QMS RE-DESIGN CASE STUDY

WHAT DOES YOUR COMPANY QMS LOOK LIKE? WHERE DOES SENIOR MANAGEMENT FIT IN?

by David Selby

THE CHALLENGE

A highly diversified pharma company based outside Europe has grown by acquisition and as a consequence has developed a range of quality management systems (QMSs) and inherited a number of others. It consisted of a number of sites managed directly by the organization, and nearly 50 subsidiaries that were managing the sale of major products.

These subsidiaries often used local contractors to manufacture other products for the local market only. Furthermore, the company strategy was to increasingly outsource more of its activities, with only a very few sites managed directly by the company. At the time of this project, there were nearly 300 external organizations across the company, directly involved in the development, manufacture, testing and distribution of the company's products. So much diverse activity proved a challenge for the global quality function.

THE SOLUTION

NSF was asked by top management to review the range and extent of GxP quality systems in place and make recommendations for a single company-wide QMS suitable for its modern business model and meeting all anticipated regulatory requirements.

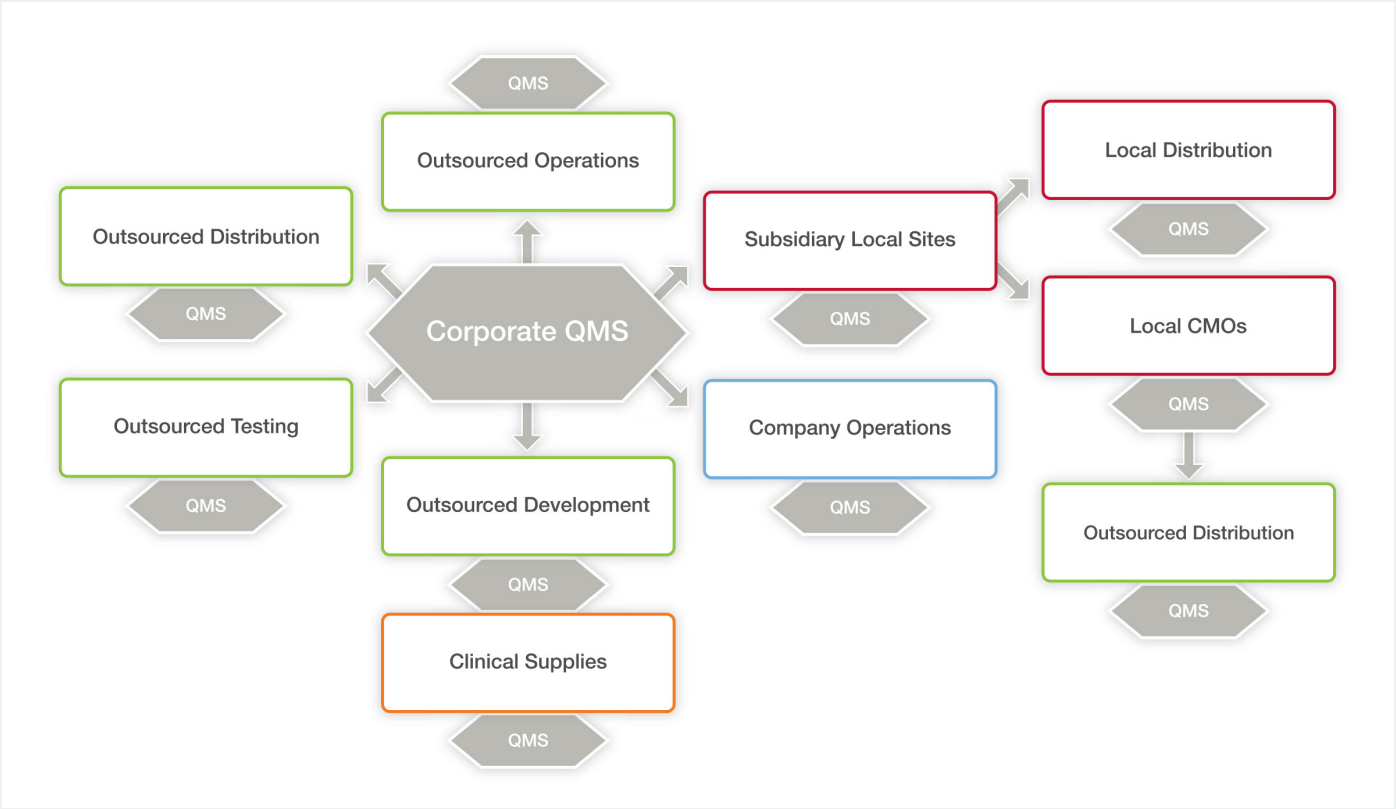
WHAT WE FOUND

Top management did not appreciate the impact the complex supply chain had on the management of quality and compliance, especially its own monitoring activities. There was no "map" of the supply chain and as a consequence the global quality function did not fully appreciate the extent of outsourced activities across the organization. There was no effective overview of the QMS at the senior management level. A quality management review did take place

occasionally in some units of the organization, but there was no review of quality and compliance at the top management level or any understanding of management responsibilities in this area.

The Corporate Quality team was expected to exercise a "light touch" approach. As a result, quality policy documents were seen as advisory and could be ignored. The Corporate QA function did not have oversight of the performance of many of the contracted operations which were mostly focused on new products. No part of the company, including senior management, had a view of the quality and compliance performance across the entire organization.

Furthermore, responses to regulatory inspections were not coordinated through Corporate QA so there was no corporate view of the commitments made to regulators. Finally, resources were heavily biased toward the delivery of new products so that the established products were inadequately managed and monitored and more vulnerable from the compliance perspective.



OUTCOME OF THE REVIEW

NSF RECOMMENDED:

- Senior management should discuss and agree to the extent of control or oversight to be exercised by Corporate QA, compatible with the oversight they wished to have from a regulatory and business perspective. The discussions were based on a number of models developed by NSF.
- Creating a global QMS designed to manage and monitor an organization where all products were developed, manufactured, tested and distributed using external organizations under contract and providing meaningful information to senior management to enable them to exercise their role of ownership and continual improvement of the QMS
- Developing key policies for those activities associated with managing and monitoring the external environment, leveraging the expertise of the staff already involved with managing that environment and other company experts.

The aim was to specify the minimum company requirements and ensure these were built into the quality agreements in an appropriate way. For example, how changes, deviations etc. should be reported, how the company should be involved in a recall of any of its products or how the APR should be compiled and reported.

- Using a series of measures including audits, regular reviews and metrics to monitor the "health" and compliance of the external environment at an external company level and a global level which is tracked and trended as far as possible in real time
- Establishing a Senior Management Quality Council including the VPs of Finance, HR and IT to own, monitor and continually improve the new QMS, meeting monthly, at least initially
- Establishing a formal system of quality planning to support continual improvement, managed by the senior management team and administered and supported by

CORPORATE QA

> Monitoring the external regulatory environment to include the development of company interpretations of new regulations for all regulatory regimes where the companies' products were sold

THE RESULTS

These recommendations when implemented would require some reorganization of the quality function and redistribution of the staff, along with a small increase in the total head count of the quality function. This increase recognized the increased regulatory burden over the last five or so years together with the need to manage the increased complexity of a predominantly outsourced organization from a quality perspective and to continually improve the products, processes and the QMS.

The implementation of these recommendations is currently a very active project within that organization and NSF continues to support its work.

ABOUT THE AUTHOR

David Selby has spent all his working life in the pharmaceutical industry, mostly in roles requiring knowledge of GMP and the regulatory environment.

After some years in research and development at Glaxo, David moved to international GMP compliance auditing, before becoming responsible for the manufacture of tablets, and then antibiotics at the Glaxo site in Co. Durham, UK. Subsequently he occupied the role of Site Quality Assurance Manager there and latterly, he was the Site Manager.

David is eligible to act as a Qualified Person under EU Law.

With this breadth of experience David is currently focussed on auditing, risk management, pharmaceutical quality systems and all aspects of validation and qualification.

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Cite as: NSF International. February 2018. QMS Re-Design Case Study. NSF: York, UK.

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