University of St.Gallen
Institute of Technology Management

Organizational Set-up in QC

St.Gallen QCEx Meeting 2
Orientation Round – Meeting Reflection Paper
September, 2024

QCEx 2024

Jessica Helbling, Lorenzo Pirrone, Prof. Dr. Thomas Friedli - University of St.Gallen

Organizational Structure

How has the organizational structure evolved over the years, and what does it look like today? What have been the benefit, limitations, and key learnings from these changes and the current structure? How should the structure evolve to meet further business needs, and what opportunities could new potential structures present?

In recent years, companies in the QCEx community have further developed their QC organizational structure to meet both local and global requirements. Traditionally, the QC department was organized locally, with lab managers reporting directly to site managers or the respective quality heads. This structure enabled alignment with local requirements but led to process fragmentation and limited synergies between sites. Around 2022, the QCEx community experienced a shift towards a global approach, particularly in promoting standardization and digitalization. This shift has improved the connectivity of QC across different locations, while harmonizing processes to increase efficiency.

The transition from local to global structures has, among other things, brought progress in process optimization, digitalization and KPI monitoring. The use of global QC functions offers the opportunity to standardize decision-making and establish a unified process landscape. That, however, comes with the disadvantage of increased coordination effort. A key lesson for companies within QCEx is the importance of not underestimating the challenges associated with change management. Successfully navigating the transformation from local to global requires more than just structural adjustments – it involves fostering a culture of adaptability. Moreover, clear communication, well-defined roles, and continuous training for employees at all levels are crucial to ensuring a smooth transition and sustainable integration of new processes.

Global vs. local – Roles & Responsibilities

What are the respective roles and responsibilities at the global and local levels within your organization (e.g., network management, compliance management, planning & testing)? Which topics should be managed globally vs. locally? What does decision-making look like (e.g., how often and in what form do global and local teams communicated, are there any veto rights)?

Global QC departments are primarily responsible for developing and implementing processes, and global SOPs. They design and monitor the QMS (Quality Management System) and promote CI (Continuous Improvement), as well as harmonization of processes, methods, and standards across the organization. Global committees often provide strategic direction, optimize processes, and ensure knowledge sharing across the network. They support local QC departments in implementing and adapting global guidelines and supervise strategic decisions. According to the QCEx community, global QC teams are responsible to standardize IT systems and laboratory equipment to increase efficiency and reduce the complexity of site-specific solutions. For example, implementing a global LIMS allows all sites to use a unified platform for data management. This not only streamlines

operations and minimizes the need for tailored local solutions but also improves data integrity and facilitates collaboration.

Local QC departments normally focus on testing, compliance, and site-specific project support. Local teams are responsible for planning, executing, and adapting global guidelines to the individual requirements of their sites. Topics such as method transfer and compliance are also implemented locally, while maintaining exchanges with global teams.

Decisions are usually made in close collaboration between global and local teams. Global guidelines and projects are defined in consultation with local units. The QCEx companies strives to foster an open culture that encourages dialogue and collaboration, where formal veto rights are rarely used. This means that disagreements are typically resolved through discussion rather than authoritative decision-making. Regular meetings, networking events, and other exchange formats ensure continuous coordination and promote knowledge sharing.

Global vs. local – Key Business Partners & Collaboration

What are the key business partners at each level (e.g., supply chain, production, R&D)? How do global and local QC teams collaborate with these key business partners?

According to the QCEx community, QC closely collaborates with business partners at both the global and local level.

At the global level, IT, Supply Chain, R&D and Finance are the most important business partners. Global QC teams work with them to make strategic decisions, integrate technologies, and define global standards. IT is an essential partner for digital transformation initiatives, while Supply Chain and R&D are central to the development of new products and preparation for market launches. Regular meetings are held between global QC and the key business partners to ensure that projects and priorities are aligned.

At the local level, QC teams work closely with Production, Supply Chain, IT, and other local functions such as EHS (Environment, Health & Safety). Local teams collaborate with the aforementioned partners to improve QC. In particular, collaboration with Production and Supply Chain is crucial to ensure that testing is performed smoothly and in a timely manner. Most companies rely on daily meetings to ensure close coordination and fast response times. In addition, regular exchanges take place with R&D to ensure that all relevant QC processes are established when a new product is launched.

Strategic Insourcing vs. Outsourcing

Under what circumstances is it advantageous to insource or outsource testing activities? How do these decisions impact quality standards, costs, and organizational agility? What strategies ensure a smooth transfer of activities between different labs within a site?

Most companies within the QCEx community have no clearly defined sourcing strategy for testing activities. Instead, these decisions are often made on a case-by-case basis, based on factors such as project requirements, technology availability, costs, and organizational flexibility.

Outsourcing is often used for complex or rarely needed processes. This option is also useful when there are resource bottlenecks, whether due to a lack of equipment or personnel, especially in cases with a high degree of technical complexity. Outsourcing can thereby help avoid capacity bottlenecks and prevent the risk of long-term internal overcapacity. On the other hand, outsourcing is associated with high costs. In addition, the outsourced activities must be monitored to ensure that quality standards are met. Furthermore, the agility of the organization can suffer because external dependencies are built up and decision-making paths can become longer.

Insourcing offers advantages when timely response and a deeper process understanding are required. For example, site-specific issues can be efficiently investigated because internal teams have direct access to production processes and data. In addition, insourcing typically enables shorter lead times and better prioritization of tasks.

Concerning the transfer or activities between different labs within a site, the QCEx agrees that a seamless transition of activities between labs requires a consistent infrastructure, including identical QMS, IT platforms, and equipment. Furthermore, standardized processes and clear responsibilities are crucial to avoid delays and quality issues. To ensure that transfers are efficient and effective, a careful co-validation should be carried out and a dedicated project team should be commissioned.