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Does Your Biologics CDMO Truly Have a Culture of Quality?

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Having a culture of quality is a characteristic claimed by most biopharmaceutical industry organizations. But what is a culture of quality, and how do you know if a biologics contract manufacturing and development organization (CDMO) can earnestly make this claim?

There was no better person to help answer this question than Joe Payne, Scorpius' President and COO (formerly the Vice President, Quality and Regulatory Affairs) at Scorpius BioManufacturing.

Joe has had a long and highly successful career in quality management and regulatory affairs well before joining Scorpius, including global regulatory compliance management for Teva Pharmaceuticals, Vice President of Quality & Regulatory at Alcami, and Vice President of Quality and Compliance at Tergus. Joe discusses his experience and vision of effective quality and compliance with Tonia Becker, Strategy Director, Nice Insight.

Tonia Becker (TB): How can you tell if a biologics CDMO has a culture of quality?

Joe Payne (JP): I've walked, audited, or assessed nearly 100 different pharmaceutical facilities and interacted with thousands of professionals at all levels – from CEOs to floor-level operators.

Virtually every pharmaceutical company has a quality culture statement of some sort. However, I have defined four characteristics that indicate whether the organization truly has a culture of quality.

First, does the company's CEO regularly mention quality in their internal and external communications, like speeches, statements, and interviews? Quality is the price that must be paid to succeed in this industry. The organization's quality culture is likely lacking if the commitment at the highest levels of the company is weak or not communicated clearly and regularly.

Second, a culture of quality means that the organization is continuously improving. Continuous improvement requires managing,

properly addressing, and closing out quality events like change controls, corrective and preventive actions (CAPAs), and formal deviations. If these issues accumulate without being addressed, the facility is not dedicated to continuous improvement, a requirement to claim a culture of quality.

Third, I look for whether the organization employs a formal process improvement construct outside its quality systems. Perhaps the construct is Lean manufacturing or Six Sigma. The selected approach must be an established system to improve the costs and/or effectiveness of the organization's processes.

Finally, a characteristic that can be difficult to judge for those outside the organization is openness. When walking the floor of a plant, if supervisors allow floor-level personnel to speak freely, there is trust, which is a great indication that there is a strong culture of quality. However, free-flowing communication from floor-level operators can be difficult to judge during a site tour because CDMOs are managing confidentiality issues, but this is a dynamic to consider.

TB: How is quality most effectively structured within a CDMO?

JP: Corporate quality and regulatory professionals translate all applicable regulatory guidances into manufacturing protocols and quality assurance testing procedures.

The established protocols and procedures must then be executed. On the biomanufacturing side, generally, the quality management floor team should not question the procedures themselves. Instead, their role is to examine whether procedures and master records are being followed.

Sometimes process adjustments must be made to save a batch, and the expertise of the floor-level team is extremely valuable when these challenges occur. However, the floor-level team must clearly record and sign off on any necessary adjustments.

From a testing and quality assurance standpoint, the same dynamics exist. Lab-level analytics professionals ensure the product produced falls into the documented acceptable ranges based on critical quality attributes. These professionals are generally microbiologists or chemists because interpreting analytical results requires considerable expertise.

Finally, the compliance group on the floor can audit everybody, including the quality unit. They must be impartial and have the authority to raise issues as needed. Essentially, the compliance group is the CEO's last line of defense before a product is shipped.

TB: How are quality systems different across the various classes of pharmaceutical products?

JP: It's a common misunderstanding that the core constructs of quality systems for different modalities are different. In fact, the demands of Good Manufacturing Practice (GMP), Code of Federal Regulations (CFR) 210 and 211, and Q9 Quality Risk Management guidance are the same across all drug classes.

The differences manifest in the complexity and stringency of the processes themselves, as there are different regulations for different classes of products. For example, the regulations for aseptic injectable products are more stringent than those for active pharmaceutical ingredients (APIs). The specificity resides in the processes, not in the requirements of what needs to be documented, how it needs to be documented, how long the records need to be retained, how the records need to be controlled, and what needs to be qualified.

TB: How do you know if you have a quality problem or a regulatory problem?

JP: This is a frequently asked question with a straightforward answer. A quality problem is when your internal team has discovered problems or deviations and resolved them without marketed material or filing impact. A regulatory problem exists when there is a marketed material or filing issue that is either voluntarily submitted or, worse when regulators learn of the issue during an inspection.

TB: What are some of the most important areas of value a CDMO brings to its clients?

JP: One of the essential ways an excellent biologics CDMO can add value to its clients is by perfecting change—being highly effective change agents.

By thoroughly understanding the processes involved and recommending ways to improve those processes continuously, a CDMO should be able to make changes to the processes, people, and documentation so that quality issues never occur and processes continually improve.

Often, clients with an early-phase product come to us unsure of how to navigate the later phases of development, ultimately to commercial production. They also often need guidance regarding the conversations that need to be held with regulators.

A CDMO partner helps clients navigate these challenges and takes full responsibility for the quality of the end product at every phase of development.

TB: How would you summarize Scorpius BioManufacturing's quality culture?

JP: Our expertise is the heart of what differentiates Scorpius BioManufacturing from our competitors and is the foundation on which our quality of culture is built.

Between the senior management team and the technical scientists, engineers, and operators in the organization, there are many decades of industry experience in all aspects of the market, including quality, regulatory, and compliance.

We are honest communicators in our client relationships, allowing us to be highly effective change agents and truly take ownership of the programs we run.

We specialize in working with emerging companies with unique therapeutics; organizations that need our expertise. We treat their molecules as our own, which drives a proactive approach to quality and continuous improvement.

At Scorpius BioManufacturing, leading with quality is simply non-negotiable. It's who we are.

ABOUT THE AUTHOR

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