QUALITY BUSINESS LEADERSHIP by qba

IN PURSUIT OF
the Promise of ICH Q10

QBL Alumni Group

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THE ISSUE

The Pharmaceutical Quality System (PQS) is primarily acting as a compliance system. It is not delivering on the full intent stated in the ICH Q10 guideline. For many companies the PQS is reactive, limiting continual improvement and impacting drug availability. It is not consistently used to improve company business and societal outcomes achieving quality excellence. The way we assess it reinforces the PQS as a compliance system. It maintains a minimum condition, not an optimal one.

Whatever the stated intent of a system, the purpose of a system is described by what it actually does (Definition by Stafford Beer). Today, the PQS in many companies acts to maintain an environment where:

- The system exists to satisfy regulatory agency investigators during inspections (avoiding potential non-compliance observations).
- Plans and progress towards quality excellence like learnings, risk-reduction, and continual quality improvement are managed outside the system.
- Improvements are triggered by compliance failures in a cause-and-effect manner and the CAPA system is used mainly to track completion of corrective actions, rather than ensuring effectiveness and adding a focus on preventive actions to improve the PQS.
- Quality leaders operate within a zero-risk historical compliance frame not fully balanced with science, compliance and the risk to supply to patients, and quality is considered a cost to be managed down.
- Business financial benefits due to quality improvements are kept strictly outside the system.

So why is that? Companies act out of fear because any plan that shows improvement opportunities not yet effectuated could result in a regulatory agency observation, which could put approval of a site, line, or product at risk. Adding to this, there is no equal partners arbitration process in case a company questions a regulatory agency observation. It is the same agency that would evaluate the relevance of the observation as the one that gave it in the first place.

The issue has been known for decades and not been reduced despite well intended attempts and dialog.

THE OPPORTUNITY

A dynamic quality system evolving in line with experience of needs, product delivery and desired intent of ICH Q10 would offer a very different picture of quality excellence. It would expand an environment characterised by:

- A quality culture and activities aimed at constantly improving the system towards quality excellence.
- Enabling agile adjustment to a rapidly evolving environment of accelerating technological advancement and increasing pressure on manufacturing costs.
- Organizational resources focused on activities that drive the greatest value for patients.
- Assessment done by company leaders and regulatory agencies, both focused on desired stated outcomes.
- Inclusion of quality plans and activities aimed at facilitating learning, ensuring consistent product supply, and with a focus on patient and business outcomes.
- Continual improvements that are proactive, structured and dynamic.
- Quality Business Leaders demonstrating the value of quality balancing risk to patients, compliance, science and uninterrupted drug product supply when making decisions.
- Inclusion of financial numbers where these can help improve quality through risk-reduction and simplification of processes. Quality creates value and is not treated as a cost.

Collectively the above would demonstrate an effective PQS more in line with its original purpose outlined in the ICH Q10 Concept Paper. A high likelihood of success would require a systems thinking approach in contrast to previous attempts all using linear thinking by each stakeholder individually. Companies that strive for quality excellence would also be less likely to face non-compliances with this opportunity realized.

THE CHALLENGE

Today each company implement the PQS in ways decided by the company and each regulatory agency and investigator inspects it to their interpretation of cGMP compliance standards. Thus, no single body owns the responsibility for evolving the PQS to become a more valuable asset.

The PQS is based on cGMP requirements and the ICH Q10 guideline. It exists within the wider environment of the pharmaceutical sector, responding to interactions with regulators, governmental and health system priorities, and societal concerns and expectations.

Ironically, the stated objectives of the ICH Q10 guideline are not compliance only (wording 'state-of-control' used) but also include 'product realization' (product availability, no shortages) and 'continual improvement'. However, only compliance (or rather non-compliance) is assessed during regulatory inspections by identifying non-compliances (and not what has greatest impact to patients).

Within the organisation the PQS exists alongside many other systems, for example, business strategy, finance, manufacturing, human resources, corporate communications and others. It is not assessed and thus not responding to executive company management business needs, because the perception of quality and the PQS also within companies is to ensure compliance only.

Put another way, the Quality function responds to the compliance mindset of external regulatory bodies by internally reproducing that compliance mindset. It remains locked into ensuring a minimum standard at the expense of drug availability and the broader quality improvement of the system for the benefit of patients and the company. These are almost positioned as lower priority than compliance, rather than as mutually beneficial and complementary outcomes.

In this environment there is a mindset about Quality that persists. A mindset that sees Quality as an enforcer of compliance, as limiting better practice, as a cost, as satisfying external needs not bringing added internal value.

Therefore, evolving the PQS to be a more valuable and meaningful framework requires a 'whole system' response. The interplay between Quality and all the environmental elements listed above is such that changes in the PQS that are driven

solely by a company's internal quality function are likely to simply perpetuate the existing process of compliance. Lots of elements need to evolve together. The whole mindset needs to shift. Amongst company and regulatory agency leaders, both. And everyone would need to appreciate and fully understand systems thinking and how 'what the system does' can be changed.

Where will the leadership needed to do this come from? Where is the understanding of how this might happen? What will encourage sceptical people for whom the existing process is satisfactory to begin to explore how to make things better?

SOME IDEAS FOR MOVING FORWARD

There is already momentum to address this from the senior leader alumni of the Quality Business Leadership program. Successive cohorts have identified the limitations in the current approach and are already looking at steps they can take to move forward. There is not a need for additional guidelines and more wording as much as there is a fundamental need to shift the dialog from each stakeholder addressing the issue from their viewpoint to applying a true systems thinking approach in words and actions.

There have been existing conversations between regulators and the industry, past and present that have explored how the current system is working for all parties and how they might evolve better ways of working. This has been slow. The legitimacy and power to act is limited and for some the status quo fulfils all they need.

What is needed is to convene a conversation at senior level between all interested parties, governments, regulators, patients, health systems, pharma companies and their suppliers. The purpose of this conversation would be to agree a purpose and direction for quality to move to a more productive space that satisfies everybody's interests. Without it, the good work already done will be limited in terms of impact. There needs to be an appreciation of how systems work and a mechanism to develop and expand the conversation, the range of parties involved, the input provided, and the impact.

Such a conversation would best take place under the auspices of an established body that is seen to be impartial and lends authority. It might be an academic institution or non-governmental body. It would be more than a 'listening session'. It should engage stakeholders to understand the situation, context, stakeholders and interdependencies. The stakeholders should together visualize the system and identify patterns.

The conversation could explore once more the purpose of the PQS, going back to the three original objectives of ICH Q10 plus an objective about desired quality culture. It should be assessed how well the current system delivers against these objectives. It might identify design principles to be followed if the system is to evolve to meet these objectives, ensuring they satisfy the needs of all parties.

Such a conversation would move to action by hosting work streams. It could identify a number of these that would be necessary for system evolution to occur. These might include:

- Creating 'safe-fail' experiments in interested organisations as probes into what might be possible. These would point the way to a better system whilst managing risk in a way that would be acceptable to all. Note: 'safe-fail' is important in general and in this case particularly because companies in many cases are not fully vocal out of fear.
- Hosting a learning environment that would surface successes, difficulties, concerns and potential new directions. If this is made a 'safe' space it would provide the necessary feedback loop for real experience, real time information to inform the development of the PQS.
- Promoting to professionals new processes that emerged from the conversations and workstreams so that they might be further explored at scale as viable routes forward.
- Develop examples (training material) of what 'good looks like' in terms of demonstrating quality excellence and generation of outcomes that better align with the desired objectives/purpose of the system.

DESIRED OUTCOMES

Some of the desired outcomes of rethinking the PQS are to:

- Encourage a desired quality culture – psychological safe environment with employees actively involved in risk identification and quality improvements, senior leaders articulating the value of quality, and quality considerations influencing major business decisions

- Make Management Review a real strategic process — intelligence loop connecting quality data to business decisions and continual improvement and simplification of quality processes.
- Make CAPA genuinely systemic — root cause analysis that reaches organisational and system design causes, and inclusion of more preventive actions.
- Embed Quality Risk Management (ICH Q9 (R1)) into the end-to-end supply chain and Product Quality Reviews— risk registers used in a dynamic way to demonstrate continual reduction in risks to quality, supply, and business. Consideration of uncertainty, importance, and complexity when assessing risks using the ICH Q9 (R1) framework
- Demonstrate a learning organization – where new knowledge is institutionalized and employees progress towards proficiency with integrated daily learning rather than relying on Read & Understand training.
- Promote a Right The First Time mindset – recurring deviations and customer complaints are effectively reduced, and human error prevention programs are in place.
- Continually improve manufacturing processes and process capability – reducing process variability and introducing new technologies in a timely manner.
- Implement new learnings – since the completion of ICH Q10 in 2008. (E.g. ICH Q9(R1), ISO 9001 Quality Management Principles).
- Fully apply systems thinking into the ICH Q10 guideline – demonstrating the achievement of all three ICHQ10 objectives (not only compliance) and adding a fourth about the desired quality culture.
- Define desired outputs of the system – how regulators and industry will assess the achievement of the desired/claimed objectives and stimulate continual improvement.

The QBL Alumni envision a revision of ICH Q10 and the development of training material, which would be managed through the ICH document revision process. The QBL Alumni plan to share this white paper broadly and develop a Concept Paper for a revision through a process of inclusion of stakeholders.

CONCLUSION

The PQS is acting as a compliance system that neither satisfies the intended set of objectives stated in ICH Q10 nor the demands of an agile system that facilitates quality excellence and desired patient and business outcomes. The QBL Alumni request the support to advance the following priorities over the next 6-12 months:

- Engage industry and regulatory sponsors to formally support this effort
- Secure participating companies to pilot and validate evolved PQS practices
- Translate outcomes into a structured path toward ICH Q10 revision

ABOUT THE QBL ALUMNI

The QBL Alumni is a group of senior leaders from industry (mainly Quality leaders) and regulatory agencies that have graduated from the Certificate in Quality Business Leadership Program offered by Quality Business Administration, accredited by the Graduate Business School Technological University of Dublin, Ireland, and taught by world renowned leaders and experts.

The QBL Alumni represent a movement for changing the role of quality from a support function to leading change as strategic business partner at company level and as a voice for quality expanding from compliance to sustainable product quality, consistent product supply and robust financial performance at global level. The group does not represent specific company views.

ABOUT QUALITY BUSINESS ADMINISTRATION

QBA is dedicated to elevating quality as a strategic business function through education, research and community. Our mission is to lead the path to one global quality regulatory framework.