



Templates to use for cleanroom cleaning



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Introduction

We have heard from the market that there is a need for support within cleanroom cleaning.

One of the needs is the actual implementation of cleanroom cleaning and especially the accompanying documentation. This document contains many templates related to cleanroom cleaning. This includes work instructions, cleaning schedules and cleaning programs that you can copy for your own use.



1. Work instructions

Purpose of the work instruction

Describe clearly and concisely what the result of this work instruction should be and how this should be achieved.

E.g. : "The purpose of this work instruction is to describe the process that ensures"
The instruction often describes an activity from a procedure.

Definitions

The following definitions shall apply in this document in addition to the definitions in the ISO standard and the quality manual. Here, a number of relevant concepts mentioned in this regulation are clearly defined and explained in more detail.

Instruction/ method

Here the course of events is described, short and concise and understandable to the reader.

Include in this document:

An instruction which describes in detail all the things needed to complete the activity (e.g. a test), supported by approved parameters. Also appoint (if applicable) who is responsible for a specific step and what frequency if necessary, for example, during a check.

Forms included in this document

Below this point, all forms and/or other documents directly related to the relevant instruction are displayed. When the instruction changes, it will be checked on whether the change will also have an effect on underlying documents.

| Document number | Title |
|-----------------|-------|
| | |

Attachments/ references

List any attachments and add them.

Examples: Flowcharts, specifications, summaries/tables, specific documents, statements, schedules.



2. Cleaning schedule example

| Area: general | Year | Month |
|--|----------------------------|---------------------------|
| Description: | Action: | Frequency |
| Floors | Wipe/ mop | Weekly |
| Floor at sink | Wipe/ mop | 2x weekly Tuesday/Friday |
| Wash trolleys | Wipe off/ wipe | Weekly |
| Doorknobs and doors | Wipe off/ wipe | Weekly/ Friday |
| Changing area/ area of the overstepbench | Clean up and mop the floor | Weekly/ Thursday |
| Telephones | Wipe off/ wipe | Weekly |
| Air vents | Remove dust. (vacuuming) | Monthly |
| Windowsills | Cleaning | Weekly |
| Offices | Cleaning/ mopping | Weekly |
| Flexi Mat/blue mat | Cleaning | Daily |
| Exterior of dryers | Wipe off/ wipe | Weekly |
| Exterior washing machines | Wipe off / wipe | Weekly |
| Work tables | Wipe off / wipe | Weekly |
| Windows | Wipe off / wipe | Monthly |
| All walls | Wipe off / wipe | Monthly |
| Cleanroom cabinets | Wipe off / wipe | Weekly/ Tuesday |
| Staircases | Wipe off / wipe. Mopping | Weekly |
| Ceilings | Wipe off / wipe | Annually (month of April) |

| | | | | | | | | | | |
|----|----|----|----|----|----|----|----|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | | |

- Put initials in the right day (date) after cleaning.
- Use the specifics block for comments.
- Return form to the production line at the end of the month and put a new form in place.

3. The cleaning SOP

Target

The SOP describes the use of the MicronSweep cleaning system for adequate cleaning of cleanrooms and adjacent areas personal and goods locks of all production and quality control departments of "COMPANY NAME".

The cleaning procedure contributes to the intended goal of achieving and maintaining the microbiological quality in the cleanrooms and adjacent locks by keeping the rooms free of dirt and dust accumulations.

A good cleaning procedure contributes to minimising microbiological contamination risks while performing (aseptic) work in cleanrooms.

Cleaning frequency is described in SOP XX to SOP XX (type I to IV).

4. Scope

This SOP applies to all cleanrooms within GMP production departments and GMP quality control departments within company name described in SOP XX to XX.

5. Responsibilities

- SECTION X is responsible for stocking sufficient materials used in this SOP.
- The department is responsible for preparing all necessary cleaning, and materials for the CLEANING COMPANY XX
- The department management is responsible that the daily activities and periodic cleaning according to this procedure.
- The management and employees of the cleaning company/operators are responsible for cleaning cleanrooms according to this SOP.
- The management of the cleaning company is responsible for the providing sufficiently qualified cleaning staff.



6. Materials

- TYPE OF CLEANING/DISINFECTANT X LITRE ITEM NUMBER
- Water for Injection (WFI) OR Purified Water (PW)
- MicronSweep cleaning mop (grey mop) in (AUTOCLAVE) packaging (packed individually)
- MicronSweep impregnation sieve (sieve with holes) ARTICLE NUMBER
- MicronSweep preparation box (box for mops) ARTICLE NUMBER
- (AUTOCLAVED) WIPES ITEM NUMBER
- MicronSweep mop frame 50 cm ARTICLE NUMBER
- MicronSweep telescopic handle 100 – 180 cm ARTICLE NUMBER
- MicronSweep trolley

7. Activities

Workplace

The preparation of the cleaning agent and the impregnation of the mops is preferably done in the material sluice, if not possible in the gowning area and if this is also not possible in the cleanroom.

Safety

When working with the CLEANING / DISINFECTION AGENT X in the department, the corresponding safety instructions must be observed.

SMALL EXPLANATION OF CLEANER / DISINFECTANT WITH BRIEF EXPLANATION SAFETY REGULATION. FOR EXAMPLE, WHETHER THE USE OF GLOVES OR SAFETY GLASSES IS REQUIRED. PHOTO CLEANING / DISINFECTION AGENT.

Preparing the CLEANING / DISINFECTION AGENT in the material sluice or in the gowning area

When working with the CLEANING / DISINFECTION AGENT X in the department, the corresponding safety instructions must be observed.

SMALL EXPLANATION OF CLEANER / DISINFECTANT WITH BRIEF EXPLANATION SAFETY REGULATION. FOR EXAMPLE, WHETHER THE USE OF GLOVES OR SAFETY GLASSES IS REQUIRED. PHOTO CLEANING / DISINFECTION AGENT.

Preparing the MicronSweep system: general

The MicronSweep cleaning system consists of a special light grey impregnation sieve with holes (size 34 x 44 x 12.5 cm), a light grey preparation box for the mops (size 25.5 x 39 x 21 cm), special (AUTOCLAVED) MicronSweep mops (grey mops) and a special wiper (see photo).

The boxes and mops should not be moved to other cleanroom spaces and associated areas without being emptied, dried and disinfected.

Templates to use for cleanroom cleaning



The impregnation sieve



Disinfection of the MicronSweep mop

Prepare the preparation box and the impregnation sieve.
Disinfect both boxes with PRODUCT X by means of spray and wipe (with sterile wipes) and dry both boxes, first both boxes on the inside, then only on the outside. Note: The boxes are suitable for autoclaving.



Positioning of MicronSweep mops

Check that the MicronSweep system mops are clean (by checking the expiry date on the autoclave bags and that they are airtight (see photo).



Remove the mop from the autoclave bag by passing two fingers through the finger loop with sterile gloves.
Fold the mops with the fibres (grey side) together (see below).

Place X number of mops with the finger loop up and forward in the box.

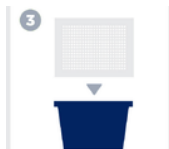


Templates to use for cleanroom cleaning

Dosing the MicronSweep mops

Place the impregnation sieve on the box (see below).

Pour the total solution (x LITRE) evenly over the sieve (see below)



Let the mops rest for 10 minutes.

Putting the mops on the mophead

Disinfect the mopheads with sterile wipers and PRODUCT X.

Set the telescopic handle at the correct height, between chin and nose. Work as much as possible with a straight back for ergonomic reasons. (see photo).

Place the handle of the mop along your body, hold the handle between thumb and forefinger and close the palm of the hand to the handle).

Take the mop out of the mop box by two fingers by the finger loop. Using the pocket system on the mop backing, place the mop over the mophead.

Pull the mop over the mophead by holding the loop (see photos).



8. Cleaning with MicronSweep

Cleaning route by area

The official routing with cleaning is, first ceiling, then the walls and then the floor depending on which cleaning is to be carried out. Always clean with gentle movements.

Route of cleaning per cleanroom with adjacent sluis

The route in a cleanroom with adjacent sluis is as follows:

Look at the SOP and assess how many mops need to be used for cleaning. With 1 mop, you can cover a maximum of 20 m² of surface space.

For ceiling, walls and floor, use a different sizes of mop except in the situation as described in small spaces.

Impregnate as many mops as necessary but impregnate X pieces at a time.

Material sluice: Pre-dose the mops.

Place preparation box(es) with X mops at the door of the cleanroom.

Dressing procedure:

Put on your cleanroom garments in accordance with the current SOP.

Cleanroom:

Take the preparation box with mop and place it at the door to the second area. The order of cleaning is ceiling, walls and then the floor depending on the kind of cleaning being carried out.

Gowning area:

Place the preparation box with mops at the door to the gowning area 2. Clean the ceiling, then walls and then the floor depending on kind of cleaning being carried out.

Gowning area:

Place the preparation box with mops at the door to the exit. Clean the ceiling, then walls and then the floor depending on kind of cleaning being carried out.

Cleanroom:

Take the preparation box with mops and place it at the door to gowning area 1. Clean the ceiling, then walls and then the floor depending on kind of cleaning being carried out. Place the preparation box with mops in the grey area.

Material sluice:

Clean the ceiling, then walls and then the floor depending on kind of cleaning being carried out.

Templates to use for cleanroom cleaning

Cleaning ceiling and wall surfaces

Use per room 1 mop or up to 20 m² ceiling or wall. Always move the mop in the direction of the arrow on the mopframe in the direction of the cleaning area (as per diagram).



Make a diagonal movement across the ceiling or the wall forming a damp track across the area to be cleaned.



Move the mophead back towards you with an overlapping S-movement so the mop continues to cross the damp track to pick up moisture.



Push the mop into corners to ensure complete cleaning of the area.

Templates to use for cleanroom cleaning

Cleaning floors



Clean the skirting board before the floor.



Make a diagonal movement across the floor forming a damp track across the area to be cleaned.



Move the mophead back towards you with an overlapping S-movement so the mop continues to cross the damp track to pick up moisture.



Push the mop into corners to ensure complete cleaning of the area.

When cleaning always keep the order, first ceiling, then the walls and finally the floor.

Cleaning small spaces e.g. locks

If you have to clean small spaces e.g. sluice, after cleaning the ceiling, you can use the same mop for the walls or floors, but you should not exceed 20 m² of coverage and undertake the cleaning in this order.

If one wants to clean the walls of small spaces, it is best to do so in the following way: On each wall, make a damp trail from below (without hitting the floor) to the top of each wall. The last wall with a damp track is the first to be cleaned with an overlapping S-shaped movement from top to bottom and then the other walls in reverse order of application of damp track.

Removing and disposing of the MicronSweep mops

Take the mop off the mophead by pulling two fingers through the loop. Pull the loop upwards and slide the mop off the mophead, without touching the mop fabric.

If the mops have been used in a room where work has been done with potentially dangerous or contagious products then the mops should be put in sealed plastic bags.

Dispose the dirty mop in a special red Elis container in which the mops are transported to Elis Cleanroom (see photo on the right for example of receptacle).

Disinfect both containers (preparation box and impregnation sieve) with PRODUCT X, by spraying and wiping the inside and outside of the box.



Logistics of disposing of MicronSweep mops

The used MicronSweep mops are picked up every week on X-day by Elis Cleanroom where they are cleaned (and disinfected) and then delivered every Y-day to the departments of "COMPANY NAME" that MicronSweep mops are used within.

The red Elis Cleanroom boxes in which these mops are transported must be returned in accordance with the "First in First out" procedure.

Control

The cleaning work carried out by an external company is visually assessed by the employees of the department (e.g. the next day).

In the case of insufficient results, the responsible coordinator of the Department X of "COMPANY NAME" must be contacted.

Record of activities

The cleaning order shall be listed by the department in the relevant logbook. The cleaning work is recorded in the relevant cleanroom logbook by the person who has carried out the work.

How to choose the right cleaning system for your cleanroom?



9. References

Appendix 1

| DEPARTMENT X | | NUMBER OF CLEANROOM MOPS PER ROOM | | | |
|----------------|--------------|-----------------------------------|-------|---------------|------------------------|
| | Space number | m2 | Floor | Floor + walls | Floor, walls + ceiling |
| X | | 20 | 1 | 4 | 5 |
| Y gowning area | | 3 | 1 | 2 | 2 |
| Z gowning area | | 3 | | 2 | 2 |
| Y | | 13 | 1 | 3 | 4 |
| .. | | 23 | 1 | 4 | 5 |
| Y gowning area | | 3 | 1 | 1 | 2 |
| Z gowning area | | 3 | | 1 | 2 |
| | | 38 | 2 | 6 | 8 |

Appendix 2

| DEPARTMENT X | | NUMBER OF CLEANROOM MOPS PER ROOM | | |
|--------------|----|-----------------------------------|---------------|------------------------|
| Space number | m2 | Floor | Floor + walls | Floor, walls + ceiling |
| | | | | |



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