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WHITE PAPER

5 Critical Keys to Avoid Derailment of Drug Development

Delaying the Application of a First-Rate Quality Systems is Risky Business

Any responsible business or industry takes quality seriously. It's crucial to customer safety and satisfaction, and its prioritization in the development of healthcare products and services – especially pharmaceuticals – is obviously even more so. There are probably fewer other endeavors in which data, consistency, and validation are more important.

Seemly, healthcare-related quality regulations have grown more stringent, though regulators will say that the expectations have always been the same.

Nonetheless, it can be easy in development for smaller teams and companies to overlook some components of Quality, despite governmental requirements around complex quality initiatives. Those concerns are well-founded, given the nature and purpose of drug development, and that interest is validated in that FDA inspections are directly correlated with improved product quality.[1] It is also evident that this attention has a positive impact on a company's bottom line, primarily through increased customer satisfaction, sales, and elimination of waste and overproduction.[2]

There are five critical keys to avoiding derailment in the process of developing new pharma products.

KEY 1

Establish and Implement a QC Process Control Strategy Immediately

This should be done in full awareness that education around the pharmaceutical quality control supply chain process is crucial to successful implementation. Establishing a system clarifies policies and objectives based on the organization's scope of activities, including the type, range, and frequency of testing, calibration, validation, and verification.[3]

Process control strategies can be categorized as "retrospective feedback control," a system based on monitoring quality within the parameters of the manufacturing processes and provide correctives to assure quality. The other is "perspective feedforward control," which utilizes intrinsically high-performing control strategies that spark corrective actions before disruptions occur.[4]

SOURCES
1 https://www.pharmaceuticalonline.com/doc/developing-optimal-pharmaceutical-quality-control-strategies-0001
2 https://www.applerubber.com/blog/the-lasting-effects-of-quality-control-on-your-bottom-line/
3 https://www.machinemetrics.com/blog/quality-control-in-manufacturing
4 https://www.applerubber.com/blog/the-lasting-effects-of-quality-control-on-your-bottom-line/

KEY 2

Create and Execute a Standard Operating Procedure (SOP) Manual

Create and execute a Standard Operating Procedure (SOP) manual immediately to clearly outline the QC system and its complexities, including who is responsible for what, when, how, and more. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Good Clinical Practice (GCP) guidelines define international ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve human subjects.[5] They define SOPs as "detailed, written instructions to achieve uniformity of the performance of specific function." [6] They establish systems for ensuring that all the people charged with consistently performing the same tasks are doing so in full compliance with the SOP.

Obviously, SOPs must be plainly written, user-friendly, and unambiguous. They must also remain subject to revision and changes as learnings developed throughout the process of drug development make alterations or changes necessary, all the while remaining compliant with company standards and applicable legal, ethical, and regulatory requirements. SOP is mandatory for the implementation of GCP, GxPs (Good x Practices), primarily cGMPs (Current Good Manufacturing Practices) and GLPs (Good Laboratory Practices). In effect, without SOPs, there are no quality control systems, so the importance of a high-quality SOP manual cannot be overstated.

This does not mean you need to duplicate your contracted partner's SOPs and you certainly should not contradict them. The sponsor's SOPs should be detailed around the activities performed in-house and point to where the contracted partner's SOPs intersect. A risk assessment should be documented to justify oversight levels.

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5 https://www.edapp.com/blog/quality-control-issues/

6 https://www.technologynetworks.com/drug-discovery/articles/importance-of-quality-control-during-drug-development-368119

KEY 3

Understand the Complexities

Understand the complexities of the treatment being developed, especially as personalized medicine is on the rise and, with it, even more complexities around quality. Its impact on the marketplace is expected to be massive. In fact, the market for new cell and gene therapies is expected to be more than $36 billion by 2027.[7]

The potential for innovation-driven profit in the development of ever more niche medicines has driven significant changes in the drug development process. Companies are conducting more complex trials with smaller, focused patient populations highly dependent on precise identification of biomarkers that have resulted in regulatory challenges, as existing standards are always at risk of constantly lagging behind scientific innovation.[8]

Combining new technologies and innovations in the effort to develop exquisitely precise treatments has driven approximately 35 new research projects at Sweden's Testa Center in the last three years alone.[9] In an increasingly competitive healthcare landscape, in which the pace of innovation is driven by speed to market as much as bringing new, lifesaving therapies to patients, the myriad intricacies around every stage require more intimate levels of understanding than ever.

7 https://www.pharmaceuticalonline.com/doc/developing-optimal-pharmaceutical-quality-control-strategies-0001

8 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3088954/

9 https://www.rockwellautomation.com/en-nl/company/news/presentations/innovation-in-biopharma.html

KEY 4

Building a Strong Quality Culture

Building a Strong Quality Culture is as crucial as ever in scaling treatment efficiently. Addressing issues, thoroughly understanding them, and having plans in place to avoid them in the future is a must. Pharmaceutical companies should plan and execute a system for monitoring all aspects of process performance and product quality to maintain ongoing and effective controls.

ELT must be engaged in quality-related activities. The company's mindset should be that quality is everyone's job. Risk assessments should be developed to justify levels of oversight of your contracted partners.

A CAPA (Corrective Action and Preventive Action) plan ensures that clear protocols are in place for the investigation of the root cause analysis of disruptions at any stage of research, development, and testing. The plan should clearly describe actions to be taken, assign responsibilities, and target progress and completion dates. To ensure organization-wide buy-in, the plan should be approved by leaders of each quality initiative, their managers, and senior leadership within the organization itself.[10]

10 https://www.gmpsop.com/fundamentals-of-quality-control-practice-in-pharmaceuticals/

KEY 5

Consult Experts

Highly trained and skilled QC professionals with deep knowledge of the pharmaceutical industry as a whole can be a more viable resource than someone on a drug development company's staff. For small companies, consultants provide flexibility based on the nature of the work and financial outlay. Midsize or larger companies may also appreciate the value of outside consultants when venturing into new areas or when augmenting internal resources.[11]

For many small biotechs, it can simply come down to cost and headcount. Many such firms are unable to employ a full-time quality specialist, so the consulting model provides a better fit for intermittent needs. Additionally, they may need immediate access to deep skills in highly specialized areas, and in the event of actions taken against the company, health authorities may request or even require that consultants review the organization's quality systems and remediation plans.[12]

Another benefit of engaging consultants is the wide range of expertise they can bring to a program that has multiple stages of development and testing, each with their own QC guidelines, plans, and requirements. At the most basic level, engaging outside consultants can be highly pragmatic and drive multiple efficiencies. Since engagements are contract-based, the timeliness of deliverables can be assured, which then keeps projects on schedule and within budget.[13]

11-13 https://www.pharmtech.com/view/consulting-quality

Top Quality QC Programs Need Top Quality QC Partners

Remembering, and implementing, the 5 Keys and their importance in the development of healthcare products, particularly pharmaceuticals, cannot be overstated. Stringent regulations and the use of enterprise resource planning software have become necessary to ensure patient safety, compliance, and public trust. By focusing on these strategies: implementing a robust QC process control strategy; creating comprehensive Standard Operating Procedure manuals; understanding the complexities of the treatment being developed; emphasizing a strong quality culture; and leveraging the expertise of consultants, companies are significantly more likely to successfully navigate the ever more intricate landscape of drug development.

These measures not only contribute to improved product quality, they also enhance customer satisfaction, increase sales, and minimize waste. As the healthcare industry continues to evolve and personalized medicine gains momentum, maintaining a strong focus on quality control is vital to meet the demands of a competitive market and deliver innovative and precise treatments to patients.

Proactive, goal-oriented companies will not delay implementing these 5 keys. That process is made more efficient, and success more likely with a partner like Syner-G, a leader in supporting life science organizations across the development continuum since 2007. Comprehensive technical, quality, and regulatory services supports the development of innovative discoveries with life-enhancing and life-saving impact.

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