknown. However, the pandemic acted as a definitive proof of concept, demonstrating the undeniable value of digital tools in maintaining **continuity** and **e˜ iciency** in **challenging times**.



By skillfully integrating hands-on engagement with strategic collaboration and advanced digital solutions, we're creating a future where quality management isn't just e˜ icient, but also inherently dynamic and continuously evolving.

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.

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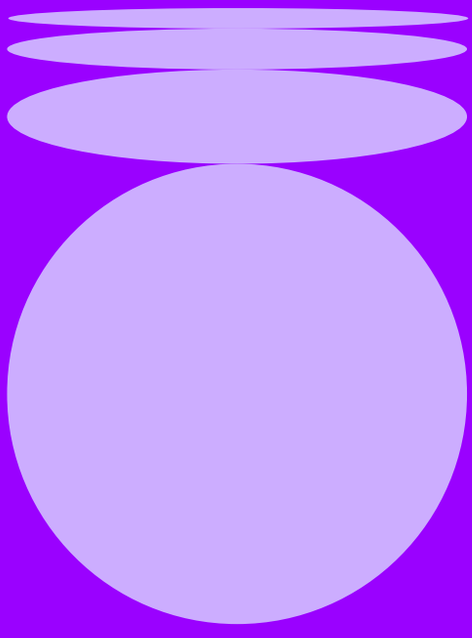
EMEA Office
Groenenborgerlaan 16
2610 Antwerpen
Belgium

US Office
Scilife Inc.
228 E 45th St. RM 9E
New York, NY 10017

Scilife



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