



Quality: from cost centre to value driver

Pharmaceutical and life sciences companies have won admirers for innovating quickly in a very tough situation this year. With unprecedented pressure on regulators and pharmaceutical organisations to bring COVID-19 treatments to market as soon as possible, we should expect quality functions within pharma companies to come under a brighter spotlight.

Based on our experience transforming quality functions with leading pharmaceutical companies, we see enormous potential for quality to act as a value creator across an organisation's operations. Here we assess the characteristics of high-performance quality functions and highlight areas of particular interest for the months and years ahead.



The role of quality: unlocking value by moving from a reactive to a fully integrated and holistic quality organisation

Pharmaceuticals is rightly one of the most regulated industries in the world. Quality assurance (QA) and quality control (QC) are the functions that make sure drugs adhere to regulatory standards and that all products are consistent through the manufacturing and distribution process.

Generally speaking, international coordination on regulations and standards is strong, and occurrences of real quality failures are few and far between. But these few failures can be fatally severe. The Thalidomide scandal in the mid-20th century is seared into our collective consciousness. More recently, manufacturing or packaging errors have had serious consequences like unintended pregnancies. On top of adverse medical outcomes, quality missteps can result in significant costs for organisations through recalls and fines, as well as impaired trust in brands.

With so much at stake, it is important to recognise that a quality function adds significant commercial value as well as preventing medical and commercial disasters. In a space as competitive as pharmaceuticals, standing still effectively means going backwards. Our view is that high-performing QA and QC functions should be fully integrated into the wider business, adding value right through manufacturing and product lifecycles. The best quality functions improve the work of all other departments within an organisation.

The remit of a quality function can vary dramatically from organisation to organisation, of course. In today's competitive market, quality organisations need to be faster, more agile, and more proactive in order to support their businesses (Figure 1).



Quality maturity

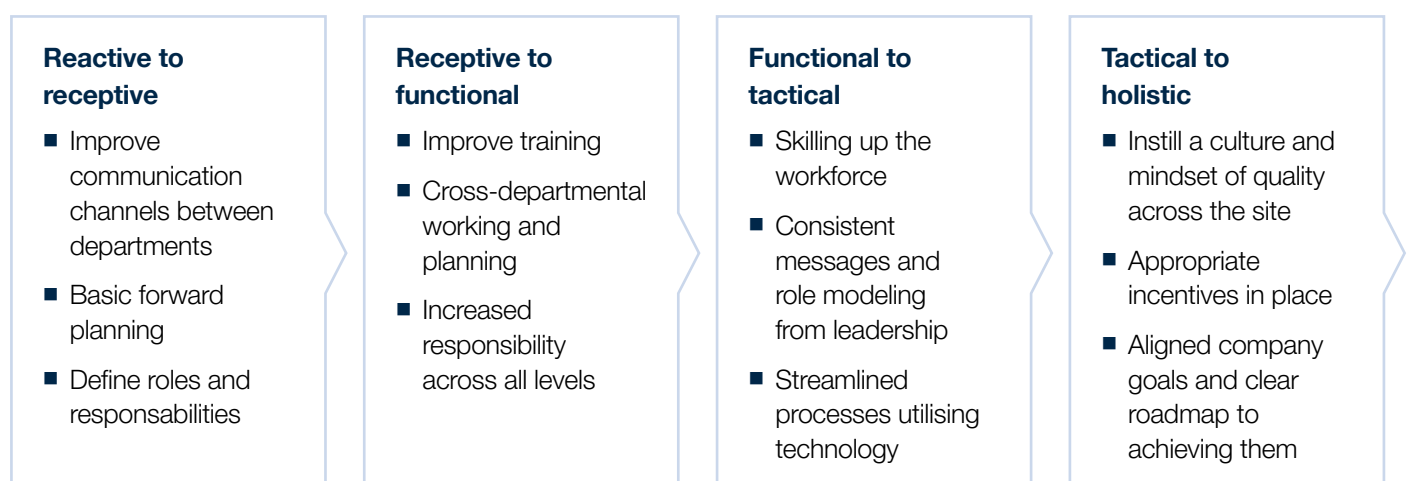
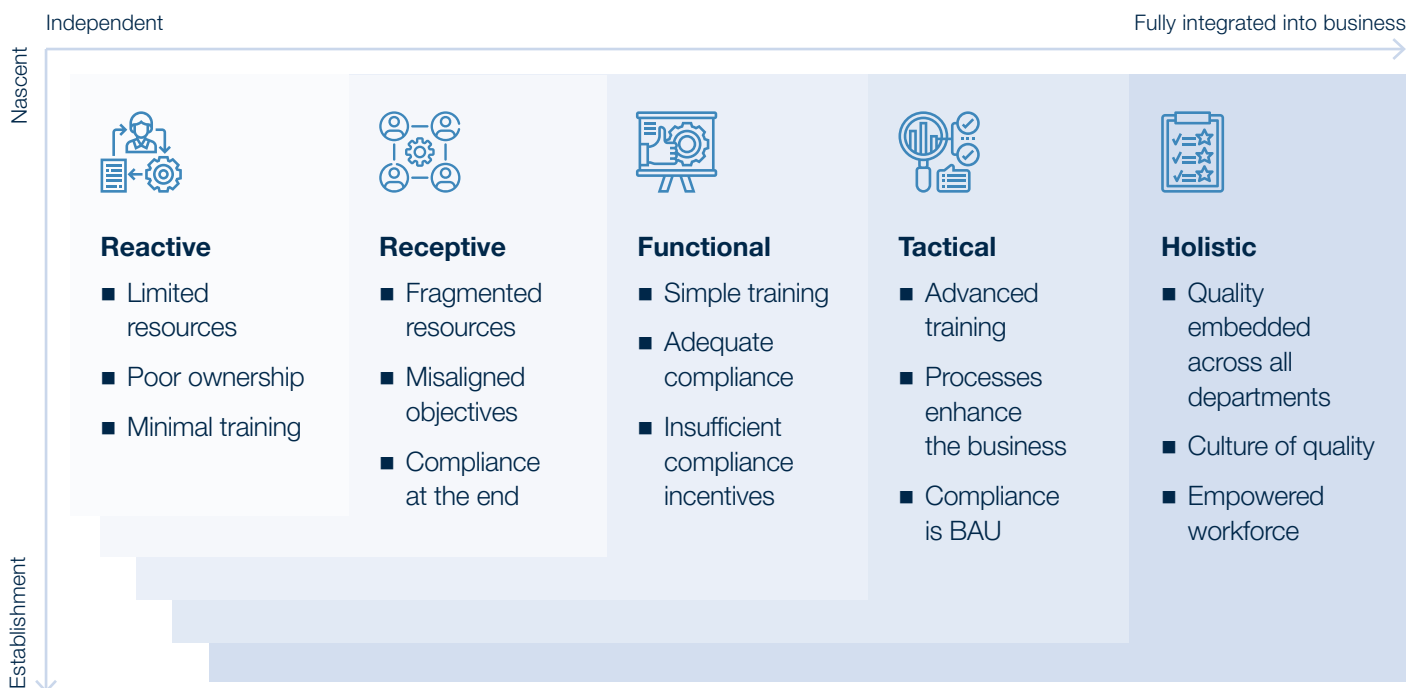


FIGURE 1: UNLOCKING VALUE BY MOVING FROM A REACTIVE TO A FULLY INTEGRATED AND HOLISTIC QUALITY ORGANISATION



Holistic quality functions are fully integrated into the wider business. The goals of a holistic quality function reflect the organisation's key strategic priorities, as well as being ruthlessly focused on regulatory compliance and upholding best-in-class standards.

So what are the benchmarks for best-in-class quality functions?

1 Managing CMO and CRO outsourcing partners

Contract manufacturing organisations (CMOs) and contract research organisations (CROs) have become more central than ever to pharmaceuticals and life sciences companies. They can deliver lower costs and increased flexibility as well as reducing time to market.

However, bringing third parties into the market access process inevitably increases complexity, and healthcare organisations have to make sure that any new growth opportunities through CMOs and CROs have to be underpinned by a laser focus on quality.

2 Effective data management and analysis

All divisions and functions within modern pharmaceutical organisations now leverage data in the normal course of doing business. Ensuring data integrity and handling data effectively is a process of constant maintenance and iteration that should be supported by a comprehensive strategic plan. For companies lumbered with legacy technologies and dealing with extensive physical records, COVID-19 could present opportunities to upgrade and reinvent systems.

Quality can be central to these efforts. Measuring success is critical to any quality function, and QC teams with strong data analysis skills can deliver value right through the organisation. Assessing quality implications when delivering system upgrades or managing commercial and operational transformations is also vital.

3 Look ahead at technologies and trends that could impact quality

Medicine is changing faster than ever before. Quality leaders must prepare for innovations that will drive change. Just one such example is the growing phenomenon of personalised healthcare, where new technologies will potentially increase the versatility of treatments and the range of bespoke use cases that a given drug can deliver. There are significant implications here for quality functions, and the best-performing leaders will be able to scope the market for the regulatory and operational changes required as different technologies become market-ready.





In our experience, transforming operations and performance within quality functions should centre on a rapid diagnostic assessment to identify ‘problem’ areas and key priorities for improvements. We have carried out this process within leading pharmaceutical manufacturers in around three weeks, rapidly delivering a baseline from which to measure subsequent achievements. From this point, efforts can be directed towards creating and sustaining a high-impact culture of continuous improvement that cements quality’s influence on the operations of the whole business (Figure 2):



FIGURE 2: A&M’S APPROACH TO QUALITY FUNCTION TRANSFORMATION PROJECTS

In pharmaceuticals, quality is directly linked to commercial growth, market share and brand reputation. High-impact quality functions are enablers of cross-business success, from R&D teams right through to sales and marketing. The companies that can most effectively integrate quality into business processes will be positioned for success in what remains a challenging market.



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119972 / October 20

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