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QUALITY ASAP: BUILDING FIT-FOR-PURPOSE SYSTEMS IN A PRAGMATIC WORLD



In the realm of regulatory compliance, quality is often perceived as an unnecessary evil. It's not uncommon for organisations to approach quality as a checklist of requirements to be met, a structure to be built once and maintained indefinitely. However, this traditional view is increasingly being challenged. The future of quality lies not in rigid ideals or gold-plated systems, but in practical, people-focused frameworks that reflect the realities of how organisations actually function day to day.

Increasingly, the emphasis is shifting toward approaches that support the development of quality systems that are adaptable, scalable and grounded in operational reality. These systems are not designed to impress auditors with their complexity, but to empower teams with clarity, usability and relevance.

This article introduces a fresh and pragmatic perspective: Quality ASAP – Agile, Simple, Accurate, Pragmatic. It's a guiding principle for designing and implementing quality systems that are not only compliant with regulatory expectations, but also realistic, sustainable and tailored to the specific needs of the organisation. Whether operating under GLP, GCP, GMP, ISO or a hybrid model, this approach encourages us to rethink how quality is built... from the ground up.

THE GOLD-PLATED TRAP

Many organisations, particularly those entering regulated environments for the first time, instinctively aim to build a gold-standard Quality System from the outset. The logic seems sound: if regulations require Standard Operating Procedures (SOPs) to be signed off, reviewed by Quality Assurance (QA) and authored by technical experts, then surely the safest route is to construct a system that covers every possible base.

But what happens when the company only has three employees? When QA is outsourced, or not yet appointed? When the technical expert is also the facility manager and the only person available to write SOPs? This is where the over-engineered approach begins to reveal its limitations. While the system may tick all the regulatory boxes and appear compliant on paper, it often proves unmanageable in practice. Instead of serving as a functional tool, it becomes an administrative burden – slowing progress, creating bottlenecks and breeding frustration. In many cases, such systems lead to delays, disengagement and a growing disconnect between the documented quality framework and the realities of day-to-day operations. When the system feels like an obstacle rather than an enabler, its value is quickly diminished.

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The goal of building a quality system should not be to tick every conceivable regulatory box from day one, nor to construct a framework that attempts to anticipate every possible future scenario. That approach often leads to unnecessary complexity and systems that are out of step with the organisation's actual needs. Instead, the focus should be on creating a system that is genuinely fit for purpose and one that aligns with the organisation's current operational reality and can evolve organically as the business grows. A well-designed quality system should be a living structure: responsive, scalable and grounded in the present, yet open to future refinement.

COMPLEXITY ISN'T A REQUIREMENT

Quality systems are often perceived as inherently complex, intimidating, and resource heavy. This perception can lead to the responsibility being delegated – typically to QA – or outsourced to external consultants. But complexity is not a prerequisite for quality. A system does not need to be elaborate to be effective. What it does need is to be is:

- Fit for purpose
- Scalable
- Understandable by those who use it.

For example, a company may not be GxP-compliant today but may aspire to be in the future. Rather than prematurely building a fully GxP-compliant system, it's far more effective to design a framework that can evolve when the time is right. This means thinking ahead, yes – but without adding more than the system truly needs. It means building with flexibility, not rigidity. One size does not fit all and it never has. What works for a large multinational company may not be suitable for a small startup. The key is to design systems that reflect the organisation's scope, services and regulatory obligations, not someone else's ideal.



THINK SMART, ACT ASAP

When building or revising a quality system, it's essential to apply SMART goals: Specific, Measurable, Achievable, Relevant, Timebound. This structured approach helps teams demystify quality and encourages shared ownership across departments. Quality isn't just QA's job; it's a collective responsibility. And when people are genuinely engaged, when responsibilities are clearly defined and well understood, what once felt like a mountain becomes a manageable hill – one that can be climbed with confidence and collaboration.

Before embarking on the development or overhaul of a quality system, ask:

- Who is driving the project and ensuring it stays on track?
- Are the goals realistic given the current resources and constraints?
- Is subject matter expertise embedded in the process from the start?
- Are you building for the regulations you actually need to meet?
- Have you done the necessary groundwork to understand your scope and obligations?

If quality truly matters to an organisation, it must be resourced with the same seriousness as any other core function. A quality system is not just a box-ticking exercise; it's a strategic investment. While it may not deliver immediate financial returns, its absence or inadequacy can lead to costly delays, regulatory breaches and reputational harm that far outweigh the initial effort required to build it properly. And when regulatory requirements begin to apply, a system that isn't ready doesn't just fall short; it becomes a liability.

QUALITY ASAP: A MODERN FRAMEWORK

Let's redefine ASAP – not as 'As Soon As Possible,' but as a framework for modern quality thinking:

- **Agile.** Build what is needed now but allow for continuous improvement. Don't reinvent the wheel; harmonise where possible and iterate based on experience. Your system should be flexible enough to grow and adapt without needing to be rebuilt from scratch every time a new requirement emerges.
- **Simple.** Avoid overcomplicating procedures. SOPs should reflect standard practice, not every possible exception. If something occurs only 1% of the time, it doesn't need to be embedded in the core process. That said, there should be a clear and robust process for managing anomalies when they do arise.

- **Accurate.** Know your regulatory target – GLP, GCP, GMP, ISO – and understand your scope. Are you covering a single site or a global organisation? What services do you offer, and which regulations apply? Accuracy means knowing what you need to comply with, and just as importantly, what you don't.
- **Pragmatic.** Real people need real solutions. A 20-page SOP may not add value for a small company just starting out. Focus on what quality needs to achieve today, not what it might need to do in five years. Systems that are overly burdensome or difficult to operate are unlikely to succeed in the long term.

BEYOND METRICS, BEYOND PERFECTION

'Quality ASAP' reminds us that perfection isn't the goal – functionality is. A quality system should support scientific innovation, not stifle it. It should be flexible enough to evolve and robust enough to deliver consistent outcomes.

Metrics are important, but they're not everything. A system that looks good on paper but doesn't work in practice is not a quality system. A system that meets every regulatory requirement but is impossible to operate is not sustainable. The real measure of quality is whether the system enables people to do their work effectively, safely and compliantly.

THE HUMAN ELEMENT

Quality systems are built for people, not robots. And people, by nature, are imperfect. They forget steps, take shortcuts under pressure, and interpret instructions through the lens of experience and context. A well-designed quality system doesn't seek to eliminate human error; instead, it anticipates it. It offers clarity where confusion might arise, guidance where decisions are needed and support where tasks are complex. Above all, it's flexible enough to accommodate the nuances of human behaviour and robust enough to uphold standards without becoming a barrier to getting the work done.

This is where the 'simple' and 'pragmatic' principles of Quality ASAP truly come into focus. A system burdened by complexity risks being misunderstood or misused. One that's overly rigid will likely be sidestepped or quietly resisted. And if it demands too much without delivering clear value, it will be begrudged rather than embraced. Quality by design isn't just about meeting regulatory expectations; it's about creating systems that work for the people who use them. When quality is intuitive, accessible and aligned with day-to-day realities, it becomes a tool for success rather than a hurdle to overcome.

FINAL THOUGHTS: DO WHAT WORKS

Start with what works, be ready to pivot and don't be afraid to admit when a path isn't right. Whether you're building from scratch or rethinking an existing system, the key is to design quality that reflects your reality, not a theoretical benchmark.

Just because something worked before doesn't mean it's the right solution now. Just because a system was inherited doesn't mean it can't be changed. And just because a process is compliant doesn't mean it's effective.

Quality ASAP is not just a methodology; it's a mindset. One that values agility over rigidity, simplicity over complexity and pragmatism over perfection. In today's regulatory landscape, that might just be the most compliant choice of all.

So let's stop chasing perfection. Let's start building quality that works.

ASAP.

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PROFILE

Victoria joined the Tower Mains team in 2021 with a background in events, marketing and clinical settings. She holds a degree in English, is a qualified journalist and is currently pursuing a degree in TV to further enhance her media skills.

In her role, Victoria supports both marketing and operations, contributing to the development of the company's marketing strategies and operational objectives. Additionally, she is developing an online training platform to keep professionals up-to-date and compliant with the latest industry standards.