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An Analysis of the Life Cycle of Managers Product Qualification Method

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Abstract: *This study provides a succinct overview of a review on the life cycle management approach to asset qualification. The review explores strategies for effectively managing assets throughout their life cycle to ensure optimal performance and qualification. Key considerations include the integration of technology, data analytics, and risk assessment methodologies to enhance asset reliability, maintainability, and safety. The review also discusses the importance of incorporating sustainability principles into asset management practices. Overall, the review highlights the significance of adopting a comprehensive life cycle management approach to asset qualification in various industries, aiming to maximize asset value and minimize operational risks*

Keywords: Risk Management, Asset Performance, Maintenance Strategy

I. INTRODUCTION

In today's dynamic and competitive business environment, effective asset management is crucial for organizations across various sectors to maintain competitiveness and ensure long-term sustainability. This review paper critically examines the life cycle management approach to asset qualification, focusing on its significance in enhancing organizational efficiency and optimizing resource utilization. Through a comprehensive analysis of existing literature and case studies, this review aims to shed light on the key principles, methodologies, and best practices associated with asset qualification within the broader framework of life cycle management. By delving into the intricacies of asset qualification processes from acquisition to disposal, this review offers valuable insights into how organizations can strategically align their asset management practices with their overarching business objectives. Moreover, it explores the role of emerging technologies and innovative strategies in advancing asset qualification practices, thereby enabling organizations to make informed decisions and maximize the value of their assets throughout their life cycle. Overall, this review serves as a comprehensive resource for practitioners, researchers, and policymakers seeking to deepen their understanding of the life cycle management approach to asset qualification and its implications for organizational performance and sustainability.

Objectives of Equipment Qualification:

1) To review the requirements of equipment
2) To improve and control overall production reliability and availability
3) To ensure safety of products

Appropriate principles about the equipment's certification are stated in Schedule M.The established equipment's two qualification criteria are determined by looking at the equipment's historical data that is now accessible. 3. All equipment utilized in the creation, measurement, or evaluation of data must meet the same standards set out by good laboratory practice guidelines and regulations, including the need for sufficient testing, calibration, and/or standardization. 4-5

Documentation:

Guidelines for the documentation needs pertaining to the EQ process are provided in this section.

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A certification program's appropriate documentation is crucial since, in the absence of recorded proof, a qualification has no significance (not documented implies not done). It should not be understood to include additional reports or paperwork about the upkeep or functioning of the instrument (such as manuals).

Stages of Equipment Qualification:

URS (USER REQUIREMENT SPECIFICATION)
DQ (DESIGN QUALIFICATION)
FAT (FACTORY ACCEPTANCE TEST)
OQ (OPERATIONALQUALIFICATION)
IQ (INSTALLATION QUALIFICATION)
SAT (SITE ACCEPTANCE TEST)
PQ (PERFORMANCE QUALIFICATION)
RQ (RE-QUALIFICATION)

Responsibilities:

1) URS:

User department- to prepare URS

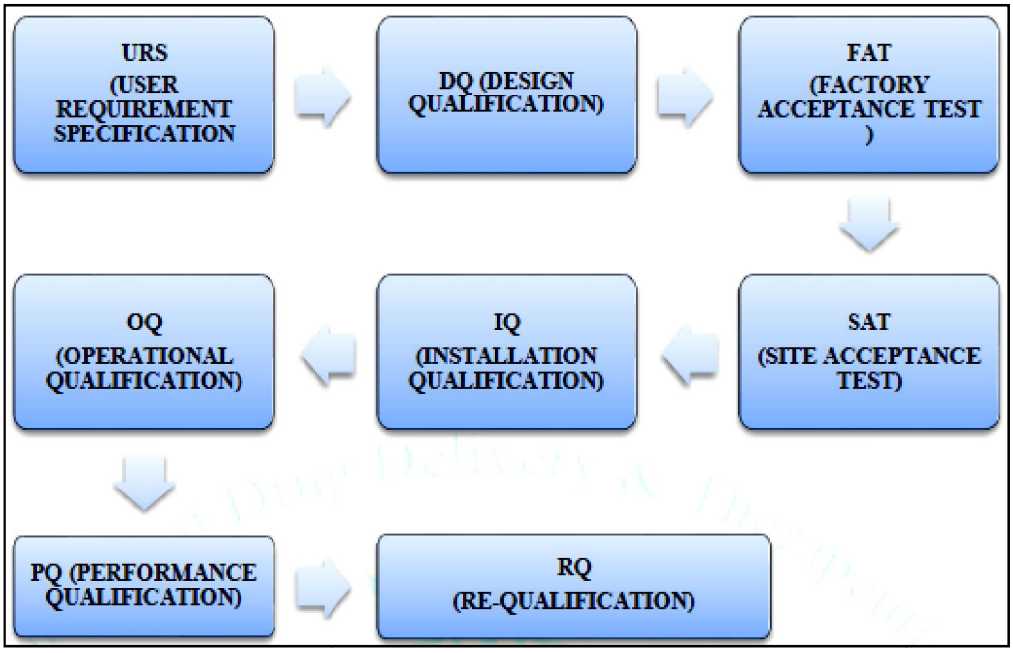

Fig 1: Stages of Equipment Qualification

2) DQ :

Engineering department/ Vendor: DQ Protocol
User department: to verify

3) IQ:

Engineering department/ Vendor: IQ Protocol
User department: to review
QA department: to approve

4) OQ:

Engineering department/ Vendor: IQ Protocol
User department: to review
QA department: to approve

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Gap analysis:

The gap analysis is suitable for the process and validation approach, is brief, and complies with regulatory standards and GLP lineament. It manages the strategy for the execution of qualification and makes extensive use of facility maintenance validity. The responsibilities of relevant personnel, the features of the equipment to be assessed, the model number, serial manufacture number, serial asset number, documents or SOP, the location, the date of the last calibration, personnel training records, a validation certificate, system controls, data storage techniques, risk type, the level of the responsible person, and the validation specialist are all included in the gap analysis. Director of Qualification Study). The quick and simple information needed for the validation process is provided by gap analysis. The director of the qualification study wishes to work with the manufacturer or vendor and inform them of any abnormalities in the facility. The gap analysis document is comparable to those shown in Table 1.

Table 1: Gap Analysis Record [10]

Sr.no	1	2	3	4
Equipment-Asset				
Make				
Model No.				
Serial No				
Inst.ID.				
Software				
21 CFR compliant status				
Critical/Non Critical Calibration				
IQ/OQ/PQ				
SOP No				
Document Archival				
Location				
Remark				

User Requirement Specification

An URS is required to establish the equipment specifications. The collection of owner, user, and engineering requirements required and sufficient to provide a workable design fulfilling the system's intended function and mitigating any GMP hazards to an acceptable degree. Throughout the validation life cycle, the URS will serve as a point of reference. URS may be seen as the first crucial stage in the qualifying "flowchart," which is shown in the aforementioned picture (Fig. 1):

The URS must address the particular needs of the equipment that has to be purchased.

The user department is responsible for creating the URS for the new machinery, utilities, and systems while taking into account the guidelines, specifications, and safety measures that must be adhered to in order to protect the site's GMP, GEP, EHS goals, and product quality.

The following, albeit not exclusive to, will be included in URS:

- Name o Machine
- Purpose of machine
- Size/capacity
- MOC
- Change parts
- Working condition requirements
- Electrical requirements

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Design Qualification

The equipment's design is deemed suitable and compliant with the URS, as verified by the DQ. The requirements for the product or process will guide the DQ process. During the design review process, the design's cGMP compliance must be proven and recorded.

Combining the user demand, design, and functional requirement specifications results in design qualification. Design qualification is utilized when a design created from the URS is examined and discussed by knowledgeable individuals to guarantee that the intended equipment will, when constructed correctly, fulfill all the specific criteria that are given in detail. In order to make sure the shelf item will meet the URS, it may also be utilized for evaluation.

User Need

The specifications for the equipment, which include both functional and design criteria, must be confirmed against the supplier's actual equipment specifics. It is advised to finish this documentation task, which goes by the name of "Design Qualification," before placing the purchase order.

The vendor is responsible for providing the design qualification procedure. If the vendor declines to supply the DQ document, the engineering department will construct the DQ in consultation with the user department, manufacturer/supplier, and URS. Every piece of equipment will have a DQ procedure established for it based on the quote or proposal and the technical talks between the user department and the supplier.

All required diagrams, layouts, equipment component specifications, location suitability, and desired special features, as well as desired material of construction (MOC), control panel location, electrical requirements, and utility requirements, must be covered in the DQ protocol. The basic guidelines outlined in the provided Qualification methodology must be followed when introducing and documenting the design's conformity with both the specification and cGMP.

Site Acceptance Test (SAT)

Applicable to the main customized machines will be SAT. The vendor is responsible for providing the SAT papers. In the event that the vendor is unable to provide the SAT protocol, the engineering department will build an in-house protocol in consultation with the user. After equipment is received, SAT will be carried out at the firm site by pertinent subject matter specialists from various functional areas, such as engineering, production, QA, and QC, with the following goals in mind:

1) To check and make sure that no components were destroyed during transit and that the equipment is in excellent condition when it arrived at the firm location.

2) To provide verifiable proof that the equipment is in excellent condition and functions as intended when it is delivered to the company's location.

• The following will comprise, but not be limited to, the core components of the SAT:

1) Equipment details

2) Receipt of consignment

3) Inspection of equipment consignment

Installation Qualification

Verification in writing that every component of a system, facility, utility, or piece of equipment that has the potential to impact product quality is installed or altered in accordance with the manufacturer's recommendations and the authorized design. Thirteen A new, previously owned, or current onsite instrument is covered by IQ; an already-existing qualifying instrument is not.14 The following are the IQ-related activities and documentation:

In order to demonstrate that all important components of the process equipment and auxiliary system installation meet the criteria of the company's authorized specification and recommendations, IQ must be done on new or modified equipment.

The vendor will provide the IQ protocol, which will then be examined and authorized by the technical department and user. The QA department will then approve the protocol's continued execution.

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Following the conclusion of a vendor-provided protocol execution, user, engineering, and quality assurance will examine the executed protocol and raw data. Start the post approval process to close the document after the protocol action has been completed successfully.

In the event that the vendor fails to provide the installation qualification document, the user department will work with QA and engineering to create the internal protocol. Following the protocol activity's successful completion, each instrument connected to the equipment must be recognized and added to the master list of instruments as needed.

Operational Qualification

Operational qualification is required to confirm that the equipment functions in compliance with design specifications, manufacturer recommendations, and operational cGMP criteria after the successful completion of the IQ protocol activity.

verified by documentation that every facet and function of a system, facility, utility, or piece of equipment that has the potential to impact product quality operates as intended throughout all expected operating ranges, in accordance with process, capabilities, procedures, and design specifications.

The OQ phase focused on following parameters:

• Prior to use, all testing apparatus must be recognized and calibrated. Test procedures must be approved, put into practice, and the resultant data must be gathered and assessed. Assuring that all operational test data complies with established acceptance criteria for the conducted studies is crucial at this point.

• The user and engineering department must evaluate and accept the OQ protocol, which will be supplied by the vendor. The QA department will then approve the protocol's continued execution.

• Following the conclusion of a vendor-provided protocol execution, user, engineering, and quality assurance will examine the executed protocol and raw data. Start the post approval process to close the document after the protocol action has been completed successfully.

•The pre-approved written procedure must be followed while doing the OQ.

•The following, among other things, must be included in the OQ: • A calibration evaluation of important instruments and components.

Performance Qualification

Operational qualification is required following the successful completion of the IQ protocol activity. It verifies that the equipment, or equipment under anticipated conditions, provides the consistent performance to produce a product that satisfies all predetermined requirements.

Verification in writing that every component of a system, facility, utility, or piece of equipment that may have an impact on product quality produces the necessary output over a long period of time while dealing with normal operating circumstances and interferences.

PQ must be conducted in compliance with a documented procedure that has been previously authorized. Along with the acceptance criteria, the particular PQ qualities derived from the completed product specifications, R&D data, cGMP regulations, and other relevant documents must be validated.

Before beginning the PQ, the SOPs for "operation and cleaning of equipment" and "PM procedure" must be authorized.

The information produced under PQ is not to be used for human usage or routine manufacturing. It must be limited to the qualifying purpose alone.

If every test result satisfies the acceptance requirements, the PQ test will be deemed successful.

Should the vendor-provided PQ protocol be accessible, the user and engineering departments must examine and approve it. The QA department will approve and then authorize the procedure to be executed further.

After the vendor-provided papers have been executed and the process has been carried out, user, engineering, and QA will evaluate the raw data. Start the post approval process to close the document after the protocol action has been completed successfully.

In the event that the vendor fails to provide the PQ document, the user department will work with the engineering department and QA to establish the internal procedure.

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PQ must include the following but not limited to;

Prerequisite for PQ

• Tests using certified stand-ins, production-grade materials, or model products created using process and equipment expertise.

• Tests including the condition, or a combination of circumstances, covering the top and lower bounds of the operational range (worst case).

• The equipment supplier's documentation or qualification efforts will also be approved by the relevant corporate staff after being evaluated for sufficiency.

•Upon PQ's successful conclusion, QA will release the equipment for regular use.

Equipment must be certified for the whole working range as per DQ during PQ. To cover the whole spectrum of produced products, PQ may, however, also be carried out concurrently with process validation of the product. A summary report of the validation activity must be generated for this kind of qualification, and it must be included to the qualification papers.

Re-Qualification

Re-qualification is the process of doing all or some of the "elements" of qualifying activities, such as IQ, OQ, and PQ.

Re-Qualification carried out for following reasons:

To overcome deficiencies observed in an qualification

Need for any new additions in qualification tests

To qualify modifications done in the equipment or a process involving an equipment Failure

Risk Assessment/ Risk Management:

• The goal of qualification is to provide documented proof that machinery and processes operate in accordance with specifications to produce high-quality goods. There are always hazards while working with machinery and processes, and these risks may or may not be acceptable.

A quality risk assessment or crisis evaluation must be carried out to guarantee the product's quality.

• To evaluate the equipment or process's possible critical and non-critical points.

Critical Equipments: These are the pieces of equipment that have direct contact with goods and might have an impact on their SISPQ (Safety, Identity, Strength, Purity, and Quality). Important equipment often affects operational processes' productivity, safety, cost, and regulatory confirmation.

Non-critical Equipments: These are the pieces of equipment that don't come into touch with the goods directly and don't have an impact on their SISPQ (Safety, Identity, Strength, Purity, & Quality).

• Risk will be measured using three-dimensional risk criteria, such as severity, likelihood, and detectability. These three elements are used to construct a risk probability number, or RPN.

• For each failure mode, the risk of occurrence, the degree of the consequence of failure, and the ease of detection are taken into account when determining the risk priority number (RPN). The following formula is used to compute RPN.

$$RPN = S \times O \times D$$

Where,

S stands for the severity of the failure's consequence, O for its likelihood, and D for its detectability.

RPN may not play a part in selecting a response to failure modes, but it will be useful in pointing out the cutoff points for identifying the regions with the highest concentration. Stated differently, the analysis and remedial action should give the greatest importance to a failure mode with a high RPN value.

• The risk-based methodology Impact assessments must to be centered on the effects on products. Each piece of equipment must be categorized as having a direct, indirect, or no influence on the product.

Purpose of the equipment impact Risk Assessment

• Ascertain the criticality of the equipment by considering its effect on product safety.

• Establish the minimum level of qualification needed for new

Direct Impact Equipment.

Establish the degree of certification needed whenever modifications are made to certified equipment

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Form FDA 483 issuance related to Equipment Qualification:.

Form 483, commonly known as "Inspectional Observations," is a summary of circumstances or methods that seem to point to a possible FDA regulation infringement.19 The FDA is able to conduct inspections of firms that produce goods under its regulation. FDA inspectors are free to visit the company and examine any facility at any time. They basically record their findings on a document known as a Form FDA 483. The observations are arranged according to decreasing significance for the adjustments. This is only a summary of potential problems that have been seen at the location; it is by no means an exhaustive list. There are many instances of form 483s being issued in relation to equipment qualification. Therefore, while carrying out the equipment validation process, analytical technique must be strong and ragged. There aren't many instances of equipment qualification-related observations in form 483.

II. CONCLUSION

An method to equipment life cycle management and certification is presented in this article. A risk-based approach to life cycle management encompasses all phases of the equipment life cycle, including specification, design, production, installation, commissioning, qualification, operation, and maintenance. The organization's adherence to sound engineering principles is largely responsible for the equipment qualifying process's success. A qualification program's appropriate paperwork is crucial since a qualification has no significance without supporting documentation. By developing a program, a user-supplier relationship may decrease redundancies and provide major benefits for both sides.

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