

CLEANING VALIDATION, PRACTICAL CONSIDERATIONS

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Abstract

The EHEDG subgroup Cleaning Validation is working on a new guideline which will be ready in 2014. Cleaning and/or disinfection validation is defined as 'obtaining documented evidence that cleaning and/or disinfection processes are consistently effective at reaching a predefined level of hygiene, if properly implemented on equipment and production environment and used as intended'.

According to ISO 22000, verification is the 'confirmation through the provision of objective evidence that specified requirements have been fulfilled'.

The guideline has as goal to provide a complete validation approach suitable for Equipment manufacturers, cleaning products and cleaning equipment manufacturers, and all food producers. Cleaning validation is a documented process that shows evidences to demonstrate that the cleaning methods which have been found applicable and acceptable for a process/product, achieve consistently the required levels of cleanliness.

The objective of the cleaning validation is to demonstrate the effectiveness of the cleaning procedures in the removal of product residues, degraded products, preservatives, allergens, and/or cleaning / disinfecting / cross contamination / enzymatic agents that can post a risk to the consumer. It is a fact that over 80 % of existing cleanings executed on a daily base in the food industry are not validated and poorly documented, and can be one of the root causes of food safety incidents.

Validation will require an understanding of all elements involved in the cleaning result such as the design and development for an effective program, the principles and calculations of residue limits for a variety of residue types, routes of administration, and dosage types the selection of available analytical methods, along with appropriate levels of analytical method validation, the selection of sampling methods and sampling sites, along with proper selection of blanks and con-

trols the appropriate strategies and documentation for sampling recovery studies, the presence of a cleaning validation master plan and/or policy components, the appropriate documentation and reports, the tools used for monitoring, verification and revalidation.

Key words: *Cleaning validation, hygiene, cleaning result, monitoring, verification.*

1. Introduction

The validation of cleaning, assuring a standard and consistent results has become a topic of high priority in the food processing industry. It is a fact that over 80 % of existing cleanings executed on a daily base in the food industry are not validated and poorly documented, and can be one of the root causes of food safety incidents. Validation will require an understanding of all elements involved in the cleaning result such as the design and development for an effective program.

2. Insights and issues in the cleaning validation process

The subgroup Cleaning Validation, chaired by Prof. Rudolf Schmitt of HES-SO in Switzerland, is working on a new guideline which will be ready in 2014. National and international legislation requests the food industry to put on the market safe food and equipment manufacturers to provide cleanable equipment. The validation of cleaning operations is necessary to ensure compliance. Further advantages are the optimization of cleaning operations, reduction of costs and use of polluting chemicals.

Surfaces that have to be cleaned are those that are exposed to the product, those from which splashed product, condensate, liquids or material may drain, drop, diffuse or be drawn into the product or onto product contact surfaces or surfaces that come into contact with product contact surfaces or packaging materials. They are designated as "Product contact sur-

faces" in the EHEDG. Cleaning validation is defined in the present Guidelines as "obtaining the documented evidence that cleaning and/or disinfection processes are consistently effective at reaching a predefined level of hygiene, if properly implemented on equipment and production environment that are used as intended".

There is sometimes a misinterpretation of the words validation, monitoring and verification. The following should be understood. Validation should not be confused with verification. Once that a cleaning process has been validated, it is routinely applied and the process is monitored and verified. In ISO 22000, monitoring is defined as: "conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended" and verification is defined as "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled".

When a change occurs in equipment, food manufacturing process, ingredient, cleaning agent, etc. and at predefined time intervals, revalidation is needed.

At present there is no law that requires explicitly a "Cleaning Validation", but there are several legal requirements on hygiene, hygienic design, cleanability, cleaning, sanitation, hazard analysis and the control of hazards and the overall requirement on delivering safe and non-hazardous food. Cleaning Validation is one important element to fulfil these requirements.

Some important laws on national, European and international level are the following:

- USA: cGMP for human food/dietary supplement. 21 CFR Part 110/111 [1];
- Canada: Cleaning Validation Guidelines [2]
- Germany: Law on Food and Feed (LFGB) and subordinated regulations
- Europe: Food Hygiene Package: Regulations (EC) 852/2004 etc., Machinery Directive 2006/42/EG
- International/several Nations: Codex Alimentarius (food hygiene, HACCP) CAC/RCP 1-1969.

In addition there are standards that concretize the requirements of the law, e.g.:

DIN EN 1672-2 "Food processing machinery - Basic concepts - Part 2: Hygiene requirements" and

DIN EN ISO 14159 "Safety of machinery - Hygiene requirements for the design of machinery" to substantiate the European machinery directive.

The new guideline has as goal to provide a complete validation approach suitable for Equipment manufacturers, cleaning products and cleaning equipment manufacturers, and all industrial food producers, from SME to multinational. Cleaning validation is a docu-

mented process that shows evidences to demonstrate that the cleaning methods which have been found applicable and acceptable for a process/product, achieve consistently the required levels of cleanliness.

The objective of the cleaning validation is to demonstrate the effectiveness of the cleaning procedures in the removal of product residues, degraded products, preservatives, allergens, and/or cleaning/disinfecting/cross contamination/enzymatic agents that can post a risk to the consumer of manufactured food products.

The validation of cleaning, assuring a standard and consistent results has become a topic of high priority in the food processing industry. This validation is used to show proof that the cleaning system consistently will perform as expected and provides scientific data that consistently will meet pre-determined specifications for the residuals. However when starting a new Greenfield plant, the integration of a validation approach from the design phase is a good base to achieve the required result. When an existing plant or line requires an effective and validated cleaning program, a huge amount of effort will be needed. It is a fact that over 80 % of existing cleanings executed on a daily base in the food industry are not validated and poorly documented, and can be one of the root causes of food safety incidents, related to underperforming cleaning routines.

The validation of process lines is more than the line-up of single equipments. Implementation of a new validation plan will require a holistic approach, and can absorb a huge amount of time of a dedicated team and will have an economic impact. Finding the balance between a theoretical and academic proven method and the practical realisation of the validation plan will require good insights in current available technologies and their practicality on the plant floor. Keeping in mind that simple engineered line modification, like changing of a pump type, addition of a valve, the addition of a new instrument can require a new validation of the process line.

Validation will require a deep understanding of all elements involved in the cleaning result such as the importance of design and development for an effective program, the principles and calculations of residue limits for a wide variety of residue types, routes of administration, and dosage types the selection of available analytical methods, along with appropriate levels of analytical method validation, the selection of sampling methods and sampling sites, along with proper selection of blanks and controls the appropriate strategies and documentation for sampling recovery studies, the presence of a cleaning validation master plan [3] and/or policy components, the appropriate documentation for cleaning validation protocols and reports, the tools used for monitoring, verification, revalidation and validation maintenance for validated cleaning processes.

The process of cleaning validation consists of 2 major phases:

- the preparation work
- the actual testing

During both phases documentation is generated.

The food manufacturer has the overall responsibility for validation within his company - this includes the responsibility for the cleaning validation. He has assured the correct cleaning of production equipment and surrounding premises in front of the authorities and he is responsible for supplying the market with safe products of good quality. To be able to perform a successful cleaning validation he should be supported by the manufacturers of production and cleaning equipment as well as by the suppliers of the used cleaning agents. Ideally these parties work together in a cooperative manner with the common goal to secure clean production equipment.

The new guideline will demonstrate a practical approach and based on all needed steps to come to a validated cleaning. The partnership between the food operator and his supplier of cleaning chemicals and optimization services is essential to assure a focused and professional validation approach.

However it will be a crucial task to define a balanced strategy in grouping the tasks and simplify the validation work, in order to keep the validation implementation a task which will not disrupt the company's efficiency.

3. Conclusions

Validation of all cleaning processes in a food production environment is a complex task and requires a multi-disciplinary approach to come to a documented and proven result. However it is not only a legal obligation, it is a basic prerequisite to assure a consistent approach in food safety.

4. References

- [1] FDA. (1993). *Guide to Inspections of Validation of Cleaning Processes*.
- [2] Canada Health Products and Food Branch Inspectorate. (2005). *Cleaning Validation Guidelines*.
- [3] Pharmaceutical Inspection Convention Draft Document. (1998). *Recommendations on Validation Master Plan, Installation and Operational Qualification, Non-Sterile Process Validation and Cleaning Validation*.