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CLEANING VALIDATION- CHALLENGES, ACCEPTANCE CRITERIA AND REGULATORY COMPLIANCE: A REVIEW ARTICLE

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ABSTRACT

Cleaning validation is a critical component of pharmaceutical manufacturing that ensures equipment and production systems are consistently cleaned to predetermined acceptable levels, thereby preventing cross-contamination and ensuring product quality, safety, and regulatory compliance. This review article discusses the concept, significance, methods, and regulatory requirements of cleaning validation in the pharmaceutical industry. It highlights the role of validation in maintaining Good Manufacturing Practices (GMP) and outlines different types of validation, including process, analytical, and cleaning validation. The article further explains cleaning mechanisms, validation methodologies, analytical method validation parameters, and lifecycle approaches recommended by regulatory agencies such as the USFDA, EMA, WHO, and PIC/S. Emphasis is given to quantitative acceptance criteria including NOEL and MACO calculations used to establish scientifically justified residue limits. Additionally, the integration of Quality by Design (QbD) and Process Analytical Technology (PAT) in modern cleaning validation strategies is discussed. The review also addresses major operational challenges such as human error, inadequate documentation, inconsistent procedures, and resource limitations. Overall, effective cleaning validation plays a vital role in ensuring pharmaceutical product integrity, minimizing contamination risks, and achieving global regulatory compliance.

KEYWORDS: cleaning validation, cross contamination, QbD, Analytical method of validation.

1. INTRODUCTION

In the mid-1970s, FDA officials Ted Byers and Bud Loftus introduced the concept of **validation** as a strategic approach to enhancing the quality standards of pharmaceutical manufacturing. It was put forth in direct response to the numerous issues with parental sterility products. Initial validation efforts concentrated on the manufacturing methods of these products, but they quickly extended to all pharmaceutical production processes. Validation is a technique that can be used in a number of disciplines, including biology, chemistry, psychology, medicine, sales, and economics. In actuality, the validation notion is applicable in the majority of contexts. A new or improved method must be validated to guarantee its integrity and quality in terms of precision, accuracy, detection limit, limit of determination, selectivity, linearity field, and, last but not least, transferability.[1] Validation is mostly based on FDA rules included in 21 CFR that describe current good manufacturing practices (cGMP) for finished pharmaceuticals.

sections 210 and 211. According to the cGMP regulations, manufacturing processes must be planned and managed to guarantee that both the final product and in-process materials consistently and reliably fulfil specified quality standards. Parts 210 and 211 of the cGMP requirements mandate process validation in both general and particular terms.[2,39]

Need for pharmaceutical validation

A crucial component of quality assurance is validation, which entails the methodical examination of facilities, systems, and procedures to ascertain if they fulfil their intended purposes in a sufficient and reliable manner. A validated process is one that has been formally certified after it has been shown to offer a high level of confidence that consistent batches that satisfy the necessary requirements will be generated. Validation verifies that processes have been appropriately developed and are under control, but it does not by itself improve processes.[3]

Thus, validation ought to be taken into account in the following circumstances

1. Completely new process;
2. New equipment;
3. Process and equipment modified to accommodate shifting priorities; and

4. Process where the final product test is subpar and an untrustworthy measure of product quality.[4]

TYPES OF VALIDATION

1) Analytical validation

1) Equipment validation

2) Process validation

(a) Prospective validation

(b) Retrospective validation

(c) Concurrent validation

(d) Revalidation

3) Cleaning validation[10]

Cleaning validation

Documented proof that enhances the efficiency and consistency of equipment cleaning in pharmaceutical manufacturing is known as cleaning validation. It mainly applies to production equipment or pieces of manufacturing equipment that are challenging to clean in the workplace. To prevent cross-contamination during manufacturing, techniques are devised to measure the quantity of residue on equipment and the cleaning process is validated.[5]

Why Cleaning Validation is Important

Preventing medication adulteration and cross-contamination with other APIs is the main objective of cleaning validation. Therefore, the primary goal is to prevent contamination and provide a product that is free of contamination while maintaining high standards of quality and patient safety.[6]

WHEN CLEANING VALIDATION IS TO BE PERFORMED?

- For non-critical cleaning, like that which occurs between batches of the same product (or various lots of the same intermediate in a bulk), it is not always necessary. procedure) or of walls, floors, and external vessels.
- It should be carried out among outside vessels, equipment, sanitization techniques, and clothing washing, and it should be regarded as significant in multi-product facilities.
- Initial equipment and process qualification.
- A significant modification to a cleaning process.
- A significant modification to the formulation.

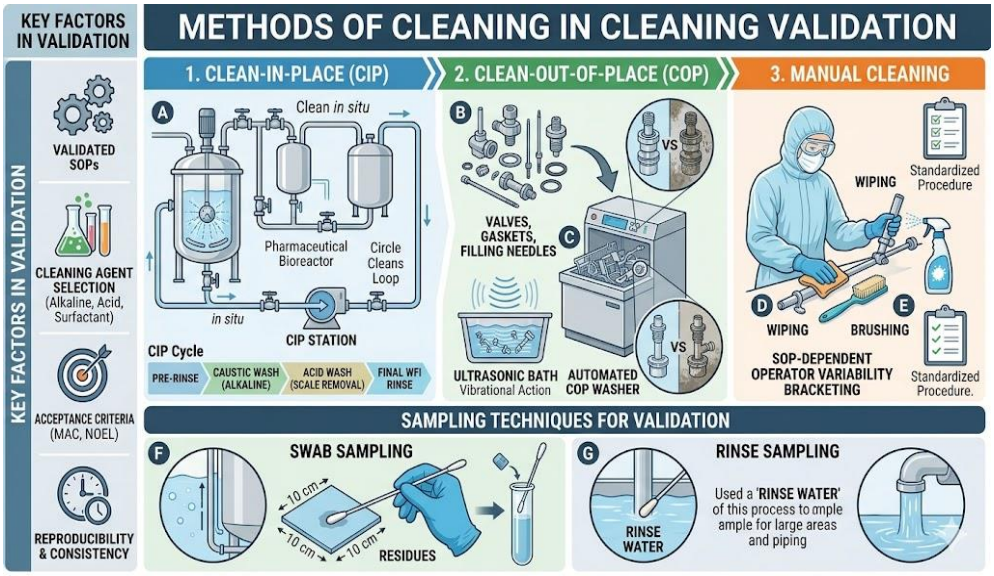
- The formulation has changed significantly.
- A modification to a cleaning procedure.
- Switching out a cleaning solution[7,8]

CLEANING VALIDATION BENEFITS

1. Making wise business choices
2. Quality expenses are decreased
3. Equipment reuse
4. Batch integrity
5. Preventing cross-contamination
6. Assurance of quality and safety
7. Governmental regulations
8. Microbe integrity
9. Product integrity[9]

2. Cleaning Mechanism

Several fundamental methods are available to eliminate residues from equipment. Mechanical action includes physical processes like brushing, scrubbing, and using pressurized water to dislodge particulates. Dissolution entails using an appropriate solvent to dissolve residues. Water is the most commonly utilized solvent due to its qualities, including being inexpensive and non-toxic, leaving no residues, and being environmentally friendly. In some cases, it may be more effective to use a non-aqueous solvent or a mixture of both aqueous and non-aqueous solvents based on the solubility properties of the materials involved. Alkaline or acidic solvents, for instance, can enhance the dissolution of materials and may provide advantages.[11,40]



Cleaning validation method

Validation of cleaning techniques

Validating cleaning methods is a methodical way to ensure that contaminants are regularly removed to appropriate levels. It includes:

Defining acceptance criteria: Using product specifications and regulatory rules as a reference, clearly define acceptance criteria.

Creating procedures for validation: Make thorough protocols that describe the validation process, including acceptance criteria, testing methodology, and sample techniques.

Conducting validation research: Using suitable sampling and analytical techniques, conduct validation studies to evaluate the efficacy of cleaning processes.

Recording outcomes: To prove compliance with regulatory requirements, keep complete records of validation studies, including test findings and variations.[12,13]

3. Analytical method of validation

Development of Analytical Methods Method validation is the process of verifying that the analytical testing technique used for a certain test is appropriate for its anticipated purpose. The outputs obtained from the technique validation procedure are used to evaluate the consistent results of analysis. This guarantees a dependable and high-quality product. A well-developed method is considered the core process for a dependable testing procedure.[35,37]

Different Types of Validation characteristics:

- Precision.
- Accuracy.

- Specificity.
- Linearity.
- Range.
- Detection Limit.
- Quantitation Limit.
- Ruggedness.
- Robustness.[36]

4. Life cycle approaches for cleaning validation

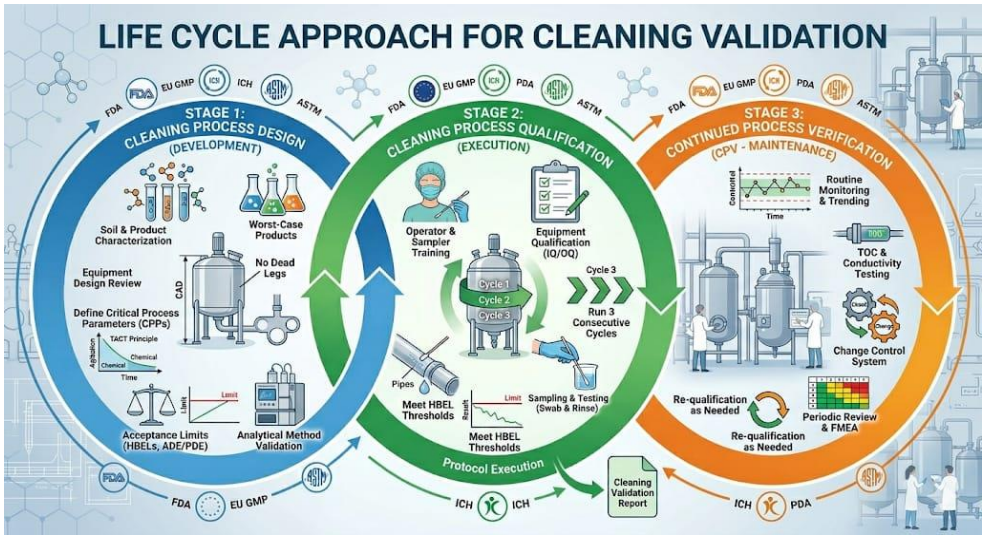
Cleaning validation using a life cycle approach:

According to the "Guidance for industry- Process validation industries:

The FDA is recommending a three-stage validation strategy based on general principles:

Stage 1: Process design;

Stage 2: Process qualification; and Stage 3: Continued process verification. This method can be used not only for a product's production process but also for subsequent and validating operations.[41]



5. Global regulatory compliances

In order to meet the following agency standards, cleaning processes have to be verified.

In 1993, the FDA released a guide for cleaning process validation inspections.

PIC/S validation guidelines, PI-006-3 (2007)

Cleaning validation is covered in a distinct chapter in Annex 15. Additionally, cleaning validation is required by ICH guideline Q7, "GMP for APIs."[23]

The Food and Drug Administration (FDA) sets rules and guidelines pertaining to pharmaceutical-grade goods.

commercially distributed in the US.

Current Good Manufacturing Practices (cGMP) standards are found in Title 21, Part 211 of the CFR Code of Federal Regulation. Currently, 21 CFR 211.67, which stipulates that "equipment and utensils be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product," is the focal point of the broad and somewhat ambiguous applicable laws. This regulation mandates that the food and pharmaceutical industries adhere to the cleaning validation procedure in order to prevent product malfunctions, contamination, and cross-contamination.[24,25]

1. US Food and Drug Administration (USFDA)

On April 1, 1993, the FDA updated its Equipment Cleaning guidelines under Section 211.67 in 21CFR. The FDA mandates that: To avoid malfunctions or contamination that would change the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements, equipment and utensils must be cleaned, maintained, and, depending on the nature of the drug, sanitized and/or sterilized at the proper intervals. The FDA has made it very clear in the Questions and Answers on Current Good Manufacturing Practices-Equipment that contamination that is removable and reasonably avoidable is never acceptable. Therefore, cleaning procedures should be based on scientific knowledge of the substance rather than being suboptimal designed to remove a predicted "acceptable" level of residue.[26]

2. European Medicines Agency (EMA)

When it comes to developing risk-based cleaning validation standards for preventing cross-contamination in shared production facilities, EMA has undoubtedly been at the forefront. Health-Based Exposure Limits must be established for all pharmaceutical products, according to EMA guidelines that went into effect on June 1, 2015. A Q&A on the application of the aforementioned guideline quickly followed. Every pharmaceutical product should have HBELs. Throughout a product's history, the toxicological or pharmacological data that the HBEL calculation is based on must be periodically reevaluated. This suggests that the alert limit should be set based on the statistical evaluation rather than the dose restriction if your past dosage-based limit is the worst and that causes CpK < 1.33.[27]

3. WHO, the World Health Organization

The FDA and WHO Cleaning Validation Guidelines are fairly similar. The fundamental standards for WHO good manufacturing practices for active pharmaceutical components are outlined throughout the paper, but particularly in Sections 5.2 and 12.7. Here are some things to remember. The worst product method is unquestionably accepted by WHO when choosing representative APIs to verify cleaning protocols.[28]

4. PIC/S, or the Pharmaceutical Inspection Cooperation Scheme0

Following EMA's lead, PIC/S swiftly published its own version of the revised Cleaning Validation Guideline to prevent cross-contamination (PI 046-1 Guideline for setting HBELs in shared facilities), which went into effect on July 1, 2018. Given that PIC/S has members from over 50 countries, this was a significant step toward a risk-based cleaning validation program.[29]

6. Quantitative Acceptance Criteria & Mathematical Modeling

Acceptance criteria are predetermined requirements that establish the acceptability of the cleaning procedure. They depend on a number of variables, including as the type of residues, how they could affect the quality of the final product, and legal requirements. Strong acceptance standards aid in ensuring that equipment is regularly cleaned to a level that guards against contamination and guarantees product safety.[15]

Testing for permissible residues comprises

- Identification of residues
- The choice of residue detecting technique
- Choosing a sampling technique
- Establishing criteria for residue acceptance
- Validation and recovery studies of methods
- Creating a protocol and educating operators.[38]

In contrast to chemicals, purification phases in the manufacturing process help remove impurities, thus it cannot be said that all of the pollutants in a train of equipment are transferred in the end product. For upstream and downstream equipment, businesses currently use separate standard approval criteria.

This method is predicated on the idea that the cleaning agent's breakdown only produces amino acids, which are completely eliminated throughout the purification stages. Based on that rationale, PDA TR 49 defines an acceptance criterion for equipment used after the final purification step (often a TFF) and a predetermined multiplication factor of 5 to 10 for equipment used for early stages of the production process.[16]

Although cleaning validation standards for pharmaceutical companies have not yet been released by the U.S. Food and Drug Administration (FDA), they serve as a guide for the routine inspections conducted by investigators and other FDA staff. The FDA often anticipates in the document:

Standard operating procedures (SOPs) for equipment cleaning methods that are written and cover many scenarios (e.g., one process for different batches, separate processes between product modifications, etc.)

Written cleaning validation protocols that specify the acceptance criteria, who is in charge of conducting and approving the validation study, and when re-validation will be necessary.[17] The residual limit's acceptance criteria must be realistic, attainable, verifiable, and supported by science. The equipment must be visually clean, dry, and unscented prior to sampling for cleaning validation. In particular, MACO (Maximum Allowable Carry Over) will be the accepted criterion for cleaning validation for oral dosage forms. The MACO is predicated on the strictest of the following three standards.[18]

Criteria of Therapeutic Dose

The allowable quantities of residual active pharmaceutical ingredients (APIs) that stay on equipment surfaces after cleaning are referred to as the Criteria of Therapeutic Dose in cleaning validation. These standards are predicated on the drug's therapeutic dose, which is the quantity normally given to provide the intended therapeutic effect. This criterion's primary features are:

Therapeutic Dose-Based Thresholds: Residual levels must be less than a threshold that is determined as a percentage of the therapeutic dose. This cutoff guarantees that any leftover API on machinery won't have a major therapeutic impact if it contaminates the subsequent batch. Regulatory Guidelines: Usually expressed as a percentage of the therapeutic dose or based on permissible daily exposure limits, regulatory bodies frequently offer guidelines on establishing these thresholds.[18]

Setting scientifically justified acceptance parameters is critical in pharmaceutical cleaning validation to guarantee that any leftover active pharmaceutical ingredient (API) on manufacturing equipment does not endanger patient health. Two important toxicological factors utilized to determine these thresholds are the No-Observed-Effect Level (NOEL) and the Maximum Allowable Carryover (MACO).[19]

1. No-Observed-Effect Level (NOEL)

The NOEL is defined as the highest dose of a pharmaceutical compound at which no adverse effects are observed in test subjects, typically animals, under specified experimental conditions. It is a foundational toxicological value used to estimate safe exposure levels in humans. The NOEL for a drug is often calculated using its Lethal Dose 50 (LD_{50}), which is the dose required to cause death in 50% of the tested animal population. The calculation assumes an average adult human weight of 70 kg and includes a conservative safety margin: Where:

$$NOEL = \frac{LD50 \times 70\ Kg}{2000}$$

- LD_{50} = Lethal dose in mg/kg (from animal studies)
- 70 kg = Average adult human body weight
- 2000 = Safety constant derived from toxicological risk assessments

2. Maximum Allowable Carryover (MACO) The MACO is the calculated limit of residual drug that can be carried over into the next product manufactured in shared equipment, without causing any adverse health effects. It is expressed in milligrams or parts per million (ppm) and is used to set acceptable residue levels in cleaning validation protocols. Where:

$$MACO = \frac{NOEL \times MBS}{SF \times TDD}$$

- NOEL = No-Observed-Effect Level (mg/day)
- MBS = Maximum batch size of the next product (mg or kg)
- SF = Safety factor (usually 1000 for oral products)
- TDD = Total Daily Dose of the next product (mg/day) This calculation ensures that any residual amount of the previous product does not exceed a safe exposure level when ingested as part of the next product's total daily dose.[20,21,22]

7. Strategic implementation of QbD and PAT

The Quality by Design (QbD) framework, which is introduced in ICH Q8, encourages manufacturers to incorporate cleaning validation from the very beginning of product and production process development. QbD helps guarantee that cleaning processes are customized, tested, and scalable—long before full production starts—instead of treating cleaning as an afterthought.[14]

Fundamentals of ICH Q8 for Cleaning Validation

Establishing a Cleaning Parameter Design Space

Contact time, cleaning agent concentration, and rinse volume are examples of cleaning parameters that should be within a validated design space. This method preserves control over important cleaning process parameters while allowing for operational flexibility.

Product-Specific Cleaning Agent Selection

A thorough grasp of residual properties, source materials, and equipment interactions should serve as the foundation for selecting cleaning products. To make cleaning easier, for example, intractable APIs or sticky excipients could need specific cleaning solvents or longer exposure times.

PAT Instruments for Cleaning Process Efficiency

Real-time monitoring of cleaning process performance is made possible by the use of Process Analytical Technology (PAT), such as TOC (Total Organic Carbon) measurement or in-line UV sensors, which makes it simpler to identify abnormalities and lower the frequency of revalidation.

Manual Cleaning Techniques for Complicated Equipment

Not every piece of equipment in many plants can be cleaned with CIP systems. Validated manual cleaning techniques are necessary to get successful results for manufacturing equipment such as fluid bed dryer bags or vessels with difficult-to-reach places.

Documentation of the Developmental Justification

Manufacturers are required to keep thorough documentation outlining the selection of cleaning parameters, the computation of residual limits, and the scaling of the cleaning validation process from lab to full-scale production.[14]

8. Critical operational challenges

Challenges in Cleaning Validation

Cleaning validation stands as a critical phase within pharmaceutical manufacturing. Ensuring a highly efficient and successful cleaning protocol is vital for preserving the overall safety and quality standards of the manufactured goods. Although executing cleaning validation presents notable difficulties, the effort is entirely justified by the resulting safety and premium quality of the end product.

Key obstacles encountered during this process include

Repetitive Cycles: The cleaning procedure often must be repeated multiple times to guarantee the complete elimination of all contaminants.

Environmental Constraints: The cleaning environment frequently demands strict control over specific temperature and humidity parameters to be effective.[31,32]

Problem #1: Insufficient Time and Resources

It takes a lot of effort and money to validate your cleaning validation processes. You can be under pressure to boost output and decrease downtime, but organizing your cleaning validation strategy is just as important as carrying it out. Lack of a preapproved plan or strategy is a surefire way to end up with FDA Form 483 observations and warning letters.

Problem #2: Human Error and Elevated Risk Even with a thorough plan in place, relying on paper to document your cleaning validation processes exposes you to the potential for human mistakes and heightened risk. Paper can be easily misplaced or lost. The effort needed to rectify errors or reproduce documents can lead to expensive delays in getting products to market. To safeguard your work, think about adopting a digital cleaning validation system.

Problem #3: Unavailable Cleaning Validation Records

You produce a substantial amount of data throughout the cleaning validation lifecycle. This data is either stored off-site or in an on-site repository in a paper-based system. Audit trails are inadequate, and important material is not easily accessible to give to auditors. Related computations, such the worst-case product and maximum safe surface residue, are frequently handled in Word documents or Excel spreadsheets, which are prone to data integrity problems.

Problem #4: Variations in Cleaning Validation Processes

Cleaning validation requires consistency, which is often impossible to accomplish without a computerized solution. Tasks are approached and documented in a variety of ways since manual cleaning validation processes are entirely dependent on individuals who adhere to their own methods; there is no standardization.

Problem #5: Use of Vague Analytical Techniques

Analytical method validation, which establishes the process parameters required to offer a high degree of confidence in cleaning results, is a component of a well-developed cleaning validation methodology. The problem: when defining your acceptance criteria, how can you make sure that your analytical techniques are measurable? The analytical method is often developed by the R&D team.[33]

For monitoring, absolute verification, and change control/revalidation performance, these PDAC cycle acceptance limits, along with their justification, unique cleaning validation processes, and modified techniques, are highly advised. These days, the pharmaceutical, biotechnology, and food industries—which use quick data collecting arrangements, thorough master plan analysis, and effective cleaning procedures—recommend CIP specialists. This approach can highlight numerous areas for enhancing drug safety, environmental effect, and "OEE" level satisfaction. After the CIP system has been effectively and successfully validated in accordance with the approved FDA and ICH Q9 criteria (Risk-Mapp baseline guide), which assign a science-based limit for APIs, a written report will eventually be prepared.[34]

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