



The Six Subsystems of a Pharmaceutical Quality System

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Risk taking is an important part of any business endeavor. Entrepreneurs and investors take risks every time they fund a start-up. Business executives take risks every day as they make decisions about which products, services, ideas and people to advance within an organization. Risk taking can be enormously profitable. But in the pharmaceutical industry, excessive risk taking can have devastating results; product delays, recalls, and enforcement actions by the Food and Drug Administration (FDA) have led to the demise of many small- to mid-size pharmaceutical manufacturers. Most importantly, consumer safety can be compromised by excessive risk taking. In the pharmaceutical industry, risk must be tempered by caution. And the mechanism for tempering risk is a robust pharmaceutical quality system based on the latest FDA guidance.

Quality cannot be an afterthought. Implementing an effective quality system involves up-front costs. An effective quality system should be in place at the earliest stages of product research and development. While the pursuit of quality can be a costly line item on a financial statement or business plan, failure to implement an effective quality system can have even more costly effects on the bottom line.

Based on the latest guidance from the FDA, an effective pharmaceutical quality system should help ensure compliance with cGMPs by focusing on:

- Quality management
- Quality assurance
- Evaluation analysis and quality risk management tools
- Preventive action
- Risk management
- Continuous improvement

This latest guidance does not replace previous FDA regulations, which require every pharmaceutical quality system to include Standard Operating Practices (SOPs), adequate personnel and training systems, and an adequate



system for recordkeeping. The new guidance is simply aimed at addressing advances in manufacturing technologies, quality systems and risk management approaches that have been developed since 1978. The latest guidance is also aimed at harmonizing the cGMPs with other widely used quality management systems, including the FDA's own medical device quality system regulations. Developing a modern, quality system approach can provide the necessary framework for implementing continuous improvement and risk management efforts in the drug manufacturing process.

While a culture of quality should permeate the entire organization, management plays a very important role in the successful functioning, design, implementation and management of a modern quality system. Not only should management align the quality system plan with the company's strategic plan, it must demonstrate strong support for quality systems. It's essential for senior leaders of pharmaceutical manufacturers to encourage internal communication about quality issues and support the production, quality and manufacturing activities needed to produce quality products.

But what does a modern pharmaceutical quality system look like? Imagine the hub and spokes of a wheel. The quality system itself is at the center (the hub), but it is connected to five other manufacturing systems (the spokes). When you include the quality system as a subsystem at the center of it all, the six subsystems of a modern pharmaceutical quality system are the:

- Quality System
- Production System
- Facilities and Equipment System
- Laboratory Controls System
- Materials System
- Packaging and Labeling System

The quality subsystem at the center provides the foundation for the five manufacturing subsystems and helps them achieve compliance. Each subsystem has an impact on the others and they all have to work together to consistently produce a quality product. But it's important to understand that none of the individual subsystems equate to a functional group in an organization or manufacturing facility. For example, the Materials System does



not simply apply to warehouse personnel. This subsystem includes the warehouse personnel who receive, store and handle components and raw materials and distribute final products, but it also includes the purchasers who buy components from qualified vendors, the manufacturing workers who request and receive components and transfer final products to the warehouse, the quality assurance specialists responsible for component and lot release, and the quality control employees who sample and test components and products.

In the coming months we will take a closer look at each of these subsystems in the hopes it will help you develop and maintain a strong overall quality system in your organization. In the end, firms with strong quality systems will be more likely to meet and exceed cGMPs while also enjoying many other advantages, including improved product and process understanding for better decision making; continuous improvement; the ability to manage change to prevent unintended consequences; minimized product variability; enhanced test method accuracy; reduced costs due to fewer investigations, deviations and rejections; minimized product loss and costs associated with scrap, disposal, rework and recalls; reduced downtime with more reliable equipment and fewer repair interruptions; and decreased labor costs associated with automation of manufacturing processes.

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