



Achieving GMP/GLP Compliance through More Efficient Equipment Validation

Streamlining the qualification process results in better business outcomes and increased productivity

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In the pharmaceutical and biotech industries, the validation of laboratory instruments and equipment is a crucial part of good manufacturing practices (GMP) and good laboratory practices (GLP). It ensures that equipment functions as intended, delivers precise and consistent results, and meets the defined parameters.

Lab managers already know the importance of GMP and GLP requirements and the challenges associated with the validation process. Here, we offer guidance and helpful tips to expedite the process without compromising compliance. By following this insight, lab managers and their teams can streamline the process, achieve success, and maintain GMP and GLP standards.

The benefits of efficient validation processes

One significant advantage of simplifying the qualification process for lab managers and teams is the improvement in overall efficiency. By reducing the complexity and number of steps in the process, laboratory teams can complete qualification procedures quicker and with fewer resources. This can increase productivity in the laboratory and free up valuable resources to focus on other essential tasks. In addition to efficiency, simplifying the qualification process also reduces the risk of errors. By eliminating unnecessary steps, laboratory teams can reduce mistakes and deviations, leading to better quality and consistency of the data generated. Finally, this approach can lead to increased productivity and faster time-to-market for new products and services. By streamlining the qualification process, laboratory managers and teams can focus on other tasks critical to driving innovation and growth, resulting in better outcomes for their business and customers.

Understanding the GMP and GLP requirements for qualification and validation

Validation and qualification are often used interchangeably in the industry, but they actually have distinct meanings. Qualification typically refers to equipment, utilities, and systems while validation is reserved for processes. To simplify, things are qualified (like equipment, instruments, and software) and processes are validated. However, it's important to remember that qualification is just one aspect of the larger validation process. The qualification process includes a series of tests and verifications to guarantee that equipment, facilities, and systems are designed, installed, and maintained according to GLP, good distribution practices, GMPs, and other industry standards.

HOW TO ENSURE A SUCCESSFUL VALIDATION PROCESS



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In addition to equipment qualification, computerized systems validation is also required for the generation, measurement, calculation, assessment, transfer, processing, storage, or archiving of data intended for regulatory submission or to support regulatory decisions. GLP principles must be followed to ensure compliance, as computerized systems used to deliver supporting data for GLP studies are also subject to validation requirements.

Following GMP and GLP guidelines is vital to guarantee that lab equipment is functioning accurately and reliably, while also ensuring the safety, efficacy, and quality of products. These quality systems provide a framework for the production, testing, and quality control of pharmaceutical and biotech products, and dictate the requirements for designing, installing, qualifying, and maintaining the equipment. This includes aspects such as documentation, record-keeping, and personnel training, all of which are essential for ensuring that lab equipment meets the necessary standards.

Ensuring a successful validation process

As a lab manager, it's crucial to streamline the validation process while adhering to GMP and GLP requirements. To achieve this, you need to focus on the key elements of equipment qualification and implement practical tips to minimize unnecessary steps and

reduce costs.

The validation process involves three qualification steps: Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). IQ ensures that the equipment is installed according to the manufacturer's specifications, OQ verifies that it operates according to those specifications, and PQ verifies that it performs consistently and reproducibly over time. Accurate documentation and record-keeping are critical components of the validation process, and personnel training is essential to ensure consistent and accurate performance.

Numerous guidelines, such as USP, ICH, FDA, ASTM, and the ISPE Baseline guide, recommend a simplified validation process that prioritizes the most critical aspects of the equipment or system being validated by adopting a risk-based approach. By doing so, you can minimize unnecessary steps and reduce costs while still ensuring full compliance with GMP and GLP requirements. A proactive approach is also necessary for a successful validation process. This involves careful planning, documentation, and the use of technology to optimize the process and ensure that our equipment is functioning correctly without wasting valuable time and resources.

Creating a schedule and identifying the necessary resources to address potential obstacles in advance is the first step in planning. Lab managers should also use a standardized approach to validation, such as a standard operating procedure or a validated master plan, to ensure consistency and minimize the time required. Leveraging technology, such as automated testing equipment, data analysis software, and electronic documentation systems, can also streamline the process and reduce manual data entry. Assigning clear roles and responsibilities to all members of the validation team will minimize delays and ensure everyone understands their tasks and timelines.

Lastly, you should focus on critical aspects required to meet GMP and GLP requirements and minimize unnecessary steps, reducing the time required to complete the process. Continuous review and evaluation of the validation process will identify areas for improvement and ensure the process is running smoothly and efficiently, addressing any issues in a timely manner and completing the process within the desired timeframe. By following these tips and implementing a risk-based approach to equipment validation,

lab managers and their teams can achieve a streamlined and cost-effective validation process that meets all regulatory requirements and ensures the safety, efficacy, and quality of their products.

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