STERIS
Life Sciences

COMPONENTS OF A CLEANING VALIDATION PROTOCOL

TECHNICAL TIP #3022

It is essential that a cleaning validation protocol contains the necessary components to appropriately challenge a cleaning process. The purpose and design of a protocol is to identify the critical points of the system and to test (challenge) those critical points by verifying that results consistently meet predetermined specifications. This outline is divided into sections with component descriptions which are found in most protocols. This outline is used to assist you in developing your own protocol format.

Scope and Objectives

Provide a brief description of the following items:

1. Identification of the product or group of products that are addressed in this protocol (product types: biologics, Over-The-Counter [OTC], liquids, solid dosage).
2. Identification of the facility (type: sterile, non-sterile) and manufacturing/filling area.
3. Identification of whether the equipment being cleaned is dedicated/non-dedicated to the addressed product or group of products.
4. A general description of the objective of this study, which refers to the execution of multiple (such as three) separate and complete studies that are conducted to validate the cleaning processes.
5. A final reference should be made to writing a validation report to document all resulting information found during the studies.

Responsibility

In this section there is a brief description of responsibilities of each department (listed below) for the writing, review and approval, and execution of the protocol.

1. Manufacturing/filling manager, supervisor and operator
2. Validation manager and specialist
3. Quality control laboratory or outside contract laboratory
4. Quality assurance manager

Equipment and Associated Cleaning SOPS

This is a list of all the manufacturing/filling equipment and associated cleaning Standard Operating Procedures (SOPs) that are evaluated during the execution of this protocol.

Cleaning Equipment Operational Status

Equipment (for example, automated Clean-In-Place [CIP]) used to clean the manufacturing/filling equipment in this protocol should meet all operational criteria. In this section, provide space to verify that all equipment has been through Inst allation Qualification/Operation Qualification (IQ/OQ), and all instrumentation is current with its calibration (for example, water meters, temperature control charts, flow meters).

Cleaning Validation Methods

A brief description of the following topics are part of this section:

1. Cleaning agent, concentration and the justification for the selection.

2. Sample collection for both chemistry and microbial sampling which may include the following subcategories:

- ☐ Control samples
- ☐ Swab
- ☐ Rinse

Sample Locations and Test procedures

A brief explanation of the justification for the selected sample sites and identification of the most critical sample areas.

This section verifies that all sampling procedures and analytical test methods for chemical and microbial residues have been qualified and validated and that recovery studies have been done. It may also include the location where these documents are filed.

Documentation

Provide a brief discussion of the necessary documentation of all the activities that may occur as a result of the cleaning validation studies. This could include the following:

- ☐ Protocol and monitoring worksheets
- ☐ Deviations, discrepancies and resulting investigations
- ☐ Analytical results
- ☐ Final report

Equipment and Sample Flow Diagram

Drawings of the equipment to be cleaned with the sample sites identified. This can be presented as a flow chart in the sequence of the manufacturing or cleaning process.

Acceptance Criteria

A discussion for both chemical and microbial acceptance criteria should be the following:

Chemistry	Microbial
1. Identify the active and cleaning agent that is analyzed, and show the justification for the selection. 2. Describe the methods used to determine the acceptance limits for swab and rinse samples. 3. Discuss the acceptance criteria for visual inspection and for swab and rinse sampling. Include the calculations for both swab and rinse acceptance limits.	1. Identify the microorganisms that are typically found in your facility in categories such as bacteria, mold/yeast and pathogens. 2. Describe the methods used to determine the acceptance limits for all sampling methods used to recover the microorganisms. 3. Discuss the acceptance criteria for all sampling methods. Include the calculations (if appropriate) and acceptance limits for all sampling methods.

Monitoring Worksheets

This is the working portion of the protocol that is divided into two sections.

1. Monitoring worksheet for the cleaning of every piece of equipment used in the manufacture of the product as indicated by the protocol. The SOP is a good resource to use to identify/include the critical points and cleaning parameters (for example, time and temperature) of the cleaning process when developing each monitoring (cleaning) worksheet.

2. Monitoring worksheet for sampling of every piece of equipment used in the manufacture of the product as indicated by the protocol. The critical sampling points should be identified and included in each monitoring (sampling) worksheet.

It is important to remember that the components of a protocol are dependent on the critical points of the system you are intending to test (challenge). For this reason, protocols do not always share all of the same components.