LIFE SCIENCES

Quality and Compliance

- Quality management system
- Regulatory compliance
- Governance
- Standardisation
- Knowledge management

why compliance isn't good enough

why wci

"we design Quality Management Systems that work"

"we ensure all stakeholder requirements are met"

Surely there is no industry where quality is seen as more important than it is in Life Sciences. Indeed, hundreds of thousands of people are employed by regulatory authorities to enforce quality through compliance to regulations, with an increasing appetite to exact heavy penalties from those that do not comply. Yet, it is possible to argue that, despite all their efforts, the regulators are failing to meet their goal. Pharmaceutical companies have to focus so much on regulatory compliance that it sometimes seems that they might not be grasping the true meaning of quality.

Customers, however, are not so easily distracted. Educated, with easy access to up-to-date knowledge, they treat medications much as they do any other consumer goods. Brand strength and recognition are increasingly important, especially now that generic competition to off-patent medication is increasing. Global media and information exchange provides marketing opportunities, but also puts the company's brand at significant risk in case of failures. Needless to say, the potential legal consequences of massive lawsuits caused by adverse events or quality defects remain a constant threat.

Compliance alone just isn't good enough anymore. There are recent examples that demonstrate significant failures in Quality Systems and Oversight do occur, even in companies that have been at the forefront of defining regulatory compliance. Quality is not just about satisfying regulatory requirements, but meeting the requirements of *all* stakeholders, including customers and shareholders. Ironically, Quality Standards that facilitate this have been around for decades and are well established in other, less regulated industries. For example, the ISO 9000 family of standards was set in 1987, but its foundation dates even further back to the British Standards of 1979. Its first certification was awarded to a company within the highly competitive road construction business, not an organisation operating in a highly regulated environment at all!

Comparing the pharmaceutical Compliance Systems with such Quality Standards reveals a number of significant differences. The Compliance Systems typically focus on providing an interpretation of the regulatory requirements, leading to standardisation of what are called the Quality Processes; such as validation, deviation management and CAPA. However, little is said about how the Quality Processes should be integrated into the business processes, or how to standardise and improve the business processes themselves. Even worse, business-critical processes that have little or nothing to do with areas regulated by FDA or EMA are strongly under-developed or even non-existing within the Compliance System. Typical examples are the supporting processes of budgeting, purchasing, invoicing and recruitment. It's almost as if quality is unimportant in these processes because compliance doesn't matter. Tell that to the laboratory manager who has spent 12 months trying to train and eventually dismissing an analyst who should never have been recruited in the first place!

Furthermore, compliance systems are often broken up into their regulatory components, so that a significant separation exists between pharmacovigilance, development, and manufacturing. This causes a number of issues for interface processes such as complaint handling, labelling and change management. Not only is there a clear risk that interfaces are not properly defined or that processes are not aligned, but it is also extremely difficult to implement improvements to such processes. For example, in one of the top pharmaceutical companies a significant compliance issue was identified in the labelling process, but it took over 18 months to draft, review and obtain approval for a new global labelling SOP to truly fix the problem. Needless to say, during all this time the company was further exposed to labelling compliance risks.

In addition, Compliance Systems are often simply document repositories of regulatory interpretation and processes. Proactive improvements to the Compliance systems themselves are rare, and they are usually only modified as a reaction to regulatory changes, inspection findings, or changes to the product-market portfolio. This lack of proactive improvement is partly due to the fact that there is no clear link between the Quality Strategy, the Quality Objectives and the Quality Plan; partly because there is poor setting and monitoring of Quality Objectives; and partly because good Continuous Improvement processes are lacking.

So, how can true quality oversight be obtained, not only across all business processes but also across the entire product lifecycle, whilst shifting from a reactive assurance of compliance to a proactive improvement of quality? The answer is simple. Quality needs to be lifted above the functional boundaries of the organisation. The pharmaceutical Quality Management System of the future is a single, integrated Quality Management System that spans the whole organisation and product lifecycle.

"we ensure a common standard of quality"

"we reduce risk management through central governance"

"we ensure critical processes are harmonised"

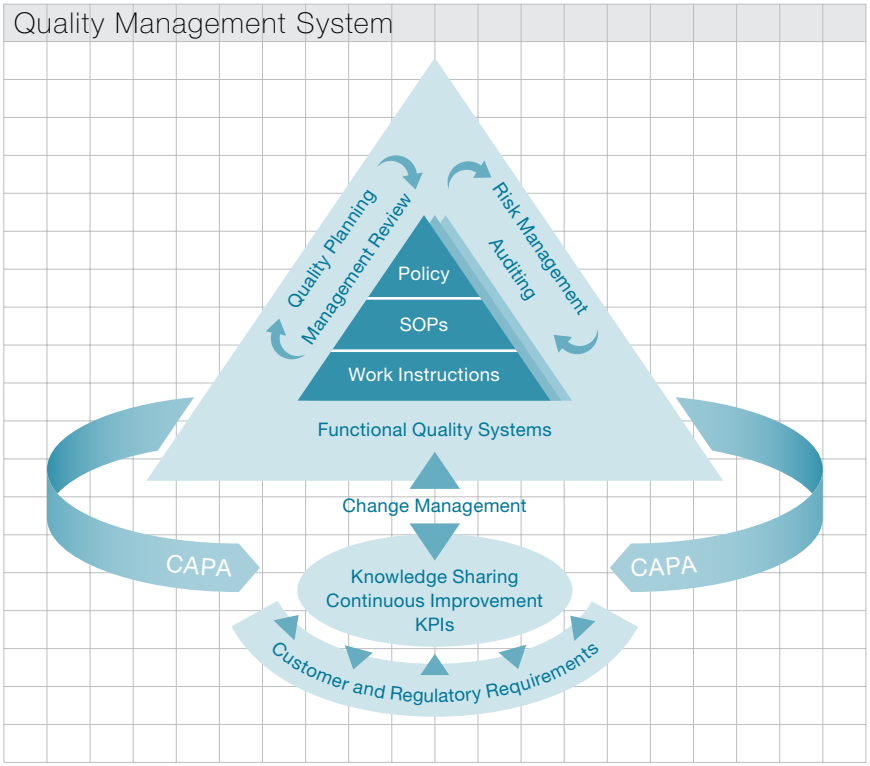

Figure 1: Pharmaceutical Quality Management System of the Future

To achieve this goal some fundamental changes will have to be made to the way in which pharmaceutical companies organise themselves. An appropriate organisational architecture needs to be established that implements central, company-wide Quality Governance at the highest level. The Quality Governance Body should represent the entire business, including compliance, operational and supporting functions. The Governance Body not only needs to be accountable for setting the Quality Strategy and making the Quality Plans, but must also have the means and authority to enforce corrective and preventative actions. Additionally, it needs to monitor process performance, product Quality and product Safety. Finally, the governance body must have the means to audit adherence to the defined processes.

Corresponding to the organisational architecture, an integrated Quality Management System is established that covers all aspects of Quality Management and includes management of the complete product lifecycle. This requires a balance between central governance and the specific regulatory requirements of the GxP disciplines. For example, to encourage innovation, the development function would require more flexibility and local freedom than the heavily GMP-regulated manufacturing. This local flexibility is provided through functionally-oriented sub-systems within the overall Quality Management System. These sub-systems are not self governing, but are a lower level, integrated element of the overall System.

To ensure Quality and Compliance in such a set up, the design of the Quality Management System framework is key and should contain three elements, described below.

1. The main quality management processes should be standardised and globally executed

- A single company-wide Quality policy ensures that a common standard of Quality is applied across the business, to all products in all markets.
- Implementation of Global Risk Management enables proactivity and consistency in prioritisation of the improvements.
- Goals and targets are set centrally.
- Quality Planning will ensure the cascade of the Quality-related objectives and targets to all business functions and levels.
- Improvements are planned and monitored centrally, with assigned responsibilities, timelines and targets.
- The Management Review is implemented to monitor this performance across the business and product lifecycle.

- A company-wide Quality Dashboard measures the results the organisation is achieving in relation to its planned Quality Objectives and Performance.
- A central auditing function ensures senior managers are aware of the company's key Quality and Compliance risks.
- An open disclosure culture is essential to enable knowledge sharing and risk reduction across the business, and to make the other Quality Management processes effective.

2. Oversight and clarity of cross-functional processes is gained through central governance, significantly reducing compliance risk and issues.

- To ease maintenance of the procedures the global level focuses on the interfaces only.
- The detailed aspects of the process itself are regulated within the functional sub-systems executing the process.

3. To aid the sharing of knowledge and to deploy best practices, critical processes should be harmonised across the business wherever possible.

- Knowledge Communities should be established to review performance and drive improvement of these processes.
- Global CAPA and Change Management systems ensure effective implementation of the improvements across the business and throughout the product lifecycle.
- Systematic mining of key data from all sources facilitates effective root-cause analysis, prevents quality issues and enables continuous improvement of the processes and systems.

Most Life Sciences companies have a long way to go to implement integrated Quality Management Systems. However, this is a path that has been taken by many other industries and, in order to remain competitive, pharmaceutical companies will simply have to follow suit, focusing on total Quality and not just Compliance. What is more, the Regulators are catching up: ICH Q 10, inspection collaboration and sharing of results between GxP disciplines are the first steps in this direction. There is no doubt that more will follow in the near future.