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Process Validation in Pharmaceutical Industry: A Lifecycle Approach as per Regulatory Guideline

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Abstract: Process validation represents one of the key components of quality assurance in the pharmaceutical industry for providing the consistency in manufacturing products of a predetermined quality. The process of validation includes gathering and analyzing information throughout the development and implementation of processes in order to verify the capability of these processes to produce products of required quality characteristics. The process validation methodology has considerably transformed due to the introduction of the concept of the lifecycle approach by the regulators, for example, FDA.

FDA's guidelines for process validation released in 2011 indicate the need for a lifecycle validation process that involves three stages: process design, process qualification, and process verification. The main purpose of process validation is not only to meet current Good Manufacturing Practices (cGMP) but also to improve product quality and mitigate potential manufacturing risks.

This review paper examines the concepts, categories, and lifecycle approach to process validation, as well as the regulatory aspects provided by the FDA and others. In addition, the significance of quality assurance and risk-based approaches in enhancing process robustness is emphasized.

Keywords: Process Validation; Lifecycle Validation; Pharmaceutical Manufacturing; Quality Assurance; Process Qualification; Continued Process Verification.

1. INTRODUCTION

The validation process is an important element of quality assurance. It is a study of facilities, systems, and procedures with the purpose of establishing whether or not the particular procedure works correctly as intended by the management. When validated, a process can be defined as the process that guarantees production of homogenous batches according to the desired standards. The validation process is not concerned with improving the quality of the process, but confirming its efficiency and appropriateness. [1]

The USFDA describes validation as follows: "Validation is proving through documented evidence that there is a high level of confidence that a particular process will repeatedly manufacture a product whose quality meets predetermined specifications." As per the European Commission, "Validation can be described as action taken in accordance with the principles of GMP (good manufacturing practices) to ensure that a process, equipment, material, etc., will result in the desired outcome."[2]

The validation of the process highlights the flexibility and limitations within the controls that have been established within the manufacturing process in order to achieve desirable attributes within the drug product without obtaining any undesirable attributes. This becomes a key issue, because it helps to define what validation actually entails, that is, validation being defined as a system of identification, measurement, evaluation, documentation, and subsequent revaluation of a number of important steps within the manufacturing process. [3]

A successful validation procedure requires information and knowledge from the development of the product and processes. Information and knowledge form the foundation for setting up a method for

controlling the manufacturing process such that the products have the desired qualities. Manufacturers should:

- Know the sources of variation
- Recognize the existence and extent of variation
- Know the consequences of variation to the process and, ultimately, to the quality of the product
- Manage the variation at levels appropriate to the risk it poses to the process and the product[4]

2. TYPES OF VALIDATION

2.1 Prospective validation:

The main purpose of the prospective validation is to ensure or prove that the process will function as expected according to the validation protocol formulated for the pilot production runs. Prospective validation should always be carried out before releasing the medicinal product for distribution or sale. The concept of Prospective Validation involves the execution of the validation protocol before using the process commercially. At the stage of product development, the production process must be broken down into component parts. These steps must be reviewed based on experience or theoretical assumptions that will lead to the identification of factors that may influence the quality of the end-product. Experiments can be performed to determine the importance of these factors, and each experiment must be recorded according to the validation protocol. [5]

2.2 Concurrent validation:

It is a system where production batches that currently exist will be utilized for checking processing parameters. It provides information on the existing batch that is being evaluated, and only provides limited information about the consistency of quality in different batches. Concurrent validation is a process where evidence is established through documentation that a process is functioning the way it should be based on data obtained during its implementation. Concurrent validation is a realistic method in some cases. It becomes crucial in such cases if the equipment and processes to be used are already validated.

2.3 Retrospective validation:

It is done for a product that has already been marked, and its validity depends on large volumes of information collected during several lots. Retrospective Validation can be carried out for those products whose validation was not conducted by the producer when marketing them, and which needs validation to comply with the requirements of Section 2 of the Regulation under the Food and Drugs Act. The use of Retrospective Validation is limited to those well-established processes and is inappropriate for recently modified products.

2.4 Revalidation:

A re-validation procedure is typically conducted according to the validation procedure for the first time. This will confirm that any changes implemented on the process or its environment do not have a negative impact on process attributes or product quality. The documentation requirements for re-validation of a process are the same as those for validation. When should a re-validation be conducted? [5]

3. VALIDATION MASTER PLAN

The Validation Master Plan should give an overall picture of the entire validation exercise, organizationally, in terms of its contents, and planning. And the major aspects would be the inventory of the items for validation and the planning timeline. All validation activities, critical in terms of their importance with respect to controlling the product and process, should be part of the validation master plan. And the Validation Master Plan should include all prospective, concurrent, and retrospective validations as well as re-validation. This validation master plan should be brief and clear because it is a summary plan. The plan should make references to other existing documents like policies, SOPs, and validation reports. [6]

- The format of the document will include:
- Validation policy and scope, location and time.
- The organization's responsibility.

- Structure: personnel.
- Description of plant/process/product: reason why it has been included or excluded from the list; scope of validation.
- Process details: those which are important and those which need special attention.
- Matrix containing list of products/ process/ system to be validated and the validation strategy.
- Re-validation program including its status and future plans.
- Acceptance criteria.
- Format of documentation.
- Reference to standard operating procedures (SOP's).
- Time schedule of each validation project/sub project.[7]

4. PROCESS QUALIFICATION

4.1 Design Qualification:

It should be clear from this certification that the design meets GMP requirements. The design concepts of the equipment should conform to the objectives of GMP. It is crucial to examine the mechanical drawings and the design aspects presented by the equipment's vendor.[8] This is critical since the vendor will manufacture the computer system based on the FS, software DS, and hardware DS. Having examined the documents and comparing the URS with the FS, SDS, and HDS, the responsible persons will then authorize the prepared document. The technical name of this document is the design qualification or DQ. [9]

4.2 Installation Qualification:

IQ, which stands for Installation Qualification, refers to the verification of the installation procedure described in the document called the "Installation Guide." In addition to that, the process involves validation of the software installed in the mentioned environment with its particular configuration. Of all phases, the software IQ phase is the most critical one, and normally, numerous issues are identified during this phase. Changes in the environment cause the occurrence of many issues because it is sometimes impossible for the development environment to give a real-time environment when checking the installation procedures in the document. Moreover, there were some documentation issues encountered while recording the actual installation procedures in the document. [10] The computer system may now proceed to OQ once issuing an acceptable and authorized IQ summary report is generated. [11]

4.3 Operational Qualification:

The OQ test confirms the effectiveness of the system and the effectiveness of the IQ process. This test includes static and dynamic processes, which ensure precise testing and documentation of all continuous and sequentially controlled graphical component operations.12 the term OQ refers to "the set of defined activities necessary to prove that the instrument will work according to its functional specification within the selected environment." It is essential to stress the expression "within the selected environment." Testing the hardware of the instrument at the site of the client is vital since the characteristics of the equipment can differ because of physical vibration during transportation from the manufacturer to the client. The most frequently posed questions regarding OQ testing include what needs to be tested, what are the minimal acceptable criteria, and who will perform the test. "Users, or their qualified representatives, should conduct these tests to prove that the instrument satisfies supplier or user specifications within their own environment," says URS as an answer to all these questions. [13]

4.4 Performance Qualification:

Once the installation and OQ processes are successfully carried out, the next step in the validation process involves ensuring that the product or software performs well according to the predetermined requirements without introducing any constraints when put under the intended workload in the production environment. The purpose of PQ is to ensure that the software works as intended on the intended system. We conduct PQ to confirm that the software always conforms to the desired performance requirements regardless of the different loads it will be subjected to. Therefore, PQ will take some time since we will have to conduct tests each day. [10]

5. LIFE CYCLE MODEL:

The objectives associated with applying a life cycle approach to verify and validate the project are consistent with those of a system architect. Management of a system that is composed of defined components enables an effective and efficient process for producing goods and services. [14] In the entire software development process, particular validation and verification activities evolve to form an inspection process which eventually results in the creation of important components in the software development process. [15] The software system is designed based on a life cycle model approach. The computer validation process links each of the stages in the process of developing the software system. Consequently, it becomes possible for such a model to cover all the stages in the CSV process. [12] It gives some indication as to the type of specifications that the system needs to be able to accommodate, including structured development, execution, utilization, and the stopping of computer programming. The diagram above shows a full life cycle of the computer system. The four phases of the computer system life cycle, according to GAMP 5 (Global Association of Pharmaceutical Industry) Pharmaceutical Engineering (ISPE, 2008), focus on the engineering processes involved in the production of pharmaceuticals. The validation process for computer system projects is carried out in planning, specification, development, verification, and reporting. When implementing the project, full CSV according to the V-model is mandatory. [16]

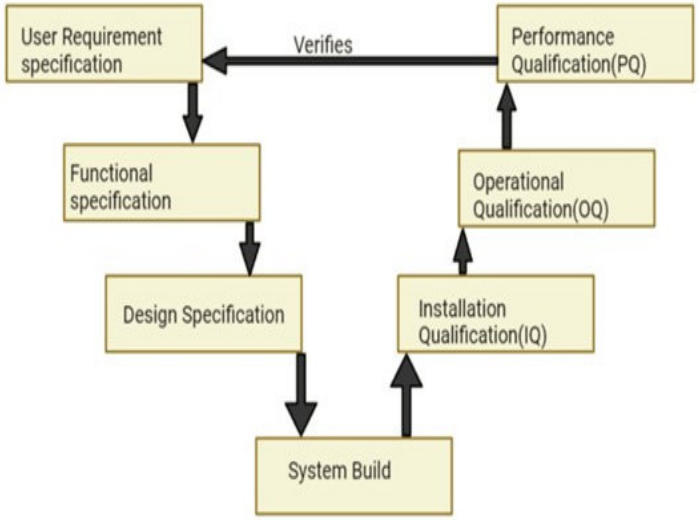

Figure: V-model of qualification

The strategy involves code generation and evaluation, functional specification (FS), design specification (DS), IQ, OQ, PQ, and user requirement specification (URS). The previously discussed technique is perfect, assuming that software development is included in the validation process. However, it fails to consider some essential aspects, including vendor evaluation. In addition, it seems overly complex for the genuine customizing of off-the-shelf commercial products. [17]

6. VALIDATION TEAM

The multidisciplinary group will be mainly charged with carrying out and managing validation studies. People who have been trained and experienced in a relevant field can carry out validation studies. Some of the staff that will be involved in the working party will include:

- Quality Assurance Manager.
- Engineering Manager.
- Validation Manager.
- Production Manager.
- Validation Discipline Specialist: all areas.
- The validation team needs to be

- Create the master validation plan of the facility including the required specifications according to company policy.
- Hold regular meetings, following a predefined schedule, to review progress and compliance with the validation plan and schedule.
- Define the systems/equipment that need to be qualified/validated and the level of validation needed.
- Define the frequency of validation.
- Create and evaluate the feasibility of the validation protocol.
- Evaluate the appropriateness of tests used for verifying that objectives have been accomplished.
- Validate that the validation study report is accurate and signed off by the validation team. Document the validation study and provide updates on validation plan/schedule to Corporate Quality Assurance.[18]

7. DOCUMENTATION

Documentation at all stages in the process validation lifecycle is necessary for clear communication in complicated, extended, and multi-disciplinary initiatives. Documentation is necessary because information that is learned about a product and its process needs to be easily understood by those in other parts of the lifecycle. This openness in information is one of the core principles of the scientific method. It is also critical in ensuring that organizations involved in the process have the ability to make well-informed science-based decisions regarding the product's commercial release. [19]

8. VALIDATION LIFE CYCLE

The validation process is ongoing and evolving. The validation process, starting from the most basic to the very wide ranging biological and systematic study of how the system and process work. It ranges from documenting to revisions controlling and even training of both the system and the process. Evidence of validation needs to be present in the company itself through its organizational structure. The process of validation is a process that creates quality. [20]

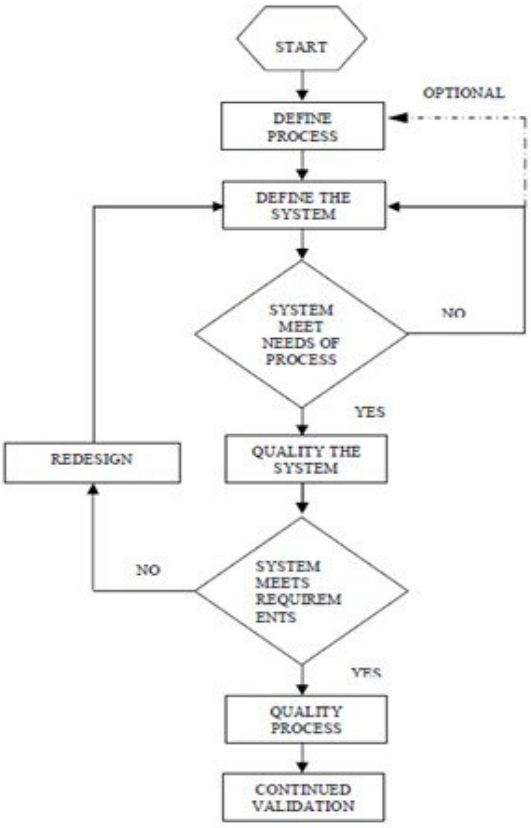

Figure: Validation Life Cycle

9. VALIDATION PROTOCOL

It will serve as a document that describes the actions that will be taken during the process validation, including information about those people who will carry out each task, the testing parameters, sampling plans, testing procedures and specifications, and the details about the product and the equipment to be utilized in the process. It is essential that the protocol specifies the least number of batches required for the validation tests to be undertaken, and also the acceptance criteria and signatures required to validate the conclusions from the study. The protocol should include the following information:

- Process Description.
- Description of key steps within the process that require investigation.
- Specifications for the in-process and finished product.
- Sampling Plans.
- Departmental Responsibilities.
- Proposed Schedule.
- Protocol Approval.[21]

10 THE VALIDATION REPORT

There must always be a written report available after the completion of the validation exercise, which must be approved and authorized if it is deemed satisfactory. The report must cover at the very minimum the following details:

- Title and objectives of study.
- Protocol to be followed.
- Details of materials used.
- Equipment.
- Programs and cycles involved.
- Procedures and test methods used.
- Recommendations for the limitations that will be applicable in the future.[22]

11. EVOLUTION OF CONCEPT OF PROCESS VALIDATION

Although the concept of “validation” entered the domain of pharma via the introduction of GMP, the requirements were not defined clearly in those days. [23] In 1987, there came out the first guidance in life science area for the process of validation.[24] FDA came up with an innovative idea regarding the quality of the final product in this guideline stating that "quality cannot be tested or inspected into the finished products and quality must be designed or built into the product." This document described process validation as "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics." This guideline emphasized conducting validation through controlling processes of each small stage in the manufacturing process. Process validation proved to be useful in demonstrating the efficiency and repeatability of the process it was known, however, that the avoidance of end-product testing could not be made possible, and hence, process validation along with end-product testing assured the consistent manufacture of the product of desired quality. The guidelines issued by the US FDA in 1987 provided the basics of process validation, but were unable to provide an accurate concept of what process validation requires and how important it is. It was mostly considered a document-based procedure which included obtaining a huge amount of data from three consecutive batches used for validation purposes. It was found that the implementation of the process validation system would not necessarily ensure that good quality products will be obtained. The quality of the products had always been doubted by the lack of robust process validation procedure, cited by compliance inspectors. According to scientific proof, process validation is not now a single activity that takes place; rather, it encompasses all of the activities within the entire product lifecycle. The basis of the product lifecycle approach includes the following ICH Quality Guidelines for

Industry, namely, Q8(R2) Pharmaceutical Development, Q9 Quality Risk Management, and Q10 Pharmaceutical Quality System.[25-27] Most regulatory authorities including USFDA,[28-29] EMA,[30-31] Health Canada[32] and India[33] have adopted the above policy, publishing their own regional guidelines in order to conform to current guideline of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).,[34] ICH, and World Health Organization (WHO).[35-37] Furthermore, there is alignment between industry and agencies for meeting ISO 9000 requirements, which include standards on QMS. Such standards assist organizations in meeting the needs of the customer as regards statutory and regulatory requirements on products or services offered by the organization. [38-40] Therefore, there is a need for industries to adjust their manufacturing and validation practices to the shifting demands.

12. STAGES OF PROCESS VALIDATION

As per the contemporary perspective, the process validation procedure is split into 3 stages. The following figure presents the stages and sub-stages of process validation.

Stage 1 – Process Design Stage

Stage 2 – Process Qualification Stage

Stage 3 – Continuous Process Verification

12.1 Stage 1 – Process Design:

Objective of the stage is to develop a commercial manufacturing process that will be capable of delivering products with expected quality characteristics. This stage includes all activities that are involved in the product development such as product research & development, selection of API & excipients, dosage form selection, formulation development, process development, pilot plant studies & technology transfer to commercial production. Information gained from this stage can be utilized for developing a complete master validation plan.

Figure: Stages of process validation

Process Design Components

12.1.1 Knowledge management (KM):

The inputs to an effective process design include knowledge about the product/process, which can be acquired using different approaches. Knowledge of the product/process that is supposed to be designed can be acquired in two ways:

1) Existing knowledge, and

2) Knowledge obtained during pharmaceutical development activities.

The existing knowledge acts as the foundation for designing the commercial process and may include information such as published information, experience with other similar products/processes, laboratory studies, pre-clinical and clinical studies, physical chemical and biological properties of the drug substance, compatibility, and others.

12.1.2 Science and risk-based approach:

Scientific information acquired from manufacturing and experiments done during the development of the drug contributes to providing a scientific background for setting up a reliable commercial scale manufacturing process. Scientific background of both product and process, when applied together with knowledge of quality risk management, contribute towards understanding the impact of variations in inputs and also help in designing a suitable control strategy to mitigate the associated risks of impact and extent of the impact. This is among the approaches to QbD recommended by ICH Q8.

12.1.3 Process Design Deliverables

The tasks carried out in this step will generate the following deliverables, which will assist in progressing towards the next phase (Process Qualification) of process validation. The process design deliverables along with the representation of the QbD approach for process design are presented below. Quality Target Product Profile (QTPP) or a proposed overview of the quality attributes of a drug product, which needs to be ideally achieved to meet the desired quality requirements considering the safety and effectiveness of the drug product. For instance, the QTPP profile of a hypothetical drug in a single dose vial form at a strength of 5 mg/mL is outlined below. The QTPP attributes have been identified using RLD Product, RLD Label, and target patients' information. The CQAs that remain unaffected by the changes in formulation or process parameters may usually be managed using good pharmaceutical practices and proper release control strategies.

12.1.4 Manufacturing process design:

Flow charts and descriptions for manufacturing processes, which give details about inputs, outputs, by-products, process sequence, process conditions, yields, and hold times, are part of the Design Document. Also, qualifications for incoming materials and intermediates and process parameters for each manufacturing step need to be documented within the Design Document. Any change in the manufacturing process as a result of Technology Transfer or Scale-Up needs to be addressed. Methods for analysis for raw materials, intermediates, and drug products, and for characterizing impurities are also included in the Design Document. Such methods could either be compendial or non-compendial methods. For compendial methods, a verification study is conducted, while for non-compendial or internally developed methods, a validation study is necessary. Parameters, which pose a greater risk to Critical Quality Attributes (CQA) of the drug product, are considered as Critical Process Parameters (CPP).

12.1.5 Process characterization and Product characterization testing plan:

These are the drug development studies done with the objective of understanding the operational parameters and their effect on the process or the quality of the drug, and which are controlled through risk assessment studies. The output from these studies helps in determining the range of process parameters. While such studies are conducted in the laboratory, they need to be indicative of commercial performance as well. These may aid in establishing confidence levels for PQ studies in Stage 2.

12.1.6 Control strategy:

Control Strategy is defined as “A planned systematic approach consisting of a defined set of criteria based on existing process and product knowledge gained by previous knowledge and experience, and process and risk assessments.” These controls can consist of criteria relating to DS and DP material/component controls, facility and equipment operating parameters, in-process controls, finished product characteristics, and the methodology of how such monitoring and control will be accomplished. Control strategy should be documented in either a product specific document or a series of documents. The example control strategy provided here pertains to a fictional generic lyophilized injection.

12.2 Stage 2 – process qualification

In this stage, design of the process is tested in action to see whether the process can sustain repeatable commercial manufacture. This stage is done prior to commercial production of the product. The stage involves these two sub-stages:

- Facility design and qualification; equipment, systems and utilities qualification
- Process performance qualification (PPQ)

It is crucial to design and qualification of facility and perform equipment, systems and utilities qualification prior to process qualification. Qualification study helps in determining whether equipment, systems and utilities are qualified for the task and can yield expected results. Master plan of validation needs to provide a clear procedure for carrying out qualification studies, the validity of which and how often to carry out requalification studies.

Figure: Process design deliverables

General plan for qualification of facilities, equipment, systems, and utilities should include the following steps:

- Confirmation that the equipment, systems, and utilities have been constructed according to design specifications, meaning their material composition, working principles, and performance capabilities (Design Qualification or DQ).
- Confirmation of Installation (Installation Qualification or IQ) and Operation (Operational Qualification or OQ) of the equipment, systems, and utilities in line with the designed specifications and the expected operating ranges.
- In certain circumstances, it may become necessary to confirm the performance (Performance Qualification or PQ) of the equipment, systems, and utilities while the process is running at the normal operating range of the desired product. This can be achieved either through simulations or together with Process Performance Qualification process.
- Any deviation needs to be handled carefully.

12.3 Stage 3 – Continued Process Verification (CPV)

At this stage, it is anticipated that the process will have assurance that the process has maintained a controlled state after the process qualification stage. Besides, through CPV, manufacturers can identify areas where the process needs to be improved. There are two stages under a CPV process, which differ according to testing done. There are two sub-stages of a normal CPV program.

12.3.1 Enhanced testing program:

Post successful PPQ, increased sampling and testing go on to continue up till the CPV process stage in order to have a clear understanding of the process variability. This is due to the fact that unexpected issues of

process variability could occur in regular production and ongoing assessment will be useful in making adjustments to the inputs variables by changing management process. The information gathered must include process trends and the quality of the incoming materials/components, intermediate materials, and the final product. This information needs to be trended statistically and analyzed by qualified personnel.

12.3.2 Routine testing program:

In this phase, data from the first phase is used to monitor products and processes regularly. The amount of testing is minimized depending upon the amount of statistical confidence achieved and the risks involved. A CPV plan is designed using the insights and information gained from phases 1 and 2 and should comprise the following components:

- Roles and responsibilities
- Sampling strategy
- Analysis techniques for data
- Criteria for acceptance
- Strategy for deviations
- Frequency of reassessment of CPV plan

14. EVALUTION OF PROCESS UNDERSTANDING

14.1 Development Phase

The bulk of learning will be gained through the phase of product and process development and characterization within the product validation life cycle. These operations will provide information and knowledge about the effects of the anticipated variation of input material and manufacturing processes upon the Critical Quality Attributes of the product. Establishing process understanding will involve an investigation of the connection between the variability of process parameter, material characteristics and other variabilities and their possible effects on CQAs.

Models can be built for predicting the effects of variation of inputs into the process and their impacts upon the Critical Quality Attributes of the product. In particular, this applies to new drug products designed according to QbD Principle.

Process variation and capabilities may be predicted based on batch development. Process critical limits will be determined based on process development, characterization and manufacturing experience (pilot, demonstration and clinical trials batches).

14.2 Prior Knowledge

In many instances, as a new product is being developed and commercialized, the platform on which manufacturing would take place in the commercialization phase is already known to the company. The manufacturing process would be one that is well understood because it was used before to make other products. It is thus possible to use this knowledge base to estimate the expected performance of similar processes currently being developed and validated.

The inherent variability of the process can be estimated based on the knowledge acquired during development, including experiments and understanding of similar products/processes. In addition, the variability that would result from operator/shift change, interruptions in the process, hold times, more than one equipment set, and different material suppliers can help determine the number of validation batches that should be run. Any high level of variability or lack of understanding of the range of variation increases the difficulty of proving process reproducibility. [41]

Process Understanding Factor	Relative Risk Ranking Characteristics of ranking assignments		
	Low Risk	Medium Risk	High Risk
Degrees of process understanding/ unit operation	• First principle knowledge: based on knowledge about the mechanisms prevailing	• Causal knowledge: which is knowledge about what causes interrelationships between variables	• Descriptive knowledge: which is based solely on observations, thus constituting facts

	and the reasoning behind them		
Process predictability and modelling	• Models based on first principle. Extension of empirical and mechanistic models • Highly predictable process and scale-up	• Use of models derived from basic physical, chemical, biological or microbial mechanisms of observed phenomena • Sufficient knowledge to employ PAT methods, if applicable and desired	• Primitive models reflecting only basic understanding of process and scale effects • Process predictability is questionable
Process response to input variability	• Design spaces identified using multivariate data and statistical methods • Impact of material attributes on product quality explored extensively in development • Material specific critical quality attributes identified and well understood or no material specific critical quality attributes	• Well-defined critically for process based on multivariate experiments • Impact of material attributes on product quality explored to some degree • Material specific critical quality attributes identified – full range of variability not explored in development	• Partially defined, primarily through univariate experimentation • Impact of material attributes to product quality are minimally explored • Material specific critical quality attributes not identified
Effects of scale changes	• Very Predictable – Data at various scales is fundamentally similar	• Predictable – Data at various scales may be projected, although scale dependency is expected	• Unpredictable – Scale dependency expected but not investigated

15 IMPORTANCE OF PROCESS VALIDATION

15.1 Assurance of Quality:

Validation can be considered as an extension of QA principles due to the need for tight control of the processes in order to ensure product quality, which cannot be achieved without an adequate knowledge of the process capabilities. Without validation and proper control, the process will not be controlled at all, making consistent production of high-quality products impossible. End product testing done without validation does not guarantee the quality of the end product for a variety of reasons, some of which are:

1. Small sample size.
2. Limited number of tests done on a sample. One may not be able to test the sample for all possible impurities.
3. Limited sensitivity of the test.

15.2 Process Optimization:

Optimization of a process to make it more efficient but not compromising on quality standards is an outcome of validation process. The literal meaning of optimize is “To make as effective, perfect or useful as possible”. When optimization is done for facility, equipment, systems, and process, the resultant output will meet all quality requirements with the lowest cost possible.

Reduction in quality costs

Quality costs are categorized in four different heads. These are:

a) Preventive costs.

b) Appraisal costs.

c) Internal failure costs.

d) External failure costs.

E.g. of internal failure costs: Whenever there is a validated and controlled process, the number of internal failures reduces considerably like:

Less number of rejects

Rework

Retests

Re-inspections [42]

16. REVALIDATION

The idea of revalidation has changed according to the principle of validation lifecycle. Earlier, manufacturing changes, including changes in formulation, packing material, raw material, equipment, used to lead to revalidation. In contrast to that, under CPV, the process data evaluation occurs relative to the variability range determined by process validation. It can happen that revalidation will not be required at all.

17. BENEFITS OF PROCESS VALIDATION

The main concept behind conducting process validation exercise in any manufacturing process is to make sure that the manufacturing process produces batches of products with the required quality. Using the lifecycle approach, this can be achieved through scientific and risk based assessment approaches. Therefore, process validation helps the manufacturer in the following ways:

- Saves time and costs related to R&D and improves performances/investigation
- Helps avoid any regulatory actions such as Warning Letters/recalls/seizures as there are fewer rejects and reworks involved.
- Produce high-quality products
- Assures patient safety
- Establishes the value of the brand
- Disadvantages of Process Validation (lifecycle approach)
- Lifecycle validation is not a one-off event but it stretches to cover the entire lifecycle of the product
- Retrospective validation cannot be conducted.
- The lifecycle approach relies on statistical analysis to assess the validity of the process.
- Process validation is ultimately reliant on a range of facilities, equipment, personnel, and procedures being qualified for successful completion. In addition to GDP and GLP, there are other areas which play an important part in completing process validation such as training and development.

18. CONCLUSION

The increase in citation cases that have weak manufacturing processes during facility inspections has compelled industry players and regulators to rethink the traditional paradigm of process validation. Following the issuance of ICH (Q8, Q9 and Q10) guidelines, there has been a shift in paradigms from traditional to lifecycle approach in process validation activities. The new paradigm is a more scientific approach based on solid understanding of product and process knowledge derived from historical records, experience and experiments. Not only does the lifecycle approach assure product and process quality but also establishes a system that identifies and implements opportunities for continuous improvements. In summary, the lifecycle approach embraces an approach that fosters innovation and implementation of advances in science, technology and quality management systems. Comparison between Traditional and Lifecycle Approach. In addition, a comparison of guidelines across different geographical regions indicates that there are no considerable variations in the guidelines as they all incorporate the ICH concepts. Therefore, it is important for drug manufacturers to conduct an audit of their existing validation processes vis-a-vis the lifecycle concept, discover any loopholes, and make modifications to their existing practices and systems. A team-based approach, combined with an efficient documentation and communications process, is quite useful in this regard.

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