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How are Quality Culture and a Symphony Orchestra Similar?

by Doris Borchert, PhD

When was the last time you went to a concert? What images have stuck? The conductor guiding his orchestra through the repertoire with grand gestures and high commitment? The first violin, connecting conductor and orchestra? Or the musicians working as a coordinated team, bringing the music to life? Either way, hopefully it was an amazing experience.

Quality culture is like a symphony orchestra with the CEO as the conductor and quality management plays as the first violin:

A high-quality experience in a symphony orchestra relies on the perfect interplay of all participants. Even small discords can affect the overall artistic experience. The situation is very similar when it comes to GMP: A standardised quality culture throughout the company is key to achieving a flawless quality result.

The following questions are addressed in detail:

- What is quality culture?
- What are the prerequisites to establish a strong quality culture?
- What are the elements of a successful quality culture?

Quality Culture

The existence of a quality culture, its evaluation, and further development are referred to in various documents – especially those authored by the FDA. However, a clear definition of the term 'quality culture' is not yet anchored in the GMP regulations. While researching the definition of the term "quality culture", I came across different variants. I preferred the following paraphrase:

"Quality culture is a fusion of quality awareness and quality-orientated action." The same text says: "Within an established quality culture, quality is unconsciously understood and implemented. Quality is not limited to the characteristics of a product or a process, but also includes people and the organisation in which they find themselves."

Long before the term quality culture found its way into the GMP world, a paradigm shift in the way organisations deal with quality has already emerged:

From detecting real existing defects in the sense of quality control to preventing potential defects in the sense of quality assurance to proactive quality management. The introduction of quality culture concepts is a consistent continuation of this development.

This makes quality culture a cornerstone of successful pharmaceutical companies.

The Pre-requisites

Promoting a culture of quality is not a sure-fire success but involves a number of challenges.

The cornerstones of a sustainable solution are active quality management and a clear quality policy that sets the tone for the company's communication and strategic direction regarding quality.

Employees often complain that the quality policy is formulated too generally and is therefore not very meaningful. In fact, it is not easy to condense the content of the entire PQS into a few principles of a quality policy.

Concise formulations are therefore important. Abstract goals must be turned into concrete projects with clear tasks and responsibilities. And it goes without saying that the quality policy must be formulated in a credible manner. A company that has been cutting jobs for years and forgoing further training is not very convincing if it emphasises how important it is to promote and develop its employees.

Last but not least, well-functioning PQA processes must be implemented.

If we recall the image of a symphony orchestra, the conductor stands for active quality management, the score for the quality policy and the instrument groups embody the individual elements of the PQS.

The Elements

Each company must find its own way to establish a successful quality culture. However, there are some common principles which are briefly outlined below.

Quality First!

In practice, this means that business interests must not get in the way of consistently meeting quality requirements. Of course, it is important to avoid time pressure or delivery bottlenecks as far as possible, but the ability to deliver must never take precedence over quality.

Quality always comes first!

Personal Responsibility

Quality is not a question of individual people, such as the Quality Manager or the Qualified Person, nor of individual departments, such as Quality Assurance or Quality Control.

Quality is the responsibility of everyone!

Therefore, quality awareness must be developed and maintained across all departments and hierarchies. This is especially the responsibility of the management. Quality culture starts at the top of the organisation and must be communicated and lived by the management.

Like a conductor, top management sets the pace and is responsible for ensuring that everyone internalises the desired quality culture.

Management Tasks

- Communication of expectations
- Meaningfulness of processes
- Role modelling
- Accountability
- Business involvement
- Setting of realistic expectations
- Provision adequate resources
- Monitoring of regulatory trends



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The Organisation

In addition to management tasks, quality management plays a crucial role. Just as the first violin in an orchestra sets the tone, quality management ensures the structure, organisation and coordination of the individual instruments – excuse me: PQS elements – with each other.

Change and deviation management, CAPA, complaint handling, self-inspection, and training all need to work together.

But just as it is not enough for everyone in a symphony orchestra to be able to play their own notes, the right interaction is also important here! This requires communication within the orchestra, but also coordination with the conductor, to stay with our metaphor.

Quality Management Tasks

- Establishment of structures
- Process organisation
- Facilitate the communication
- Coordination with senior management



The Culture of Error

Nobody is perfect. You should allow yourself and others to make mistakes. Of crucial importance is the way you deal with mistakes. You need to be aware of the potential consequences of mistakes and be watchful enough to spot them.

Openness, trust and appreciation are important when dealing with colleagues, superiors and employees, especially so that mistakes are not concealed out of fear or shame. Transparent communication about errors, their causes and actions, as well as their significance, is the basis for quality awareness at all levels.

Open and good cooperation is therefore an important pillar of the quality culture. Under no circumstances should anyone be blamed or stigmatised for making a mistake. On the contrary, one should be rewarded for recognising a mistake and reacting correctly.

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