Redesigning Quality: The Third Wave of Quality Transformation

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We all know that compliance is essential. It protects patients, builds trust, and provides the consistent structure that highly regulated industries depend on every day. In the pharmaceutical industry specifically, many of the regulations and GMP framework in place today were created in response to patient harm or manufacturing failures.

The compliance framework exists because the consequences of poor quality are too significant to rely on inconsistent assumptions, good intentions, or individual expertise alone. Over time, however, the industry has come to define quality solely through this regulatory lens.

The question is not whether compliance is necessary - it absolutely is. And that will never change. Being compliant with the cGMP framework sets the floor, it is the minimum to operate in the pharmaceutical industry. The real question is whether we are positioning quality to evolve and contribute as fully, strategically, and effectively as it was always intended to. Beyond compliance. What it *needs* to do.

Interestingly, the building blocks for this evolution have existed for decades. Thought leaders such as Dr. W. Edwards Deming and Dr. Janet Woodcock challenged the industry to think beyond inspection and oversight toward systems thinking, leadership responsibility, system optimization, and quality excellence.

In 1982, Dr. Deming provided us with the 14 Points of Management and later, the System of Profound Knowledge (SoPK, 1993). He placed the ultimate responsibility for quality on senior management and emphasized the “appreciation of a system”.

He also reinforced the importance of quality improvement in one of his 14 Points of Management: *“Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decreasing cost.”*

Unfortunately, counter to Dr. Deming's long-term quality systems thinking, the pharmaceutical industry has largely approached quality and the quality system through short-term linear thinking (cause and effect). Although well-intended, this approach does not improve the system overall. It doesn't generate quality excellence as an output.

Dr. Woodcock challenged our traditional approach to quality in the FDA's GMPs for the 21st Century (2004) by stating the vision of "*a maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drug products without extensive regulatory oversight*". Essentially, a less rigid oversight system to make space for quality excellence. Her vision was behind the development of ICH Q8, ICH Q9 and ICH Q10 (2005-2008).

Adding to that, Juran's Cost of Quality (CoQ) model had already demonstrated in 1961 that the *cost of prevention is lower than the cost of correction*, and that *appraisal activities do not actually prevent failures*. Despite all this data and logic, during the 1980s and 1990s, Operational Excellence (OpEx) largely became a cost-cutting exercise instead of having a focus on *"customers' needs, keeping the employees positive and empowered, and continually improving the current activities in the workplace,"* as Juran had originally suggested in the 1970s.

With the introduction of Lean principles, waste elimination was rapidly reinterpreted by finance functions as a tool for justifying workforce reduction. OpEx became a consulting product focused on near-term, quantifiable cost savings. The original intent of improving quality, reducing variation, and strengthening systems was often overshadowed by the pursuit of short-term financial gains.

It is no surprise then, that many of the quality crises resulting in drug shortages, patient harm, and regulatory actions can be traced back to cost-cutting decisions that weakened both process understanding and the manufacturing robustness upon which product quality depends. And yet the "solution" seems to always go back to more compliance.

Dr. Woodcock's famous quote from FDA's GMP for the 21st Century was a deliberate challenge of the prevailing model, which assumed that more inspection and more compliance activity was always better. The ICH Q10 Guideline Pharmaceutical Quality System (PQS) Concept Paper (2005) stated:

> *"Currently, there are differences between industry and regulatory agencies in the different regions in the definition and interpretation of quality system terms, principles, application andexpectations. Therefore, while the three regions are using various aspects ofquality systems and concepts, a strong potential exists for further divergence…This divergence is not in line with the need for an efficient and effective industry and regulatory processes."*

The anticipated benefits of ICH Q10 included:

a) harmonized concept of quality systems,

b) a commitment to robust quality systems, technical innovation, and consistent availability of medicines,

c) innovation and continual improvement,

d) management commitment to quality, and

e) a preventive action culture.

When completed (2008) ICH Q10 Annex 1 stated that companies demonstrating an effective PQS and product and process knowledge could be granted operational flexibility including less Post Approval Changes (PACs) requiring prior approval by

regulatory agencies. This would facilitate more continual improvement activities and faster implementation of PACs.

The envisioned post-approval operational flexibility was not achieved as written in the ICH Q12 Lifecycle Management Concept Paper (2014), which also suggested that *"adoption of this guideline (ICH Q12) will promote innovation and continual improvement, and strengthen quality assurance and reliable supply of product, including proactive planning of supply chain adjustment"*.

When finalized ICH Q12 (2019) stated that *"A harmonized approach regarding technical and regulatory considerations for lifecycle management will benefit patients, industry, and regulatory authorities by promoting innovation and continual improvement in the pharmaceutical sector, strengthening quality assurance and improving supply of medicinal products"*. This is similar to the three ICH Q10 objectives 1) product realization, 2) state of control, and 3) continual improvement.

So, why was the original intent of ICH Q10 not achieved?

To answer this question, it is useful to return to Dr. Deming's System of Profound Knowledge (SoPK). One of its core elements is an appreciation for a system. It was emphasized that meaningful improvement begins with understanding how systems actually work.

Another valuable insight in this regard comes from Stafford Beer, who defined the purpose of a system with a simple but powerful statement: "*The purpose of a system is what it does*" (POSIWID). In other words, a system's true purpose is revealed *by its outcomes*, not by its intentions, aspirations, or claims.

So, what does the PQS actually do? Compliance. It does compliance.

The output of the PQS is compliance. That is how we assess it. ICH Q10 states it this way: *"When implemented, the effectiveness of the pharmaceutical quality system can normally be evaluated during a regulatory inspection at the manufacturing site."*

There is a fundamental disconnect between the stated objective of the PQS (what we claim it to be) and the results it actually produces (what it does). For decades, regulatory inspections have focused primarily on identifying cGMP non-compliance rather than looking for evidence of quality excellence. As a result, the system naturally reinforces compliance as the primary outcome.

Essentially, it has settled into a "punish, no reward" system. Companies are penalized for falling below the compliance threshold, but they are not rewarded, for example, through greater regulatory flexibility for setting the bar for quality higher than compliance itself. An analogy to the education system is that regulatory inspections use a pass/fail approach. Companies are not rewarded for striving for an 'A'. 'D' is satisfactory.

At the same time, responsibility for quality has increasingly been delegated to the quality organization rather than remaining a core responsibility of senior leadership, despite Dr. Deming's clear assertion that management is ultimately accountable for quality. Over time, this contributed to a model in which manufacturing makes the product, quality approves it, and when something goes wrong, quality bears the responsibility.

The result has been a growing disconnect between quality leaders and senior leadership. Without a shared understanding of quality's role in achieving business objectives, alignment becomes difficult, limiting quality's ability to influence decisions and contribute fully to organizational goals.

The quality organization is now a policing/enforcing function focused on representing the regulator inside the company. Internal quality activities are centered around preparing for inspections and asking, “What will the inspector look for?” rather than taking it a step further by asking, “What does this medicine need to reliably deliver quality outcomes for the patient?”

Quality leaders have become a support function aimed at ensuring compliance and the system has been very successful at what it actually does, which is producing compliant pharmaceutical manufacturers. It has been less successful at producing a better functioning pharmaceutical manufacturing sector, *which is what ICH Q10 says it is actually for*. It is the predictable result of building a quality system inside a regulatory framework where compliance has consequences and improvement does not. We designed a compliance machine. We got a compliance machine, and we built an entire industry around achieving compliance - not quality excellence.

As a result of the compliance focus, anything that could lead to a regulatory inspectional finding, such as visible work in progress or known issues awaiting mitigation, is often kept outside the PQS out of concern that it could delay approval of a new product, a manufacturing site, or ongoing product availability. This includes company-identified risks, improvement initiatives, resilience planning, and much more. Many companies are undertaking activities to strengthen quality performance, but because they are assessed primarily on non-compliance, these efforts often remain outside the system.

The pharmaceutical industry has spent decades building a strong foundation of compliance. The next step is to build on that foundation and begin the third wave of quality transformation. Increasing pressure on manufacturing costs, persistent drug shortages, growing scrutiny of the industry, and accelerating technological advances, including AI, are changing the environment in which we operate, and quality needs to change with it.

Addressing these challenges will require redesigning both our quality system and the role of the quality organization itself. Quality must evolve from a support function into a strategic business partner that improves patient outcomes, strengthens business performance, shapes key decisions, and drives innovation. Achieving this transformation will require new skills, new capabilities, and a better-equipped community of quality leaders. Quality leaders need to demonstrate and apply quality business leadership skills.

If these are the outcomes we want the pharmaceutical quality system to achieve, then they are the outcomes it should be designed to measure, encourage, recognize, and reward.

In terms of measuring, the traditional Cost of Quality (CoQ) models should evolve toward a Quality Value Index (QVI) approach. While CoQ focuses primarily on measuring and minimizing the costs associated with quality activities, failures, and appraisal, QVI expands further - on understanding and maximizing the value that quality creates for patients, regulators, employees, and the business.

This represents a significant shift in thinking: from minimizing cost to maximizing value; from a defensive mindset of avoiding losses to an offensive mindset of creating value; and from short-term operational cost reduction to long-term investment in quality outcomes. Rather than viewing quality as a cost center, QVI positions quality as a strategic business capability that contributes to reliable

product supply, patient trust, regulatory confidence, operational resilience, and financial performance.

Importantly, QVI enables organizations connect quality investments to business results. It provides a framework for evaluating how quality systems, process understanding, culture, and knowledge management contribute to patient outcomes and organizational performance. In doing so, it encourages decisions that create long-term value.

However, an improved measurement system alone is not enough. If we want different outcomes, we must also redesign the systems, incentives, and behaviors that shape them. And all the key players have a role to play.

On the regulatory side, this would require a more outcome-based inspection framework that evaluates both compliance and the continuous improvement of quality outcomes. Organizations that consistently demonstrate exceptional quality performance should experience tangible benefits, such as greater regulatory flexibility, more risk-based oversight, and reduced regulatory burden. This would create incentives for companies to pursue quality excellence rather than simply avoid non-compliance.

On the company side, the PQS should be expanded beyond compliance to focus on patient outcomes, including uninterrupted supply, which should be considered a Critical Quality Attribute (CQA). Achieving this requires continually deepening product and process understanding while embedding a culture of learning, knowledge management, and continuous embedded improvement throughout the organization. At the same time, the Quality function must demonstrate its value to the business and no longer simply be managed primarily as a cost center.

It would also require more direct involvement of senior leadership as quality accountable, changing the CAPA system from problem solving to knowledge generation, using Annual Product Quality and Management Reviews to identify trends and set new objectives aimed at improving quality (not only compliance) performance, and establishing an internal audit function that expands from compliance administrators to executive peers analyzing performance data, investigating problems closely, building process models, and challenging the organization on quality grounds.

At the individual level, quality leaders must become stronger business leaders by:

- Understanding how systems truly work and how the desired quality culture can be achieved.
- Acting as architects of processes that ensure quality is owned by all.
- Engaging employees, both intellectually and emotionally, to participate in and lead better quality outcomes.
- Making patient-centered decisions that balance risk to patients with risk to supply, while also balancing science with compliance requirements.
- Being financially savvy and able to demonstrate the value created by quality activities.

Collectively, the quality community must evolve beyond influencing actions and decisions within individual companies. It must become a movement that helps redefine the role of quality *across the industry*, positioning quality professionals as strategic partners and leaders of quality-related topics rather than leaving this responsibility primarily to regulators, who largely operate at a national level.

Making this change is not simple, but it is necessary and entirely achievable. It is not

complicated, it is complex. It is not about more words or guidance documents, it is about doing the work differently. The future of quality requires adaptive leaders who are willing to learn, challenge existing assumptions, and think differently. That is the work behind the 6 Traits of Quality Business Leadership.

For several decades, the industry has invested enormous effort in improving compliance. Those efforts have succeeded generally speaking for most companies.

Yet many of the challenges we face today, including drug shortages, rising complexity, increasing costs, and growing pressure on quality systems, remain. This should not surprise us.

As Stafford Beer observed, the purpose of a system is what it does. We designed a system that measures compliance, rewards compliance, and inspects for compliance.

Compliance alone is not enough.

If we want a system that delivers uninterrupted supply, deeper process understanding, stronger quality cultures, greater organizational learning, continuous improvement, and better patient outcomes, then we must redesign and manage the existing system to achieve those outcomes.

The path forward is clear: fully embrace Deming's System of Profound Knowledge, advance Woodcock's vision of a modern and flexible manufacturing sector, transform the Pharmaceutical Quality System into a driver of quality excellence, and develop quality leaders into strategic business partners capable of leading change across the industry.

The opportunity before us is not to become better at compliance. The opportunity is to redefine what quality leadership can achieve.

It starts with a simple expansion in mindset: “Am I being compliant?” becomes “Am I being compliant and advancing quality excellence?”

Because the future of quality will belong to those who are willing to improve the system, not just comply with it. The rest will be left behind. If we want better outcomes, we must redesign a better system.

That work starts with us individually and together as a community. The time is now.