Quality Assurance And Your CDMO

It's no longer just a cost of doing business; your outsourced manufacturing partner's approach to QA can save you money and reduce time to market.

Like you and every other developer and manufacturer in our space, we is held accountable to quality standards by a host of regulators with indisputable requirements and expectations. The scrutiny is constant and the standards high, but none of this is necessarily unique to us. Compliance with industry guidance and client requirements is a fact of doing business in biopharma.

There is an inherent advantage in having experience from different angles (both as a customer receiving services and as a CDMO providing services). These perspectives have contributed to the development of QA processes that provide ample room for efficiency-enabling flexibility, differentiation, and cost savings.

What Is "Quality" In Biopharma?

While the end result of regulatory compliance with quality standards is binary, the processes employed to get there do not need to be rigid, prescriptive, inefficient, and expensive. In fact, updating quality assurance strategies and business practices with a healthy dose of flexibility and innovation can create an important point of differentiation by driving lower costs and higher efficiencies. We will explore some examples of said flexibility and innovation here, but first, let's level-set on the central tenets of quality.

The four pillars of an effective and compliant QA program are:

- **Safety:** Is the product safe for the customer to use? Has a device or device-enabled therapy minimized the risk of injury? Have all side effects been explored and disclosed?
- **Reproducibility:** Can we do it the same way every time in a consistent manner? Does the product perform the same every time?
- **Effectiveness:** Does the product do what it's supposed to do?
- **Customer focus:** Is the customer experience positive and expected?

If these tenets serve as our guide, compliance with regulatory requirements will follow. To ensure that we're continuously tracking toward these pillars, the monthly review of deviation, compliance, validation, and reproducibility metrics is a best practice.

Again, there is nothing incredibly unique in this *philosophy* on quality compliance. The real opportunity for differentiation lies in the *strategy* and *tactics* deployed to support these tenets and the *culture* developed among the people tasked with executing on that strategy.

Means To A Quality End

There is no denying that the time and cost commitments associated with implementing and maintaining a quality compliance initiative is seen as a barrier by some in biopharma organizations, particularly the R&D and manufacturing departments. Often, this perception is reality. Quality assurance requires checks and balances and measurement, and these cost time and money.

The degree of slowdown correlates with the organizational QA/QC processes in place. Adherence to legacy quality processes often results in tighter, efficiency-killing bottlenecks that cost more money than necessary and slow time to market. Many organizations, though, are hesitant to consider more innovative approaches

to quality assurance efforts. Why? Is there an unwritten rule or code that suggests the means to achieving a quality outcome must match the unforgiving rigidity of the quality requirement itself?

The focus is on maintaining a quality system which is effective in meeting the necessary regulatory requirements, yet also efficient both from a process and cost standpoint.

- **The quality philosophy:** It does not involve the dreaded "red tape" caused by inefficient procedures and administrative systems, which reduce response time and decision-making.
- **Personnel:** That at the appropriate levels are empowered to make decisions and move the process along without the need for unnecessary upper level escalation and approval.
- **Procedures:** They are streamlined and direct and do not contain additional out-of-scope or non-value-added requirements.

As expected in today's industry, many of our quality systems (including deviation, corrective action, preventive action, change control, training, and lab data management) are currently paperless, adding to our efficiency efforts. Yet, we also understand the need to be flexible when working with our customers. Our extensive experience in managing quality allows us the expertise to quickly and seamlessly create quality processes specific to our clients as applicable.

Technology Supports QA/QC Efficiencie

An average chemical quality control lab can reduce costs by 25 to 45 percent by reaching the digitally enabled lab horizon, pegging potential savings at an average microbiology lab in the 15 to 35 percent range. In its definition, defines "digitally enabled" labs as those achieving at least 80 percent paperless operations.

These savings, the authors say, come from two primary sources:

- The elimination of up to 80 percent of manual documentation work.
- The automation/optimization of planning and scheduling to improve personnel, equipment, and materials usage.

The next step toward digitization is electronic batch records. While digitizing once paper-based processes requires a bit of extra effort up front — such as the development of good IT backup processes and compliance with mandates such as FDA 21 CFR Part 11 guidance on electronic signatures — the back-end ROI and efficiency gains are demonstrated. Fewer manual errors and data-enabled analyses of root causes help labs reduce investigation workloads by as much as 90 percent.

A Consultative Approach To Quality

New technologies aside, it's also important to remember that the approach to achieving quality standards is not a one-prescription-treats-all proposition. In our CDMO operation, we produce a range of materials from raw materials to drug substance and active ingredients for further manufacture for clinical trials and approved products. Quality assurance tools allow us the flexibility to develop a quality strategy — through concerted consultation with the client — that is commensurate with the client's needs.

For example, validation of the manufacturing process and QA oversight is a requirement for a commercial therapeutic product but is not necessary — and would be inappropriate — for material produced for early stage clinical trials, where the process is still undergoing changes and will be scaled up for long-term manufacturing. Environmental monitoring can range from monthly static monitoring with reporting and trends to dynamic reporting on every lot, with actions and alerts depending on the need of the client, product

type, and development stage. The goal is to determine the right conditions for the product without overburdening the project with unnecessary costs and time.

Many manufacturers and CDMOs tend toward a blanket approach to quality controls, ignoring the fact that requirements are very project-specific. Adjusting the approach accordingly to avoid unnecessary and costly steps can yield substantial savings while keeping the project "in bounds" of the desired regulatory outcome. We have developed a systematic, client-centered approach to determining the appropriate level of quality control required on a project-specific basis.

Quality Is A Culture

The value of culture in quality assurance and control programs is inherently difficult to measure, but it is even more important than technology and tools. A quality department with a good cultural environment is marked by:

- **Staff:** An experienced staff.
- **Innovate:** Encouraged to innovate.
- **Unencumbered:** Unencumbered by red tape.

We attribute that longevity to creating a flexible work environment where efficiency-enabling innovation is rewarded, not stifled by the debilitating "this is how we've always done it" excuse.

The technologies enabling the innovative approaches to quality assurance and control are widely available today. It is up to the industry to embrace and employ them, and to encourage flexibility and innovation on the path to regulatory conformation. The future of quality is in being able to exceed customer expectations through increased efficiency while continuing to manufacture safe and effective products. Technology advances in addition to a strong training program and experienced QA teams who collaborate with manufacturing are key to reaching our potential.

Reference: Quality Assurance And Your CDMO (pharmaceuticalonline.com)