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REFRAMING QUALITY: 25 YEARS OF QA EVOLUTION AND THE ROAD AHEAD

Over the past 25 years, Quality Assurance has evolved from a compliance-focused function into a strategic, data-driven discipline, moving from retrospective oversight to an embedded role in system design, governance and adaptive quality management across digital and interconnected life sciences organisations.

As Tower Mains marks its 25th anniversary, it is an opportune moment to reflect on how profoundly the quality profession has evolved and where it may be heading next. Since the company's founding in 2001 by Dr Andrew and Fiona Waddell, Quality Assurance (QA) has developed from a largely compliance-focused discipline into a more strategic, forward-looking function. It now helps organisations navigate growing complexity, support innovation and maintain trust across the life sciences sector.

Twenty-five years ago, much of the industry relied on paper-based systems, manual review processes and relatively stable technology environments. Audits were largely retrospective, validation assumed fixed platforms and QA functions were often separated from operations, becoming involved only after critical activities had taken place.

Today, QA operates within highly connected environments shaped by digital transformation, Artificial Intelligence (AI), decentralised trials, automation and advanced analytics. Established frameworks such as GCP, GMP, GLP, GVP and data integrity requirements remain fundamental, but they now coexist with technologies that are reshaping how quality is designed, monitored and governed.

Across regulatory and industry discussions, a clear message has emerged: quality can no longer rely on retrospective inspection alone. It must be designed into processes from the outset, supported by continuous oversight and strengthened through data-driven insight. As Rhona McAteer, Director at Tower Mains, puts it: 'Quality can no longer be inspected into systems after the fact; it must be designed, embedded, predicted and continuously improved.'

Drawing on insights from across the Tower Mains team, this article examines how QA has developed from a function associated primarily with regulatory oversight into a strategic enabler of organisational success. It explores QA's expanding role at the intersection of regulation, technology and people; considers how the profession's skillset is changing; and reflects on how AI, automation and predictive assurance are likely to shape the next phase of its evolution.

FROM GATEKEEPER TO STRATEGIC QUALITY PARTNER

One of the defining shifts of the past 25 years has been QA's transition from gatekeeper to strategic partner.

Historically, QA functions operated separately from operational teams. Quality was closely associated with enforcing compliance, approving documentation and preparing for inspections, while operational teams focused on delivery and timelines. While this model created robust governance structures, it also reinforced the perception that quality sat within the Quality Unit rather than across the organisation. As a result, QA was often regarded as a barrier, brought in only after key decisions had already been made.

With more than 30 years of experience across GxP environments, Rhona reflects on how this separation shaped earlier models of quality. QA carried primary responsibility for compliance and was often seen as independent but disconnected from the business. Over time, as industry approaches evolved through Quality by Design, risk-based thinking, and Pharmaceutical Quality Systems, ownership of quality gradually shifted into operational teams. QA, in turn, became more embedded within the organisation, contributing earlier to decision-making and system design.

For Andrew, this evolution highlights the limitations of earlier definitions. He suggests that if the Principles of GLP were written today, they would distinguish more clearly between 'audit and inspection' and the broader role of Quality Assurance. In this sense, QA has always extended beyond formal audit activity.

In his view, QA is evolving into a 'quality professional' role, focused on actively promoting and 'engineering quality into systems and processes,' rather than acting solely as an independent inspector.

This progression is clearly reflected in practice, with QA teams involved earlier in operational activities, supporting system implementation, supplier oversight, digital initiatives and risk management. Rather than reviewing outputs after they are completed, QA now supports decision-making throughout the entire lifecycle.

Drawing on her early experience, Anna Lothian, Senior Associate at Tower Mains, highlights that when QA is brought in too late, it leads to rework, inefficiency and avoidable risk. Early engagement, by contrast, allows stronger controls to be integrated into processes from the outset.

This perspective reflects a broader change in how QA is viewed. In Anna's view, QA should function as a collaborative function that helps teams get things right, rather than simply meeting compliance expectations after the fact.

The direction aligns with approaches such as Quality by Design, Pharmaceutical Quality Systems and risk-based governance. As Stacey Harding, Associate at Tower Mains, notes, QA is taking on a more proactive role, working more closely with IT and operational teams to shape systems and build quality in from the start.

As Rhona puts it, the shift is from 'quality policing' to true embedded partnership, where quality is no longer owned solely by the Quality Unit but is fully integrated across the organisation.

CONNECTING REGULATION, TECHNOLOGY AND PEOPLE

QA's broadened remit is perhaps most visible in the way it now connects regulation, technology and people.

Stacey describes QA as uniquely positioned at this intersection, with these areas becoming more interconnected as technology advances. She emphasises that QA plays a crucial role in ensuring that new technologies are 'used in a compliant manner, with participant safety and data integrity in mind'. While the core principles of quality remain unchanged, they are applied through a more digital lens.

As she puts it, QA should be seen 'as an enabler that helps balance innovation and compliance', allowing new approaches to be adopted without compromising regulatory expectations, while ensuring that, as technology evolves, judgment, oversight and accountability are not diminished.

In large, cross-functional organisations – where scientists, engineers, IT specialists and operational teams must work in alignment – QA increasingly serves as both translator and connector. It interprets regulatory expectations, understands technical realities and helps teams navigate complex decisions with confidence.

Rhona suggests that QA may operate less as a standalone department and more as an organisational integrator, connecting people, processes, technology and governance. She also highlights that QA is well placed to bridge gaps between innovation and regulation, technology and people, and speed and oversight, helping organisations develop a more coherent and effective quality model.

'While the core principles of quality remain unchanged, they are applied through a more digital lens.'

Despite rapid advances in automation and AI, human judgment remains essential, particularly in applying critical thinking, ethical judgment, communication and the ability to challenge decisions when required.

Andrew emphasises the need to rebalance how QA operates. Future quality professionals must avoid both blind faith in systems and overly burdensome assurance processes that delay progress. This will require closer collaboration with operational and technical teams, alongside a softening of the traditional divide between independent audit and active contribution to quality improvement.

THE EVOLVING SKILLSET OF QA PROFESSIONALS

That broader remit has also reshaped the capabilities expected of QA professionals.

Twenty-five years ago, a strong grounding in regulations, auditing techniques and validation principles was often enough to build a successful QA career. Today, those foundations remain essential but are no longer sufficient on their own. As environments have become more connected and sophisticated, QA professionals must engage more deeply with the science and technology they review, apply risk-based thinking and collaborate more proactively with operational teams.

As Anna explains, 'technical fluency in QA is not about having all the answers; it is about asking the right questions in increasingly complex systems'. This shift places greater emphasis on curiosity, judgment and critical thinking in navigating modern QA challenges.

QA professionals are now expected to understand digital platforms, electronic data flows, AI governance, cybersecurity and advanced analytics. As these technologies become more integrated and automated, quality teams must not only interpret regulatory requirements, but also recognise how systems operate and where new risks may emerge.

As Rhona highlights, the industry has moved from paper-based systems to highly integrated digital environments, where decisions are increasingly driven by data rather than static documentation. As a result, QA professionals are expected to be 'technology-literate', with sufficient understanding to assess systems, interpret outputs and identify areas of risk, even if they are not technical specialists.

Based on her laboratory background, Anna notes that technical experience does not provide all the answers, but it gives enough understanding to ask the right questions, dig into processes and recognise when something does not fully align.

Andrew also identifies a change in how QA expertise is defined. Where auditors were once expected to compare requirements against practice without needing detailed subject knowledge, modern QA professionals require a stronger understanding of the science and technology underpinning what they review, particularly when assessing the impact and significance of non-conformances.

The move towards risk-based and technology-enabled operating models has further reshaped expectations. The transition from ICH E6(R2) to R3 reflects a move away from procedural compliance towards more holistic quality management, focused on risk and lifecycle oversight.

Anna also emphasises that comfort with ambiguity is becoming essential. As regulatory guidance struggles to keep pace with innovation, QA professionals must rely less on fixed rules and more on applying first principles and sound judgment. In this context, Stacey adds that the evolution is not solely technical, but also one of mindset. QA professionals do not need to be technical specialists, but they do need sufficient understanding to assess risk, challenge appropriately and support effective governance. As systems become more complex, particularly with the growing use of AI, this level of understanding is increasingly critical to ensure that risks are identified early and managed effectively.

For Rhona, one of the most significant changes is the need to think beyond documentation and compliance activities. The future QA professional will need to combine systems thinking, data fluency, risk intelligence, collaboration and adaptability to operate effectively in complex and interconnected environments. The traditional image of QA as purely documentation-focused is therefore continuing to evolve into a more strategic, technology-enabled role.

Alongside technical expertise, communication, adaptability and critical thinking have become equally important. As operating models become more integrated and global, QA professionals must influence decisions, navigate changing demands and support sustained improvement across increasingly interconnected disciplines.

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AI, DIGITAL TRANSFORMATION AND THE CHALLENGE OF DYNAMIC SYSTEMS

The challenge now facing QA is not wholly new, but it is unfolding at a very different scale and speed.

Traditional validation and audit models were designed for environments that could be configured, tested and reviewed before implementation. AI-driven technologies challenge that assumption, as they can learn, adapt and change over time.

For Anna, AI does not represent an entirely new challenge, but a familiar one at greater scale. Through her experience in computer system validation and risk assessment, she observes that the fundamentals remain the same. However, expectations are shifting towards earlier involvement and the need to build appropriate checks and balances from the outset. She describes it as 'the human in the loop isn't a temporary workaround; it's a necessary control'.

Andrew notes that this shift requires a fundamental change in mindset. Traditional audit and validation approaches were built around the post-validation review of static systems. By contrast, AI derives value from dynamic environments that learn and improve over time. As he observes, approaches that depend on locking these down risk 'negating the benefit' of technologies designed to evolve. In this context, Andrew highlights the need for a 'shift left' in assurance, placing greater emphasis on inputs and processes, rather than relying solely on outputs after the fact.

This presents a significant challenge for regulated industries. Traditional models prioritise stability, traceability and control, while AI-driven approaches are designed to adapt over time. As Andrew observes, organisations must strike a careful balance between enabling innovation and maintaining appropriate assurance. Overly conservative approaches risk delaying improvements, whilst insufficient oversight undermines trust in these technologies.

As a result, governance considerations such as explainability, accountability, bias, transparency and data quality, are moving to the centre of regulatory confidence.

Rhona argues that QA's role is expanding beyond preventing risk to enabling responsible innovation. This requires looking beyond compliance to assess whether technologies are explainable, data is trustworthy, decisions are defensible and risks remain visible as they evolve.

THE FUTURE OF QUALITY AND PREDICTIVE ASSURANCE

The future of quality is no longer theoretical; it is already beginning to take shape.

Andrew frames this development within a near-term horizon, suggesting that these changes are likely to become established within the next two to five years. He anticipates that self-testing systems, developed with input from quality professionals, will support ongoing, near real-time monitoring, while QA takes on a more active role in shaping how quality is delivered.

Concepts such as predictive quality, autonomous testing, AI-assisted governance and data-driven oversight are moving from theory into practice. Organisations are exploring how advanced analytics can strengthen oversight and enable earlier identification of risk.

Anna anticipates that tensions between innovation and compliance will persist in the immediate future, emphasising that the key challenge is no longer whether AI will be used, but how it can be governed effectively within regulated environments through appropriate training and proportionate controls. She also notes the divergence in regulatory approaches, such as the EU AI Act compared with the more innovation-focused positions of the US and UK, where concerns remain that overly strict frameworks may stifle progress. For organisations operating globally, this fragmentation is likely to create practical challenges. At the same time, many remain in a learning phase, still defining how AI should be used and governed, even as employees begin to adopt these tools in practice, often without fully understanding the associated risks.

Building on this, Stacey suggests that the definition of 'high quality' will remain fundamentally consistent, while the way it is achieved continues to evolve. Rather than relying on retrospective or periodic checks, AI and digital systems are enabling more immediate, continuous oversight and earlier identification of risk, supporting a more consistent and proactive approach to quality management.

This is further reinforced by Rhona, who describes a shift in emphasis within QA activities, moving from manual record review towards the oversight of algorithms, data governance and predictive risk models. In this environment, maintaining transparency and trust becomes a central responsibility.

Taken together, these developments point to a broader transition from periodic, retrospective assurance to more dynamic, system-enabled quality management, where quality is monitored, predicted and managed in real time.

LOOKING AHEAD: CONTINUING THE JOURNEY

Despite the scale of transformation over the past 25 years, QA's core purpose remains unchanged: to protect patients, ensure integrity and maintain trust. The evolution of the profession reinforces a principle that has only become more relevant over time – quality must be built in, not inspected in. While technology continues to advance, it cannot replace the human responsibility at the heart of quality, where accountability, integrity and ethical judgment remain fundamental.

Looking ahead, the future of QA will be defined not only by how effectively organisations maintain compliance, but also by how well they design systems that are resilient, transparent and trustworthy from the outset. As technologies become more dynamic and interconnected, QA professionals will play a central role in shaping how innovation is governed in practice.

In this context, QA is no longer simply responsible for evaluating what has already happened; its value lies in influencing what comes next, ensuring that quality is considered early, embedded effectively and sustained over time.

The challenge itself has not changed, but its scale has. The task now is to make quality intrinsic, adaptive and continuously trusted in a complex and fast-moving landscape.

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PROFILES

Victoria has a multidisciplinary background in marketing, events and clinical environments, underpinned by degrees in English, TV Production and professional training in journalism. At Tower Mains, she supports both marketing and operational functions, contributing to the development of company strategy and business objectives.

With over 40 years of experience, Andrew is highly experienced in GLP, GCP, GMP, ISO 9001, ISO 17025, ISO 14155 and related standards. He has worked extensively with government, industry bodies and served as an advisor to the OECD during the development of the original OECD Principles of Good Laboratory Practice (GLP).

Rhona has been working in the pharmaceutical industry for over 30 years, initially in steriles QC microbiology before moving into pharmaceutical and medical device QA. Her career spans manufacturing, clinical research and regulatory affairs, providing extensive expertise in the development, implementation and oversight of quality systems across GMP, GDP, GCP, GCLP and medical devices.

Anna's career spans the medical device and research sectors. She began her professional journey as a laboratory technician before progressing into technical management roles within Research and Development. Through this experience, she has developed extensive knowledge of laboratory operations and quality systems, with expertise in ISO 13485, GLP and GMP standards.

Stacey has been working in clinical research and quality assurance since beginning her career as a Clinical Trial Assistant in a Phase I unit. She transitioned into quality assurance within a global CRO, gaining experience in GCP auditing across investigator sites and sponsor-led activities, as well as the development and delivery of training programmes for data recording in GxP environments.