perennia
ideas • innovation • success

FACT SHEET

DECEMBER 2022 | ©Perennia 2022

HOW TO VALIDATE A SANITATION PROGRAM

Cleaning and sanitation are fundamental elements of a quality and food safety management system. Validation of the cleaning and sanitation procedures is critical to determining if the procedures, when followed properly, can adequately clean equipment and control identified biological, chemical and physical hazards to produce safe quality products. This fact sheet provides a step-by-step procedure for how to complete a validation study for your sanitation program.

1. Assemble a Cross-Functional Team

This includes representatives from each department that impact the success of your sanitation program and validation, such as Quality Control, Sanitation (may include a member from your contracted sanitation service provider or a field expert), Production, Maintenance and Management.

2. Gather Information

- Are there testing or monitoring programs already in place from which you can use the information/data? i.e., sanitation records, ATP/swab results, chemical concentration checks, finished product microbiological records, consumer complaints, etc.
- Are you familiar with the equipment/utensils used?
- Are manufacturer's requirements/recommendations available for equipment sanitation and chemical usage?
- Are there written Sanitation Standard Operating Procedures developed to review?
- Are there other food safety programs that have been developed which support or impact the Sanitation Program? i.e., Maintenance Program, Allergen Management, Environmental Monitoring Program, etc.

3. Identify Requirements

- Are there specific elements that your facility must include to meet regulatory, third-party or customer requirements?
- Are there manufacturer's requirements/recommendations that must be met for equipment sanitation and chemical usage?

4. Identify the Hazards to be Controlled

Identify what hazards the cleaning procedures are going to control. Biological hazards may include bacteria, viruses, yeast and mould. Chemical hazards may include allergens, and physical hazards may include foreign matter associated with the raw material, such as sand, dirt, bones, etc. If equipment, surfaces, utensils, etc., are not adequately cleaned, these hazards can contaminate the final product or packaging, potentially leading to consumer illness and recalls.

5. Identify the Control Measures

When validating the sanitation program, the sanitation standard operating procedures (SSOPs) are the measures that will control the hazards and need to be validated. Similar cleaning and sanitizing procedures can be categorized together to eliminate the need to complete multiple validations. However, depending on what the procedure is used for and if there are significant differences (i.e., controlling different hazards), it should be validated separately. Written SSOPs should be as

detailed as possible, approved by a team and outline the following, where applicable:

- Frequency of cleaning
- Responsibility of cleaning
- Chemical use, including the type, mixing and handling instructions, concentration, application, contact time and rinse requirements
- The acceptable chemical concentration ranges and the method to determine the chemical concentration
- Water quality, temperature, flow rate and pressure
- Cleaning method (i.e., detailed step-by-step procedure, foaming, manual scrubbing)
- Equipment disassembly and reassembly instructions
- Requirements for cleaning tools, equipment, and personal protective equipment
- Verification of the effectiveness of the cleaning and sanitation and how this will be conducted and documented

6. Determine the Validation Methods

Establish which sampling and test methods will be used to determine if the hazards have been controlled. Consider the following:

Sampling Method:

- Determine the type of sampling (e.g., direct swabbing of equipment, rinse water for CIP systems)
- Determine the sampling location(s) samples are going to be taken from
- Determine how many samples are going to be taken
- Determine if there are any tools or equipment required and if so, ensure they are fit for purpose, used before expiration dates, and calibrated (e.g., swabs, ATP meter)

Testing Method:

- Determine what test method(s) are going to be used to analyze the results (i.e., methods for pathogens, yeast or mould, organic debris, proteins, allergens, etc.)
- Establish the acceptance criteria (i.e., upper and lower limits)
- If using an external lab, determine if the lab is accredited to perform the analytical testing

7. Training

Ensure all employees (and their alternates) responsible for cleaning and sanitation activities are trained and competent in performing the required tasks, record keeping, performing verifications, and performing sampling and testing (as applicable). Proficiency testing for in-house laboratories that are conducting analytical testing must be completed to verify the accuracy of the laboratories' test results.

8. Execute the Validation Study

The validation study will begin by watching the employee perform the cleaning procedure to ensure it is being done as per the written procedure. If not, you will need to determine whether the procedure is correct or if the employee requires further training. Next, you will use your sampling method to collect samples. The samples may be sent to an accredited lab for analytical testing, or if using a rapid swab test, the results may be immediate, or the swab may need to be incubated for a period of time. The validation should be evaluated using worst-case scenarios such as swabbing hard to reach or clean areas, after the longest production run, if cleaning was delayed for a period of time or having the least experienced employees perform the procedure.

9. Collect and Analyze the Data

Once you have sampled and collected the results, you can now determine whether the results are acceptable or unacceptable based on the established acceptance criteria. Statistical analysis of the results and plotting the data on a graph can help visualize the data and determine variability in the procedure. The results and data should be reviewed with the team to reach a conclusion.

10. Document the Conclusion

If the results indicate that the cleaning and sanitizing procedures are capable of consistently controlling the hazards, then the procedures are considered effective and validated. If not, corrective actions will need to be implemented and followed up, and the validation study will need to be repeated. The cleaning procedure may need to be changed. Keep in mind, only one factor, such as the chemical concentration, should be changed each

time, so you can determine which factor is impacting the results. If finished product testing or shelf-life studies have been conducted, these can also be used to support the validation of the sanitation program.

11. Reassessment/Revalidation

Schedule and complete a regular review of your sanitation program to ensure procedures remain valid. At a minimum, the program must be reassessed annually or when there are:

- Product failures (e.g., product not meeting shelf life, increase in customer/consumer complaints)
- Failures to identify and address significant issues (e.g., monitoring or verification results identifying re-occurring and/or unresolved issues)
- Changes in production and sanitation conditions, process flow, new equipment, facility construction
- Changes in regulatory requirements
- New developments in scientific information
- Consistently no issues identified during monitoring or verification procedures
- Product recall or withdrawal

Resources and Further Reading:

Grassmann, D. (2019, February 20). Validation, Verification, and Monitoring of Cleaning in Food Processing Factories. **https://www.food-safety.com/articles/6117-validation-verification-and-monitoring-of-cleaning-in-food-processing-factories**

For More Information Contact:

Perennia Food and Agriculture Inc.
Phone: 902-956-3376
Email: foodsafety@perennia.ca