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Qualification and Validation of industry scale equipments in pharmaceutical industry: A review

Udaykumar Dasharath[1], Dr. K Selvakumar[1], Ms. Kalpana N[1], Natarajan S[1], Gajendran P[1], Vivekananda S[1], Tanya Maheshwari[1], Misba kauser[1]

Department of Pharmaceutical Quality Assurance Acharya & BM Reddy college of Pharmacy Bengaluru
Head of the Department of Pharmaceutical Quality Assurance Acharya & BM Reddy college of Pharmacy Bengaluru
AGM & Head of the Department of Quality Assurance Bioplus life sciences Hosur
Validation Engineer CSV Novo nordisk engineering Bengaluru
Manager Department of Quality Assurance VB Medicare Pvt, Ltd Hosur
Officer Department of Quality Assurance VB Medicare Pvt, Ltd Hosur
Department of Pharmaceutical Chemistry MS Ramaiah college of pharmacy Bengaluru
Officer Department of Quality Assurance Sai life sciences Bidar

ABSTRACT :

Validation is a bold way of addressing the process and evidencing the processes with it. 21CFR 820.75 talks about validation must be done for those processes when the outcomes are not probably verified and to the subsequent interrogation, testing and admissible verification must be done.[1] As the process must be validated which signifies the class of high degree of assurity and approved as to the existing process controls? When a process's outcomes cannot be completely confirmed by additional testing and inspection, the process must be very assuredly validated and authorized in accordance with protocols.[2] Documentation must include the validated procedures and outputs, as well as the date and signature of official personnel authorizing the validation and, if probably, the primary equipment verified.[3] To ensure that the necessary standards are upheld, manufacturers must establish and maintain the protocols for monitoring and controlling the process parameters for processes that have been that have been verified in order to make sure that the required standards are still maintained and validated.[4]

Every producer is required to make certain that the person or people performing the validated procedures are competent. In the case of verified processes, the date of execution, the data and techniques for monitoring and control, and, for procedures that have been validated, documentation must include the process's monitoring and control techniques, data, execution date, and, if applicable, the person(s) carrying it out or the main piece of equipment utilized.[5] The manufacturer is responsible for reviewing, assessing, and, if necessary, revalidating the process if modifications or departures from it occur. These actions need to be recorded.[6]

Introduction :

Apart from 21 CFR 210/211 and the associated Guidelines to Inspection and Guidance's to the Industry, an additional way of interpreting US cGMP prerequisites is through Warning Letters. The FDA's answer to a pharmaceutical company who claimed not to know that process validation was required is as follows.

The Food and Drug Administration made mandatized on process validation in the Warning Letter to attify that the items have quality, identity, strength, and purity, citing its process validation guidelines in support of this demand. The FDA contends that manual tasks result in a varied process. The FDA also anticipates a corrective action plan and a retrospective evaluation of the possible effects on product quality to guarantee that improved management supervision is continuously accessible alongside of the product life cycle of every product.[7]

Likewise, some of following are indispensable.

- The complete wide-ranging strategy establishing Development, Augmentation, validation, , monitoring, control, and maintenance of each manufacturing process; a data-driven, science based approach program that reveals the causes of process variability and assures that production operations adhere to the required standards of quality (appropriateness of the equipment, the raw materials quality requisites, resiliency of every production phase and its controls, as well as a vigilant configuration of process result and product quality). The observation of within and inter-batch variability is part of the program.[8]
- An equipment and room qualifying program
- A thorough description of the internal validation program and related processes of the business. Specifically, definitions of "PPQ" and "persistently Process Verification" are needed.
- Work instructions and PPQ guidelines for room and equipment qualifying.[9]

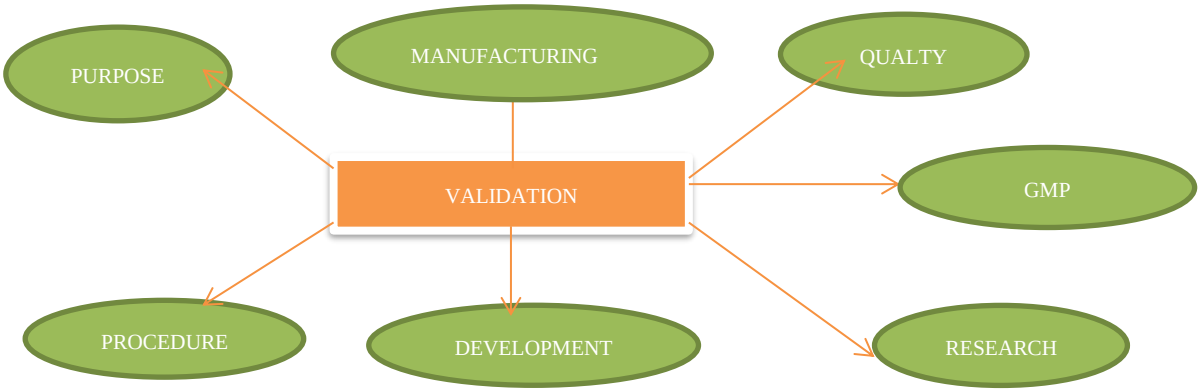

Fig 1: Vlidation Intent gram

On behalf of ICH Q7 the FDA, EMEA, PIC/S talks about the qualification and the validation says that it doesn't impede the product lifecycle approach for the process validation acceptable for API under ICH Q7 Section 12.10 ICHQ 10; ICH Q11. For process validation Additional scrutiny requires to support in the API source change as key Initial material shall be taken for the impact assessment in the process of API manufacturing that yields to give Quality API [ICH Q7, Section 7.14] furthermore validation swotting for the API process can be decreetized if in change of key initial material is expedite cogent. In the most of cases the validation must be expected for a different sourced material unlikely justifies [ICH Q7, Sections 12.1, 13.13][10, 11]

The Approach of retrospective validation PIC/S gives a verge of justification with acceptancy with the exception of existing and the established products precede of implementation. [ICH Q7, Section 12.44]. All where the normal acceptancy for the prospective validation over expectation if the protocol setting forth the retrospective review of the information together with the obligation for contemporaneous or prospective validation could be a feasible choice if regulatory talks reframe a step that was previously thought to be non-essential as critical. The system of quality should verify the process's continued robustness, regardless of the kind of validation. [12,13]

ICH Q7 Validation policy and APIC interpretation

As the ICH Q7 section 12.10 states for the validation policy for a firm responsible for activities It is important to document the company's overall intent and approach for the validation

of its in-process control test procedures, analytical techniques, cleaning protocols, validation of its computerized systems, production processes, and personnel in charge of designing, reviewing, approving, and documenting each validation phase. [14]

Clear and unequivocal policies pertaining to all validation operations should be documented by the organization. Activities related to qualification are regarded as essential components of validation.

A company's validation strategy should be outlined in depth in the policy, along with the steps it will take for each major task. The guidelines for validation by the Health Authorities should be reflected in the policy. It is important to establish and maintain clear and documented roles and responsibilities to guarantee that the right amount of commitment is provided.[15]

ICH Q7 Validation policy 12.11 states that the validation policy for Normal practice is to identify the essential parameters/attributes either from prior data or during the development stage, and to specify the ranges required for the repeatable operation. This ought to consist of describing the API upon the basis of the essential features of its product. Finding range for each essential process parameter anticipated to be employed during normal production and control over process. The recognition of process parameters that may have an impact on the critical quality characteristics of the API. Critical parameters/ attributable considerations the critical process parameter is one that affects a quality aspect of the final API across the whole process, from the introduction of the beginning material to the finished API. Current of Critical Quality Attributes is necessary for Continuous Process Verification, or CPV. A risk assessment is used to address the Critical Process Parameters could be trended. "Key" process parameters can be established to ensure conformity to the specific specs, ensuring that non-critical process stages are made within the established standards of that specific step. A material's unique characteristic that, if uncontrolled, will affect its overall API quality is known as a crucial material attribute.[16]

ICH Q7 Validation policy 12.12 states that validation policy over Operations interpreted essential to both the purity and quality of the API should be included in the validation process. The operations that are considered critical should be included in the validation. Equipment, Process, facilities, analytical, utilities, IT and other protocols utilized in validation should cover the operations that are considered essential. Upon validation, that continued process validation can be utilized. To assess the impact of any modifications on the operation's present validation state, change control processes must be followed. The validation research does not have to include non-critical processes.[17]

In the ICH Q7 section 12.20 its states for the documenting the validation activities that it is mandatory to provide a stipulated validation procedure that details the steps involved in validating a certain process. The selected units and the quality unit must review, evaluation for deficiencies and approve the protocol.

Prior to any validation operations begin, protocols must be reviewed, evaluation for deficiencies and approved by Approved personnel who are qualified and able to assist the validation. It is important to specify roles and duties precisely to ensure that commitments are made at the proper departmental level.

In the ICH Q7 section 12.21 the Critical process steps, acceptance criteria and the sort of validation to be executed (e.g., concurrent, prospective, retrospective) and the quantity of process runs ought to all be defined in the validation protocol.
In advance of initiation of process validation, the validation procedure ought to mention the conclusion for unit of operations qualification and analytical techniques validation.
The FDA and EMA mandate that the justification and documentation for the number of validation runs be based on scientific evidence.
The protocol has to outline all important and crucial details. For instance, any registered specification must be followed while controlling the impurity levels during process validation. One important acceptance criterion would be to regularly meet the limitations for these impurities.
To ensure the manufacturing process is reliable and consistent, validation processes provide acceptance criteria. Additional validation tasks could be required depending on the particular process (change); some examples include homogeneity, drying profile, and quality of individual centrifuge loads.
The validation methodology needs to include the requirements for including the batches in the stability strategy as well as the batch release strategy.[18]

In the ICH Q7 section 12.22 the validation analysis that summarizes the findings, discusses any deviations found, and makes the necessary recommendations for fixing flaws should be written and cross-referenced with the validation process.

Every variation pertaining to the validation process must to be recorded, and the validation report ought to provide a thorough explanation for any significant deviations. Documentation of the findings of the deviation's effect on the validation process and the necessary remedial measures is required. The validation should be assessed to determine whether it is preferable to cease the validation or modify the methodology in order to produce more batches after the acceptance criteria are not fulfilled. Before making this choice, careful thought must be given since the fundamental cause of the failure must be identified and addressed. Failures of equipment, insufficient yield, etc., unrelated to the process may permit extending the validation runs to finish the process validation.[19]
In the ICH Q7 section 12.23 the documentation of any deviations from the validation methodology must provide acceptable rationale. The rationale justification for the departure explicitly ought to be included in the validation report. It's not always necessary to change the protocol. It is important for assurance of traceability.
ICH Q7 talks about the qualification in section 12.3 that it is necessary to properly qualify essential equipment and auxiliary systems before initiating process validation efforts. Usually, to qualify, one must perform the following tasks, either alone or in tandem.[20]
Design Qualification (DQ): verified documentation demonstrating the suggested facilities, equipment, or system design's suitability for the intended use.
Documented proof of design qualification indicates that:
Technical and maintenance departments, as well as production, have to generate the user requirements document. Concerned units, including production, technical, quality control, and maintenance and quality assurance departments have approved the technical proposals presented by the engineering department in terms of equipment design and automatic operation design. [21]
A cross functional team on all dedicated departments gathered for the Qualification require an equipment impact assessment is developed by a cross functional team.
The formal approval requires the documented evidence includes

- Meeting briefs,
- Facility layouts,
- Piping and instrumentation diagrams,
- Suppliers detailed layouts

The following should be considered by design qualification (in terms of apparatus and/or automated operation):

- A new procedure; a new stage in the real procedure
- altering machinery used in a procedure

Installation Qualification (IQ): logged confirmation that the systems or equipment installed or altered, adhered to manufacturer’s recommendations, the authorized design, and/or the needs of the user.
A PI&D that has been constructed should be the result of the IQ exercise.
Operational Qualification (OQ): verified documentation demonstrating the systems' or equipment's performance within the expected operating ranges when installed or upgraded.
There are two stages that operational qualification might go through. OQ part 1: component by component OQ part 2: the entire installation (for instance, a batch of water or solvent)
Performance Qualification (PQ): verifiable confirmation that the accessory systems and equipment can operate well when coupled together.[22]

- PQ may be taken into account during Process Qualification or during OQ Part 2.

Periodic Review of Validated Systems
It is important to regularly assess systems and procedures to make sure they are still functioning as intended. Revalidation is often not necessary if the system or process has not undergone any major modifications and quality assessment verifies that the process or system regularly produces output material that must satisfies standards. [23]
As in the WHO GMP the stated format for the execution for the qualification and validation as
The following documents are related to qualification and validation:

Validation master plan

Every manufacturer has to possess a validation master plan which explains the essential components of validation in order to validate the sequence of validation events. It is quick, straightforward, and at the very least includes a mention of or a brief explanation of equipment qualification, process validation, cleaning validation, etc. In accordance with GMP, the validation master plan has to be updated and evaluated at regular intervals.[24]

Validation master plan

- Standard operating procedures
- Specifications defining the materials, processes, and final goods to be tested
- Protocols cum reports for the process of validation and qualification
- The outcomes of risk assessment
- The process flow chart for manufacturing of certain products
- Manuals for the operation of manufacturing processes
- Personnel and training records
- Records for the instrument calibration procedures
- Methods of sampling and methods of testing plans
- The applied methods of statistics and reports
- The memoir of qualification and validation
- The for plan for assurity, continuity and the status of validation including review
- The issue of unique numbering and versions to the relevant documents
- The resources that convey the path to perform qualification and validation
- The services outsourced to the external agency
- The degree of qualification and validation
- The requirement of documentation for qualification and validation for in brief of procedures, certificates, protocol and results
- Qualification of the premises, including, if necessary, room verification
- Utility Qualification.
- Equipment qualification;
- Process validation;
- Cleaning validation
- Personnel or operator qualification
- Analytical method validation
- Computer system validation
- Articulating expectations for acceptance criteria
- Management of life cycle with inclusive of decommissioning policy
- Revalidation and requalification
- The Quality management system reactive effects
- Validation matrix
- Retention of documentation
- The management of deviation
- Change control forum
- Approach to risk management [25]

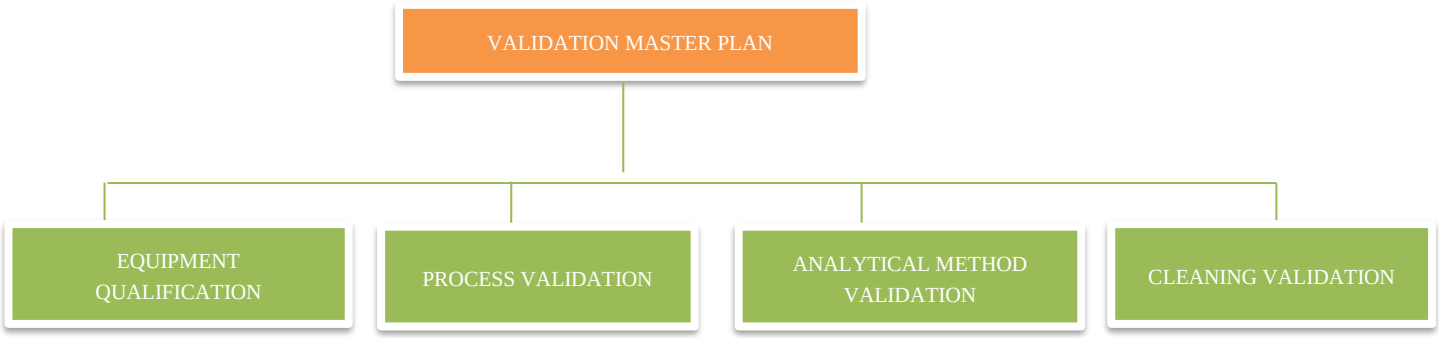

Fig 2: Categorization of Validation

Qualification and validation protocols

Qualification and validation norms specifying what is required for each should be in place.

The protocols should at the very least, be suitable for carrying out the qualification or validation. They may contain the following important background details

The abstract and aim of this conducted study and references to protocols the mention of the relevant risk assessment that specifics the material, tools, programs, and, procedures, data, cycles used, test methods, modifications and deviations that implicated the unbiased and transparent results of non-conformance and out-of-specification having suitable traceability, and a decision ought to all be included in reports that precisely convey the protocols and procedures followed.

The outcomes must to be documented and adhere to appropriate data and record-keeping procedures.

Reviewing, analysing, and comparing the results to the pre-established acceptance criteria is important. When necessary, statistical analysis and interpretation should also be done.

Findings must satisfy the requirements for acceptance and outcomes that go outside of the parameters and beyond the acceptable range should be recorded and looked into using the proper protocols. Should these be approved, an explanation must be provided. Additional research should be taken into consideration as needed.

The report's conclusion should indicate regardless or not to use the results of qualification or validation were deemed to be lucrative. If appropriate, it should also include suggestions for upcoming observation and the establishment of warning and action limits.

The finished report should have the approval of the departments in charge of the qualification or validation process.

The report must be approved by the quality assurance department when applicable. The approval criteria must to align with the quality assurance system of the organization. [26]

- The enclosures of validation cum qualification protocols
- The extents and objectives
- The onsite plan
- Trained personnel
- Standard operating procedures References
- The usage of equipment/ instrument
- References to Support the standards
- The status of qualification/ validation and the calibration requirement
- The requirement of sampling, testing, monitoring and stress testing
- Pre-established Acceptance criteria to opt the conclusions
- Raise of change control and deviation forum
- Attachments of references, archive and the retention policy

Qualification

There are predetermined multiple pathways for qualifying. The maker must to choose a suitable method for carrying it out.

During qualification, all pertinent SOPs for operation, calibration and maintenance planner should be created. Operators should get training, and training records have to be kept up to date. In most cases, process validation should come after qualification is finished.

The qualifying procedure need to be a methodical, logical process that proceeds logically in the premises via equipment, utilities, processes and procedures

Creating the user requirement specifications (URS) should often be the first step in the qualifying process. Depending on the utility, equipment, or system's function and operation, different qualification stages such as design qualification (DQ), factory acceptance test (FAT), site acceptance test (SAT), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) follow, as appropriate.[27]

Before moving on to the next qualification step, the previous one must be successfully finished. For instance, OQ typically comes after IQ, but it may also be carried out as an integrated installation/operation qualification (IOQ) based on the complexity of the equipment. Where some Conditional permission to proceed to the next qualifying phase may be given if certain acceptance requirements or deviations are still not fully resolved and there is a documented assessment that they won't significantly affect the following activity. In certain circumstances, the equipment, service, or system's proper functioning may be deemed to be an adequate indication of its performance, in which case just IQ and OQ may be necessary but major machinery, vital utilities, and systems could need URS, DQ, IQ, OQ, and PQ. [28]

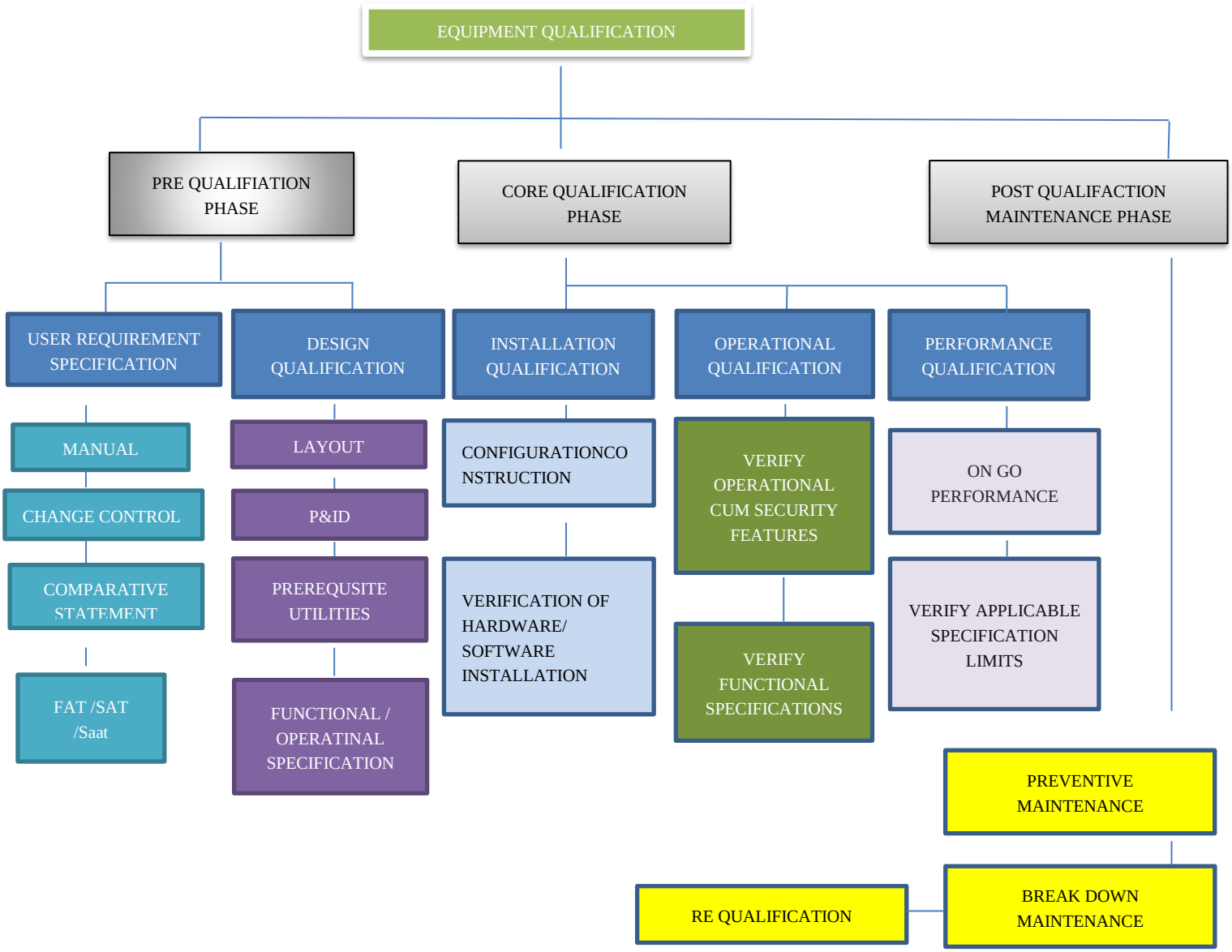

Fig 3: Equipment qualification

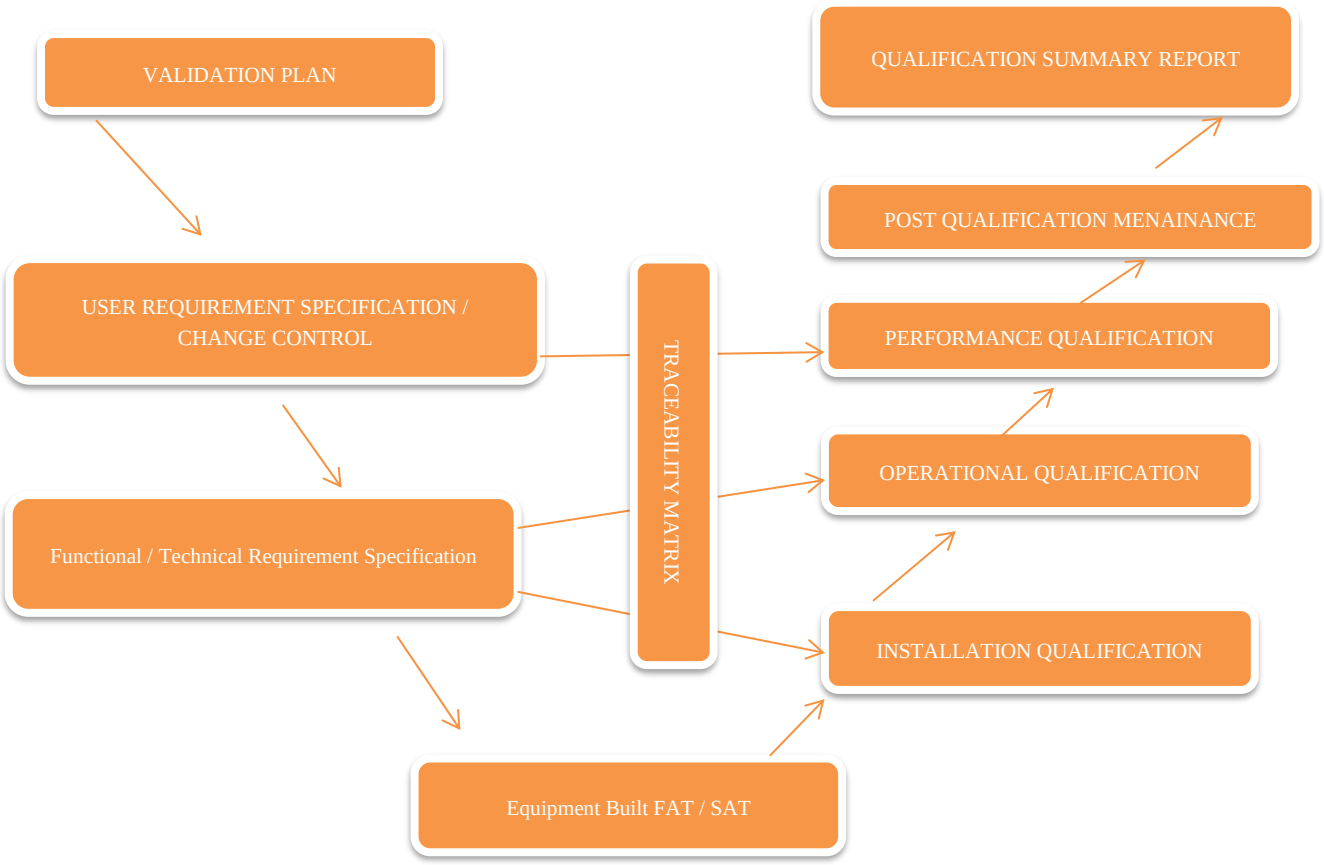

Fig 4: V model approach for Qualification

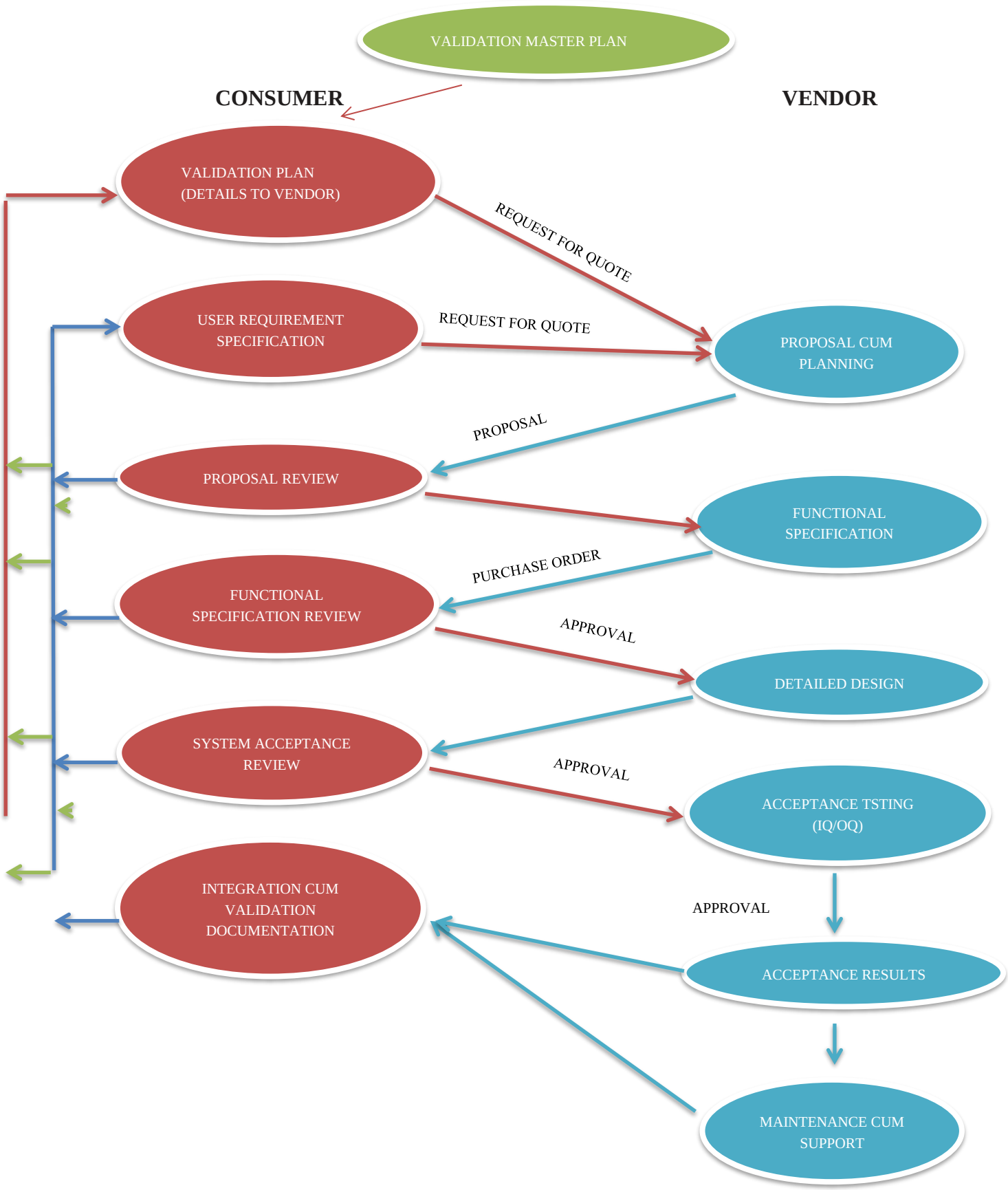

Fig 5: Baseline Equipment acquisition model

User requirement specifications

A document outlining the specifications for the product (such as the system or systems) for a utility or the equipment to be sourced should be prepared by the manufacturer.

The specifications should guarantee that any potential GMP hazards are taken into account. They should also contain technical requirements and provide references to related literature.
The needed item should be chosen from an authorized source using the URS, and it should be used to confirm appropriateness at each level of qualification that follows.

This is an early written document before commencement of qualification process with the raise of change control the functional requirement of the user department will set forth to the procurement.
The written format of original equipment manufacturer to the end user

The user requirement specification as document it contains

Purpose/ Objectives: Including the system's reach, the project's main ambitions and the relevant legal regulatory issues
Schematic requirement: the tasks and processes that the system has to be capable of being carrying out.
Information requirement: the set of data required for those systems need to be able to handle
Span requirement: including the maintenance and user training procedures for the system[29]

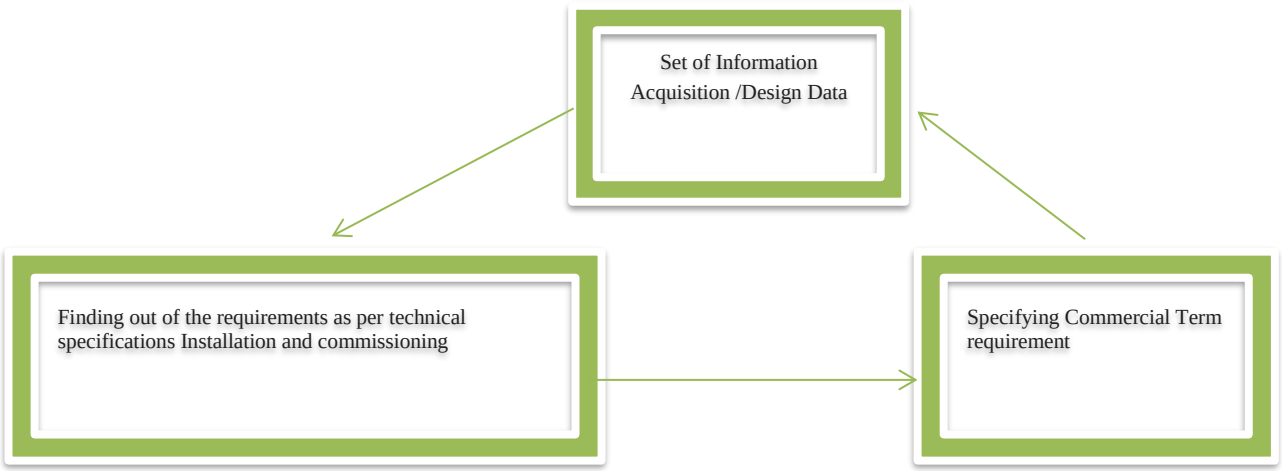

Fig 6: Lifecycle of User requirements Specification

Factory acceptance test and site acceptance test

Before moving on to the next phases of certification, FAT and SAT should be carried out as needed to confirm the system's acceptability at the location. This has to be suitably recorded.
an evaluation was carried out, on vendor's property, to testify that the system, equipment piece or spare, or service, complete or partially built, satisfies authorized requirements. installation prerequisites. testing to make sure that the Premises used in a manufacturing process, such as equipment, measuring instruments, utilities, and production areas, are selected and set up correctly
test of site acceptability. an examination carried out for system, equipment, or utility's place of use by the manufacturer to confirm that, fully or partially built, it satisfies authorized specifications.
statement of the user's needs. an official report that outlines the requirements needed to run a utility, equipment, or system in the manner for which it was intended to be utilized in production.[30]

Design qualification

In order to demonstrate that the design parameters were fulfilled and the URS was followed, DQ must present documented proof in writing demonstrating, for instance, that superior manufacturing methods were taken into consideration while designing the buildings, utilities, equipment, and supporting systems, and for their intended uses.[31]

Installation qualification

If necessary, IQ should offer verified proof that the installation was finished and up to par, along with the tools that supported it. Outlining every design, process, and/or quality system control needed to guard against these possible dangers. In order to guarantee that a "failure" won't affect the quality of the finished product, these controls either mitigate or decrease risks or identify their potential influence on quality or the process.
The configuration standards for the planned operating environment and the design specifications, which include purchase specifications, drawings, manuals, lists of spare parts, and vendor information, should also be confirmed ongoing IQ.
Installed components must be confirmed to fulfil specifications, be traceable, and be made of the right building materials. Documented proof of this must be given.
Measurement and control tools that are relevant, as determined by impact or risk analysis, ought to be adjusted. [32,33]

Operational qualification

In order to demonstrate that equipment, systems, or utilities function in compliance to operational standards, OQ must produce documented proof. It is important for tests to show that a device functions satisfactorily both within its typical operating range and beyond its working circumstances. The testing may cover worst-case scenarios. Tests should be conducted on operation controls, displays, switches, alarms and other components. A detailed description of all measurements conducted using a statistical technique should be provided.[34]

Performance qualification

PQ should typically be carried out before utilities, systems, or equipment are released. To give documented proof that things can reliably function in line with the specifications under regular use, PQ should be carried out in settings that mimic the anticipated use.[35]

Requalification

Systems, equipment, and utilities must all be kept in good working order. The change-control technique should be used to handle any modifications made to them. Based on risk management concepts, the extent of qualification or requalification resulting from such a change should be decided.
Requalification needs to be commenced as accord to risk management guidelines and determined requirement. Considerations may include elements like regularity of usage, malfunctions, operational outcomes, criticality, preventative maintenance, repairs, calibration, and verification.
Requalification ought to be taken into account following cumulative or multiple modifications.
It is important to decide on the amount and scope of requalification whenever parts or components are changed. [36]
In cases when a system, piece of equipment or utility has not been utilized for a prolonged length of tenure, requalification could be necessary.

Procedure validation

The validation process should be followed when doing the validation. All attributes should have processes and acceptability criteria included in the protocol. The validation report has to provide a record of the outcomes.
If pharmacopoeial procedures are available, then justification must provide when non- pharmacopoeial methods are employed.
Test procedures must to be thoroughly explained and ought to supply enough data to enable suitably qualified analysts to carry out the analysis in a trustworthy way. In the case of chromatographic testing, the description should at the very least contain the chromatographic conditions, necessary reagents, sample preparation, reference standards, equations for calculating results, and system suitability tests. [37]

Revalidation

Procedures, processes, and techniques should be kept in a verified state by means of, for instance, periodic review or verification (as in the case of analytical method validation and cleaning validation).

Revalidation ought to carry out in accordance with the recognized necessity and risk management guidelines.
Any modifications made to processes, procedures, or techniques, for instance, should be handled via the change-control mechanism. Based on risk management principles, it should be decided how much validation or revalidation is necessary as a consequence of this modification. Periodic revalidation may be carried out as needed. [38]

DISK STACK CENTRIFUGE

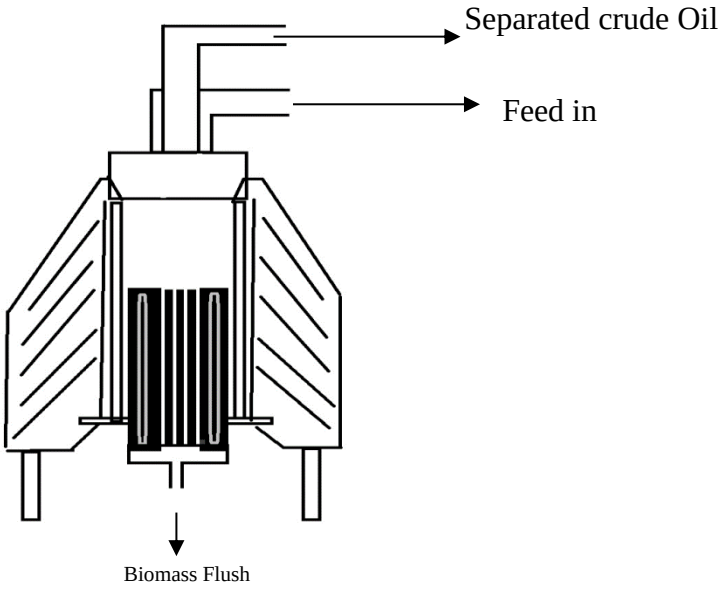

Fig 7: Disk Stack centrifuge

Alfa Laval produces the commercial disc stack centrifuge known as Culturefuge 100TM, which is used to harvest cells for the synthesis of biotherapeutics.

It is composed of a shallow cylindrical bowl with conical disc arranged tightly together, stacked one on top of the other to form a disc stack

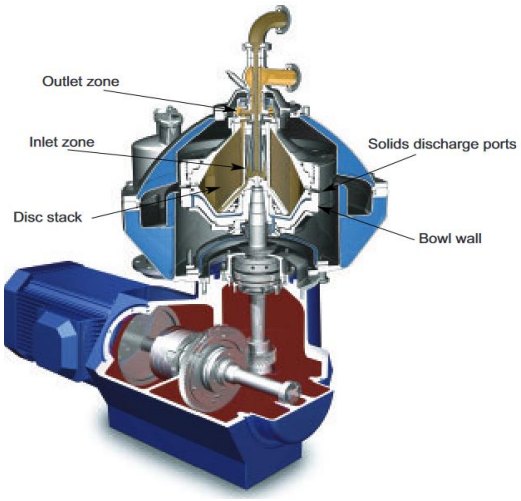

Fig 8: Disk Sack Centrifuge

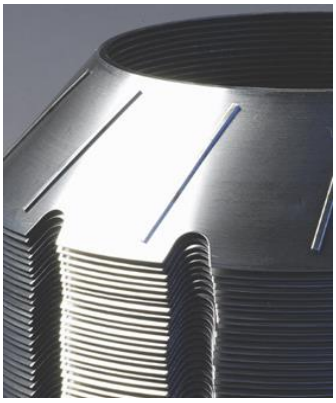

Fig 9: vertical stack centred disks

Via the entrance pipe, the feed—which is made up primarily of liquid with a tiny amount of solid cells enters the centrifuge.
A deflecting plate assist in feed go into the centrifuge's disc stack portion, where it is pushed, by diverting the axial flow go toward the disc's edge as a result of centrifugal force. Because of their greater densities, the solid cells go outward and toward the bowl's edge, while the liquid that has been cleared moves in the direction of the rotating axis. Caulks establish the flow passage for entering the separation channel above, and the spaces between discs produce the consecutive split conveyor where separation occurs.
Liquid that has been clarified exits at the top. This is the process by which the cells are separated from the broth that is cell free. The Culturefuge 100TM has conical discs spaced 3-5 mm apart, which is the spacing between them (Perry and Chilton, 1973). The hydraulically operated sliding bowl bottom regularly expels the accrued sediments on inner sides of the bowl through the discharge docks. [39, 40]
The flow in a disc stack centrifuge is mostly bidirectional, with a high velocity main flow in the tangential direction and a lower velocity secondary flow in the axial direction. This is because of the transfer of flow from one disc to the next as well as for the flow up to the deflecting plate. The centrifugal force that cells undergo causes the tangential velocity. The centrifuge's axial flow controls how long the cells stay there.
The inclined plate sedimentation theory underlies the disk-stack centrifuge.
By opposing the Coriolis-driven flow, spacing bars between disks can reduce the negative effect caused by the Coriolis acceleration. In certain designs, they also act as spacing components between neighbouring disks. There are other descriptions of manual, dropping bottom, internal, exterior, and small-diameter discharge disk centrifuges.
It has been explained how to gradually accelerate the feed stream and how to release the divided liquid streams such that the kinetic energy is converted to pressure head.
Concentrate that is flow able and semi-granular can be treated. Feed accelerator experiments for centrifuges have shown a substantial qualitative and quantitative difference between good and bad feed accelerators. When many factors are taken into account, a centrifuge with a correct design may still work well even when separating challenging biological cell suspensions since it truly utilizes high centrifugal acceleration to produce separation.

Design Qualification :

Technologies for separation come in a variety of forms. Centrifugation, a separation technique where different phases of solids and liquids are segregated from one another based on the difference in densities, uses a disc stack separator, also known as a centrifuge.
Disc stack separators work similarly to settling tanks in that they utilize gravity to separate liquids of a certain density from other liquids and solids. Centrifugal separators employ mechanical force to separate liquids and solids with various densities from one another, as opposed to settling tanks that use retention time as the primary parameter to allow liquids of different densities to split into layers and solids to precipitate into the tank. A disc stack separator is essentially a settling tank with its base wrapped around the bowl's center line. When the separator bowl rotates quickly, the gravitational force known as G-force—a regulated centrifugal force that may be up to 10,000 times stronger than gravity—replaces the impact of gravity. Subsequently, G-force is employed to effectively and rapidly separate liquids from other liquids and solids in an easy-to-control way. By significantly expanding the separation area in the separator bowl, a disc stack inside the bowl helps to increase separation efficiency. This indicates that employing a centrifugal separator for the separation process not only happens much faster but results in higher quality and higher yield.
Depending on the volume of materials involved in the particular application, the solids that concentrate at the outside edge of the bowl are removed manually, intermittently, or continually.

Conical plates are piled within the bowl, one on top of the other, to create additional surface area for separation and improve separation efficiency. The particles precipitate from the liquid much more quickly thanks to these stacks, also called bowl disc stacks.

Installation Qualification

The purpose of this to qualification the equipment/instrument/ system/utility including software and IT system so as to verify that the following is complied with.

- The agreed design specification is meeting the requirements.
- The equipment/ system is installed as per the recommendations of the manufacturer.
- Instruments are identified for calibration
- The required utilities are connected
- SOPs are identified for operation and/or cleaning and/or maintenance
- Other requirements as stated in the URS and / or DQ are met
- In the installation phase the physical pre requisites were being checked such as
- The machine is physically verified and no damage observed.
- All the major components are securely anchored and protected from shock.
- P&ID diagram is verified against the equipment Installed (if applicable).
- Sealing and Leakage Verification
- Instrument Drawings.
- Filter(s) position / sequence.
- P&ID diagram is verified against PLC mimic with respect to installation (if applicable).
- The foundation arrangement has been made for proper fixing of equipment (if applicable).
- All pipes including drain system and connections are properly concealed, dressed and covered to facilitate cleaning (if applicable)
- Utilities lines, gauges are properly identified with labels[41]

Operational Qualification

In this the operational requisites were addressed for the qualification event

- IQ availability
- Quality Risk Management (QRM) document availability (if applicable)
- Availability of SOPs (including draft SOPs if any) as identified in IQ
- Availability of Utility services
- (If applicable)
- P&ID Diagram (List all Applicable Drawings) as identified in IQ
- Schematic Diagram (List all Applicable Drawings) as identified in IQ.

Performance Qualification

In this phase of qualification, the impact of gravity is replaced with a regulated centrifugal force that can have an effect up to 10,000 times stronger when the entire unit rotates quickly.

Conclusion :

The Validation is an important aspect of the pharmaceutical operation in the manufacturing industries such as pharmaceuticals, nutraceuticals, biotechnological etc

The major aspect of commissioning of the equipment will be done with the qualification of the equipment with the major phases of4Q's and the requirement of this in accordance with the guidelines and international standards.

Disk stack centrifuge is an important equipment in the pharmaceutical, nutraceuticals, biotechnological industries for the separation of multiphasic liquids and the elemental separation and requirement will be fulfilled by this equipment efficiently.

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