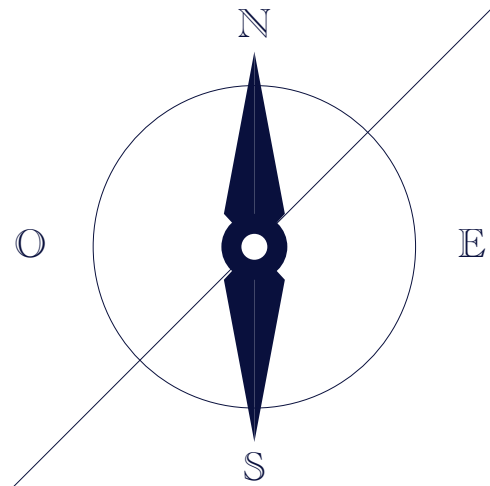




GAMP: From theory to action
in compliance management

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 The real challenge lies in changing people's mindsets, behaviors, competencies and outdated ways of working.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

Meet the expert behind the talk	5
Key Takeaways	6
Introduction to GAMP 5 From Regulation to SOP Predicate Rules	7
GAMP 5 Implementation Validation Deliverables Formally Validation Deliverables in IT Speak	8
Thank you	11

**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



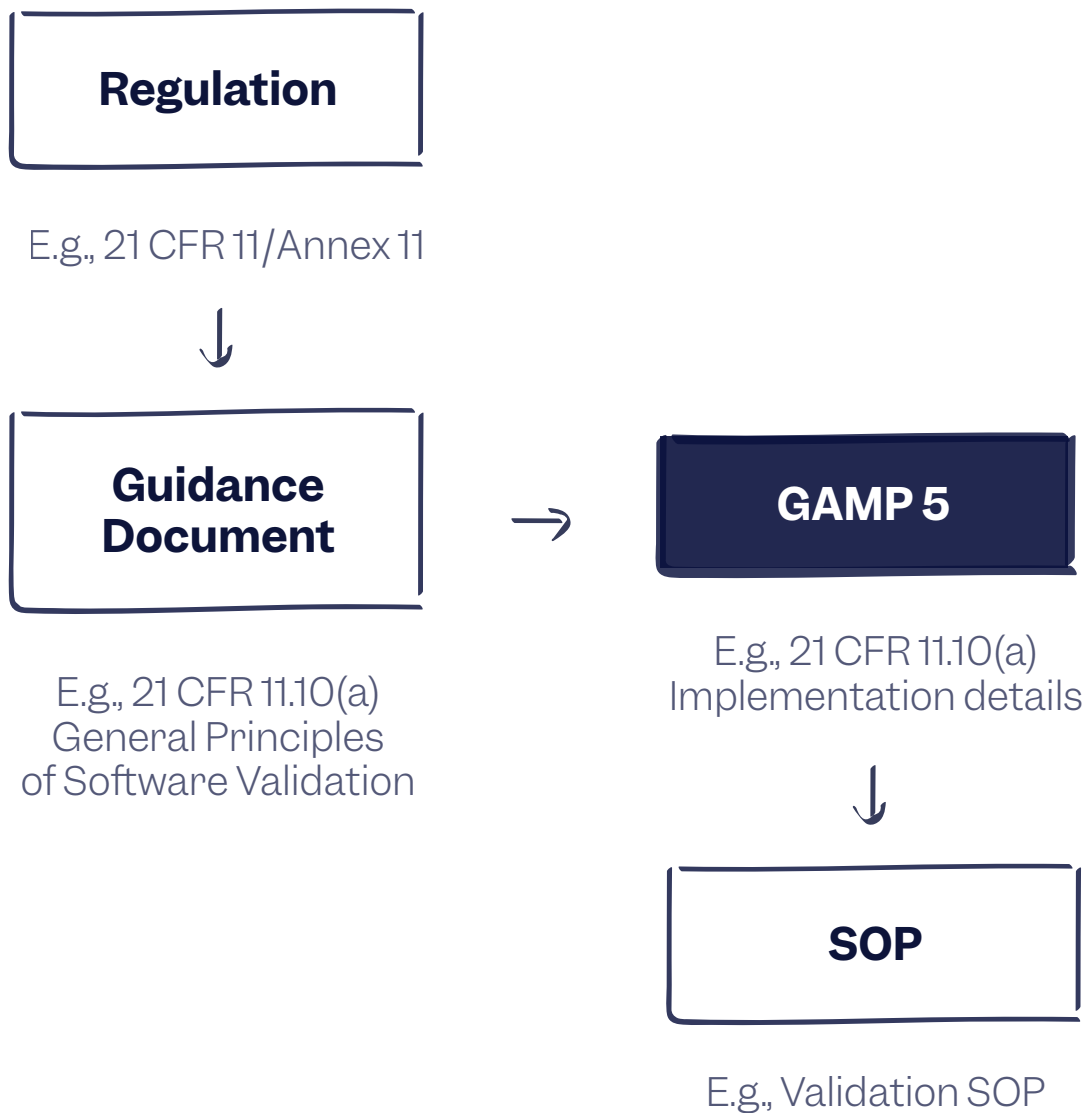
GaMP 5 deliverables are designed to ensure that **regulatory authorities** are all looking at the same thing when **inspecting a company**. They are mandatory because regulatory authorities do not have the time to understand each company's processes for every inspection.

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

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

Introduction to GAMP 5

From Regulation to SOP Predicate Rules



GAMP 5 Implementation

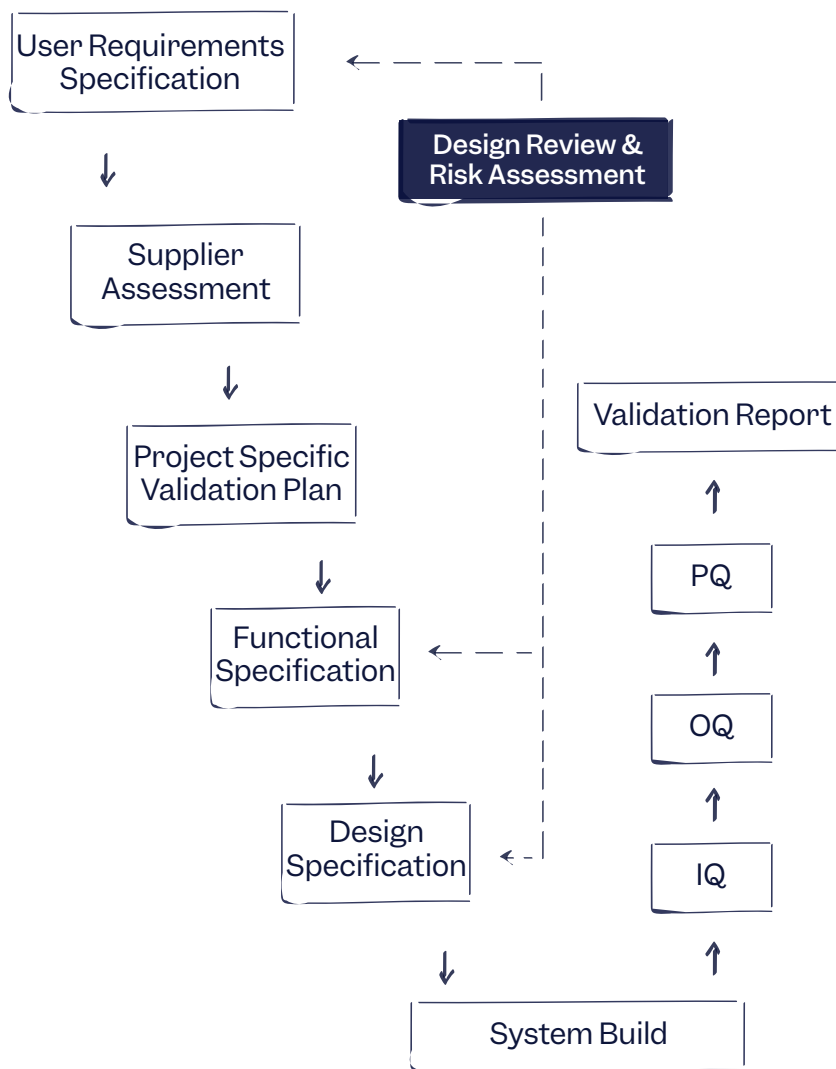
Validation Deliverables Formally...

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

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



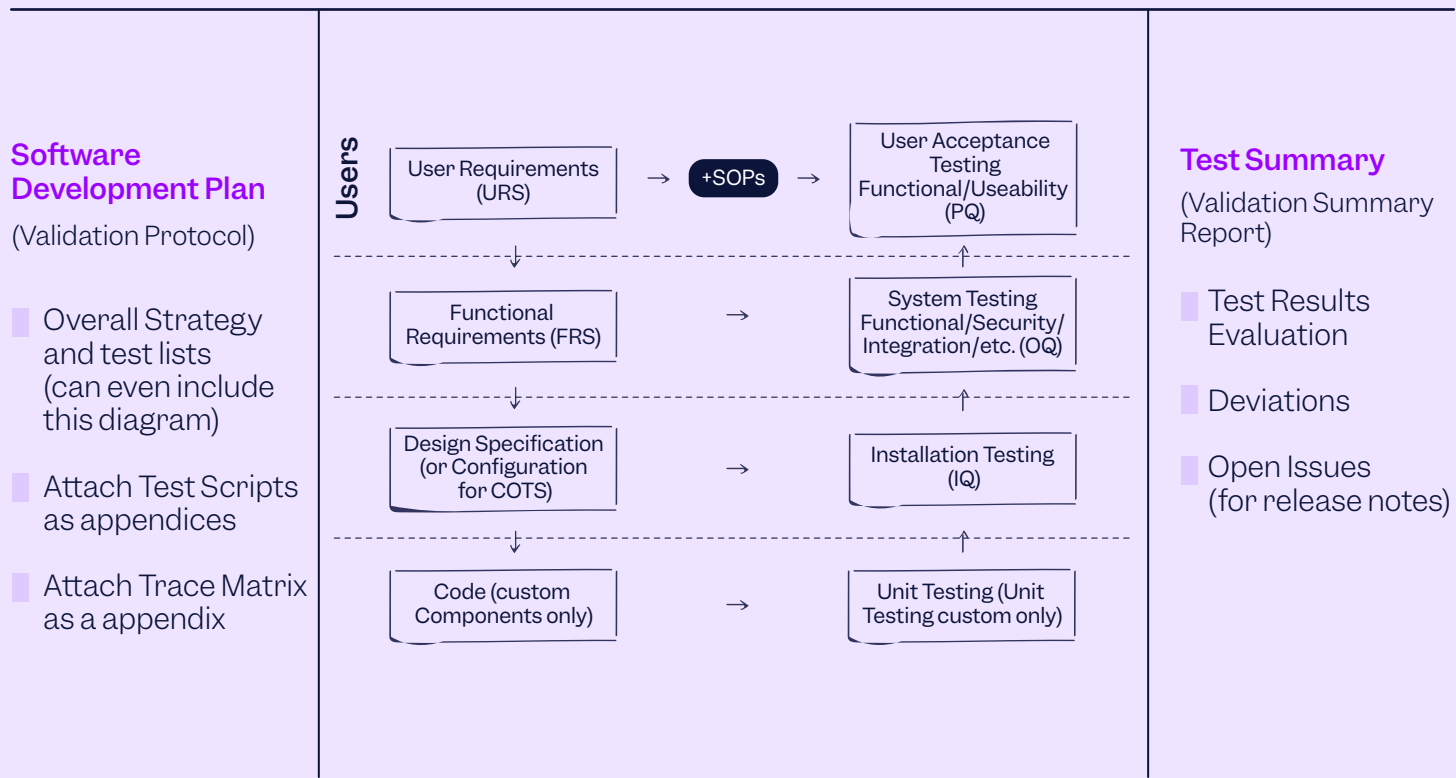
Phase by Phase

GAMP Planning/Reporting Relationship

GAMP 5 Implementation

Validation Deliverables in IT Speak...

Hazard Analysis / Risk Assessment Software Development Lifecycle - CUSTOM & COTS



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 >>>](#)

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 >>](#)

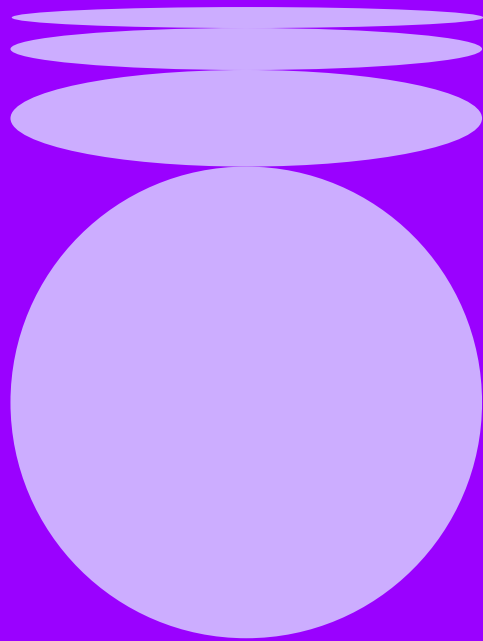
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