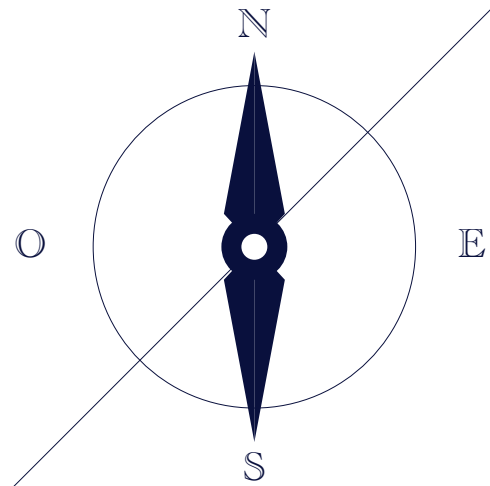




Integrity of Quality and the Quality of Data Integrity

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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



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

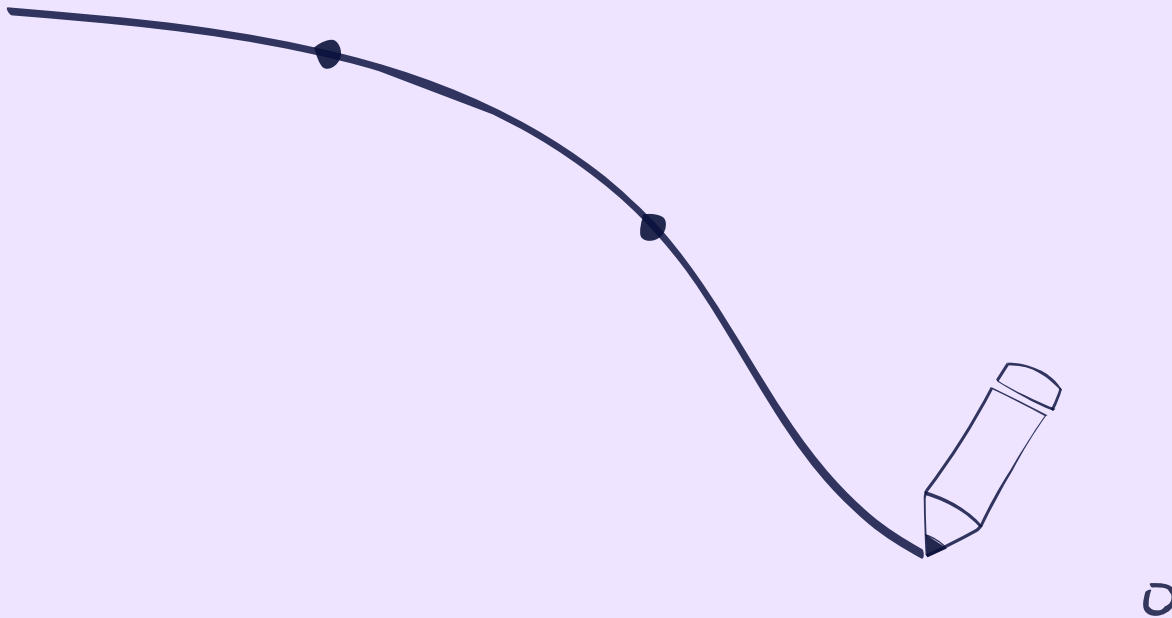


Data Integrity requires **determination, attention,** and **ongoing effort.** Stopping or slowing down could result in setbacks or regression.

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**

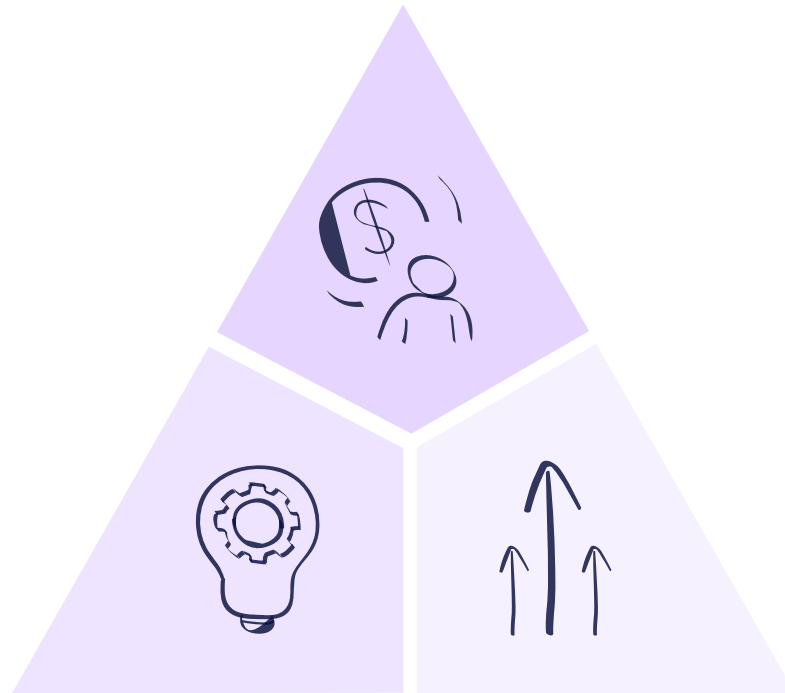


The **'Connecting the Dots'** game

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.

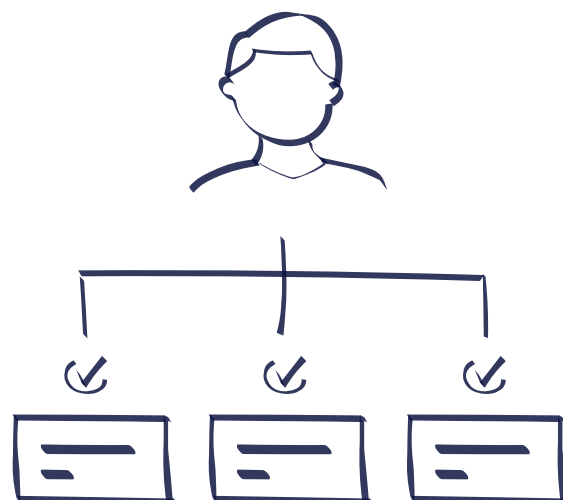


The Golden Triangle and Segregation of Duties

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 >>>](#)

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 >>](#)

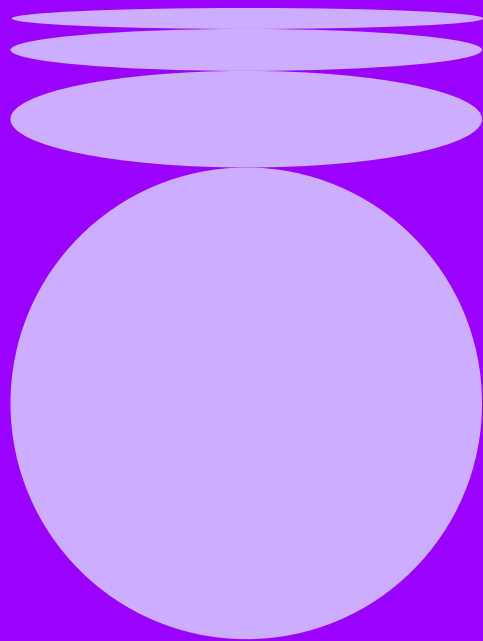
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