

Equipment Qualification: Ensure Fit for Intended Use



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Abstract

Equipment qualification is necessary to ensure that manufacturing equipment is fit for its intended use. Regulatory requirements are quite specific about the expectations related to equipment qualification. Unfortunately, sometimes regulatory requirements are not well understood and translated into policies, standards, and procedures that are communicated to the industry.

The GxP impact of the equipment is sometimes not very well understood due to the lack of adequate assessment processes and procedures that define the impact of the manufacturing equipment. Many companies continue to struggle with equipment assessments that determine if the automation related to the equipment has Part 11 impact.

Equipment risk assessments tend to be time consuming, inefficient, and inadequate due to the lack of adequate processes.

User requirements is another area that continues to be a challenge for the industry due to the lack of adequate ownership and engagement by the system owner. Inadequate procedures that define the process and expectations for user requirements is another challenge that is quite common in the industry. Unfortunately, companies continue to struggle with implementing equipment that is both fit for its intended use and compliant with user and process requirements.

This article will discuss some of these challenges and explore potential solutions overcome them.

Regulatory Requirements

Equipment qualification is a global regulatory requirement for the pharmaceutical, biotech, and medical device industry. The FDA Code of Federal Regulations and ICHQ10 communicate the regulatory requirements for the industry.

One such code, 211.63 Equipment Design, Size and Location states the following:

“Equipment used in the manufacture, processing, packing, or holding drug product shall have the **appropriate design, adequate size, and suitably** located to facilitate operations for its intended use and for its cleaning and maintenance”

In order for equipment to have the appropriate design, size, and be located suitably, we need to understand the equipment impact and requirements to ensure that it is fit for intended use.

Code 211.68 regarding automatic, mechanical, or electronic equipment communicates the following requirements:

“Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that **will perform a function satisfactorily**, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, **it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance**”

To ensure that equipment will perform a function satisfactorily, we need adequate and concise user requirements. Expectations of user requirements need to be communicated in a written formal program that has an adequate document hierarchy that meet industry standards and expectations.

Expectations related to routine inspection and checking of manufacturing equipment requires an adequate, robust, efficient, objective and meaningful periodic review and requalification program.

ICH and other regulations communicate similar requirements that are intended to ensure that the industry implement equipment that is fit for its intended use.

Unfortunately, these regulatory requirements are frequently not well understood and sometimes downplayed due to convenient interpretations that create a compliance risk for the industry.

These challenges also create an environment where the high cost associated with not implementing equipment that is fit for intended has a negative impact on the business performance and ability to meet the need of the patients.

Document Hierarchy

Regulatory requirements expectations are that regulated companies have a written program designed to assure proper performance of manufacturing equipment that have GxP impact.

In order to have a written program that is designed to ensure proper performance of manufacturing equipment, regulated companies need an adequate document hierarchy that consist of the following structure:

- Validation Policy
- Equipment Qualification Standards
- Equipment Qualification Procedures
- Equipment Validation Master Plan

The Validation Policy is a high level document that describes the requirements for the validation program and provides alignment with regulatory requirements.

The Validation Policy should include high level requirements for the following areas:

- Process Validation
- Equipment Validation
- Computer System Validation
- Shipping Validation
- CIP & SIP Validation

The Validation Policy should describe the high level roles and responsibilities for each functional area. The policy is the foundation for the written program designed to assure proper performance.

The equipment qualification standard is the document that describes the specific requirements for the equipment validation program. It should provide alignment with the policy requirement and use industry standards, regulatory guidance, and requirements as inputs to create the standard.

In addition, the equipment qualification standard should provide detailed roles and responsibilities for all impacted functional areas and specific instructions and detailed requirements for the creation, review, and approval of all validation deliverables.

The equipment qualification procedure should describe the specific steps to validate manufacturing equipment and translate standard requirements into “how to” actions. The procedure should also provide detailed roles and responsibilities for all functional areas involved in the process, it should also provide specific instructions and detailed requirements for creation, review, and approval of all equipment validation deliverables.

How to Determine the Equipment Impact

Prior to the creation of user requirements, companies need to understand the equipment impact.

Normally the equipment impact is an informal assessment process that relies in SME's to determine whether the equipment has GxP, Part 11, and the risk level. This usually leads to frequent meetings being held, which are often fruitless when they yield inconsistent results during the assessment process.

System assessments should be a formal process driven by approved procedures that consistently deliver accurate and objective assessments of the GxP and Part 11 impact and associated system risk level.

System assessments are intended to deliver consistency, support accurate interpretations of regulatory requirements, eliminate misinterpretations, and provide inputs to the validation planning phase.

The GxP is the initial assessment to determine the whether the equipment has GxP impact and if it requires validation. This assessment identifies applicable regulatory requirements and support for the creation of URS statements related to those requirements.

The Part 11 assessment determines whether the equipment has any Part 11 impact and is intended to identify the applicable regulatory requirements for the equipment.

This assessment also identifies applicable Part 11 requirements such as whether the equipment automation is an open or close system, has e-records, and also e-signatures.

Furthermore, this assessment supports the creation of URS statements related to Part 11 regulatory requirements.

There is a system level risk assessment to determine whether the equipment is high, medium or low risk and it evaluates the risk impact to the following areas:

- Product Quality
- Patient Safety
- Compliance
- Safety
- Business Process

- Complexity

Equipment User Requirements

There are a significant amount of challenges and issues that regulated companies face when creating equipment user requirements.

The following challenges are normally found in even the most regulated companies:

- Inadequate procedures
- Ownership of requirements is not well defined
- Equipment impact is not well understood
- Equipment risk level is not well understood

Delivering a document instead of clear and concise requirements is another challenge for the industry. Generally, the functional area responsible for creating the equipment requirements is more concerned with delivering a document by the project plan due date, instead of providing an adequate document that meets industry standards. Poor communications between functional areas is another challenge because groups involved in the equipment qualification process often work in siloes, instead of an integrated team with a common goal.

Multiple requirements in a single statement create another challenge for validation engineers when defining the acceptance criteria in equipment qualification protocols. Not classifying requirements between “must have” and “nice to have” creates the challenge that critical must-have requirements are not documented and implemented in the equipment.

In addition to the challenges above poor understanding of the manufacturing process and intended use of the equipment normally results in inadequate requirements and equipment that is not fit for its intended use.

Equipment requirements need to be unambiguous, concise, and clearly understood by vendors and engineering teams responsible for delivering equipment that it is fit for its intended use. Requirements need to articulate the need of the system owner and business and while also translating applicable regulatory requirements into clear requirements, to then be implemented in the equipment and associated automation.

Equipment requirements should include the following:

- Operational
- Mechanical
- Performance
- Design
- Physical
- Utility and Environmental
- Capacity
- Automation
- Safety

The process for creating equipment requirements should include the following activities to ensure that equipment is fit for its intended use:

- Discussions and interviews
- Observation
- Workflow analysis
- Workshops

In order to implement equipment that is fit for its intended use, regulated companies need to have adequate procedures that define the process requirements for the creation of specification documents. The cost, business, and compliance risk of implementing equipment that is not fit for its intended use is very high and can have a negative impact on the regulated company business performance.

Translating Requirements into a Qualification Protocol

As previously discussed, system assessments performed early in the equipment lifecycle are an input to the user requirements and other specifications. These assessments facilitate identifying the equipment impact, applicable regulatory requirements, Part 11, impact and the risk level.

Equipment requirements that are clear, concise, unambiguous and verifiable facilitate the creation of qualification protocols that are adequate and provide evidence of the equipment being fit for its intended use.

Equipment qualification protocols need to have clear acceptance criteria that is based on the user requirements and other specifications. The equipment qualification protocol must also cover the operational range including the manufacturing process.

All critical process parameters and requirements that have process impact must be qualified to ensure and provide documented evidence that the equipment is fit for its intended use.

It is highly recommended in industry standards such as GAMP 5 to perform a requirement level risk assessment to facilitate a risk based qualification approach. In this risk-based qualification approach, the qualification effort should be proportional to the risk level of the equipment and its requirements. For example, all requirements should be verified for high risk equipment that have a potential to have a negative impact on critical quality attributes. For low risk equipment, a risk-based approach will be to qualify only high risk and sample medium risk requirements with the most impact to critical quality attributes.

Equipment qualification protocols provide documented evidence that requirements are met and successfully implemented. At a minimum, all equipment qualification protocols should be reviewed and approved by the system owner for quality.

Summary

In conclusion, in order to implement equipment that is fit for its intended use, regulated companies need an adequate document hierarchy that consists of a validation policy, equipment qualification standards, and procedures. In addition to the document hierarchy, regulated companies need to have formal equipment assessments that are consistently executed and documented according to an approved procedure.

User requirements are critical to ensure that the equipment is fit for its intended use and they must be clear, concise, verifiable, and unambiguous. The system owner must be engaged in the gathering process of requirements, while also supporting the technical and quality teams.

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