Cleaning and disinfection program: A justified process

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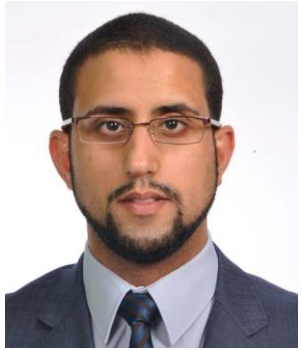

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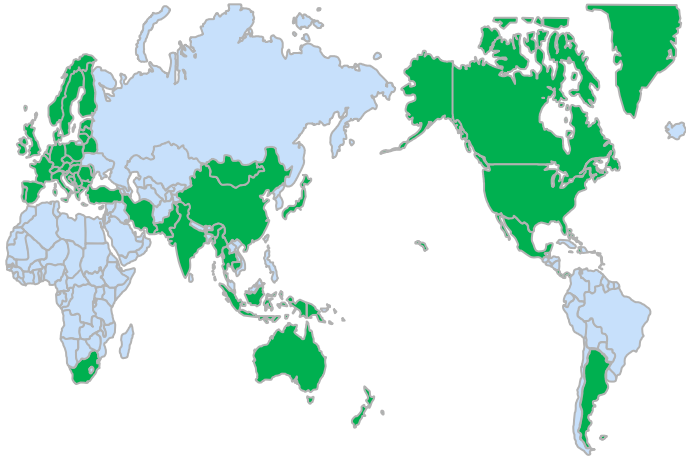
European Medicines Agency (EMA) EudraLex Annex 1 – Draft v12



Disinfection

4.36 The disinfection of cleanrooms is particularly important. They should be cleaned and disinfected thoroughly in accordance with a written programme. For disinfection to be effective, prior cleaning to remove surface contamination should be performed. More than one type of disinfecting agent should be employed to ensure that where they have different modes of action and their combined usage is effective against all bacteria and fungi. Disinfection should include the periodic use of a sporicidal agent. Monitoring should be undertaken regularly in order to assess the effectiveness of the disinfection program and to detect changes in types of microbial flora (e.g. organisms resistant to the disinfection regime currently in use). Cleaning programs should effectively remove disinfectant residues.

4.37 The disinfection process should be validated. Validation studies should demonstrate the suitability and effectiveness of disinfectants in the specific manner in which they are used and should support the in-use expiry periods of prepared solutions.

One or two step cleaning and disinfection

What are the elements/parameters to analyze to determine if a cleaning prior to disinfection is required?

" For disinfection to be effective, prior cleaning to remove *surface contamination* should be performed."

What are the elements/parameters to analyze to determine if a cleaning prior to disinfection is required?

01 **Amount of residue & potential interaction**

02 **Ability of disinfectant to clean and disinfect (EPA claims, EN soiled, etc.)**

03 **Application technique**

04 **Location**

What are the elements/parameters to analyze to determine if a cleaning prior to disinfection is required?

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People

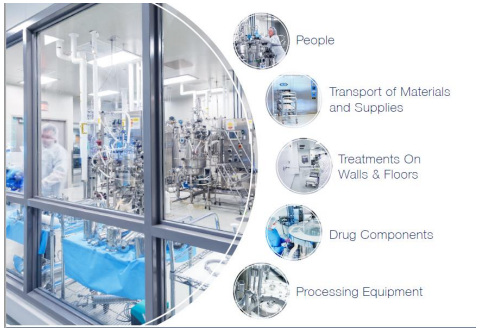
Transport of Materials and Supplies

Treatments On Walls & Floors

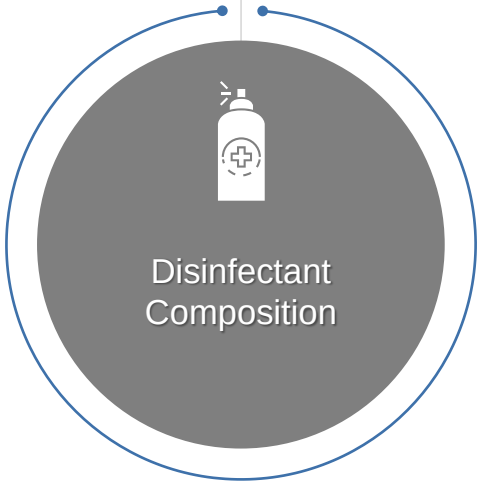
Drug Components

Processing Equipment

What are the elements/parameters to analyze to determine if a cleaning prior to disinfection is required?



a. Residues & interactions



01 Contains a blend of effective surfactant

02 EPA registered as cleaner and disinfectant

What are the elements/parameters to analyze to determine if a cleaning prior to disinfection is required?

a. Residues & interactions

b. Disinfectant composition

01 Spray, fumigation or vaporized

02 Mopping or wiping

What are the elements/parameters to analyze to determine if a cleaning prior to disinfection is required?

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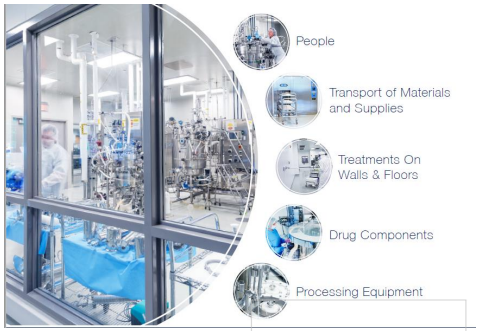
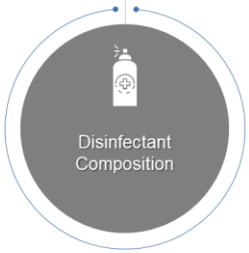


a. Residues & interactions



01 Contains a blend of surfactant

02 EPA registered as cleaner and disinfectant

b. Disinfectant composition

01 Spray, fumigation or vaporized

02 Mopping or wipping

c. Application Technique

01 Cold room

02 Ambient temperature

d. Environment

Cleaning and disinfection a one or a two-step?

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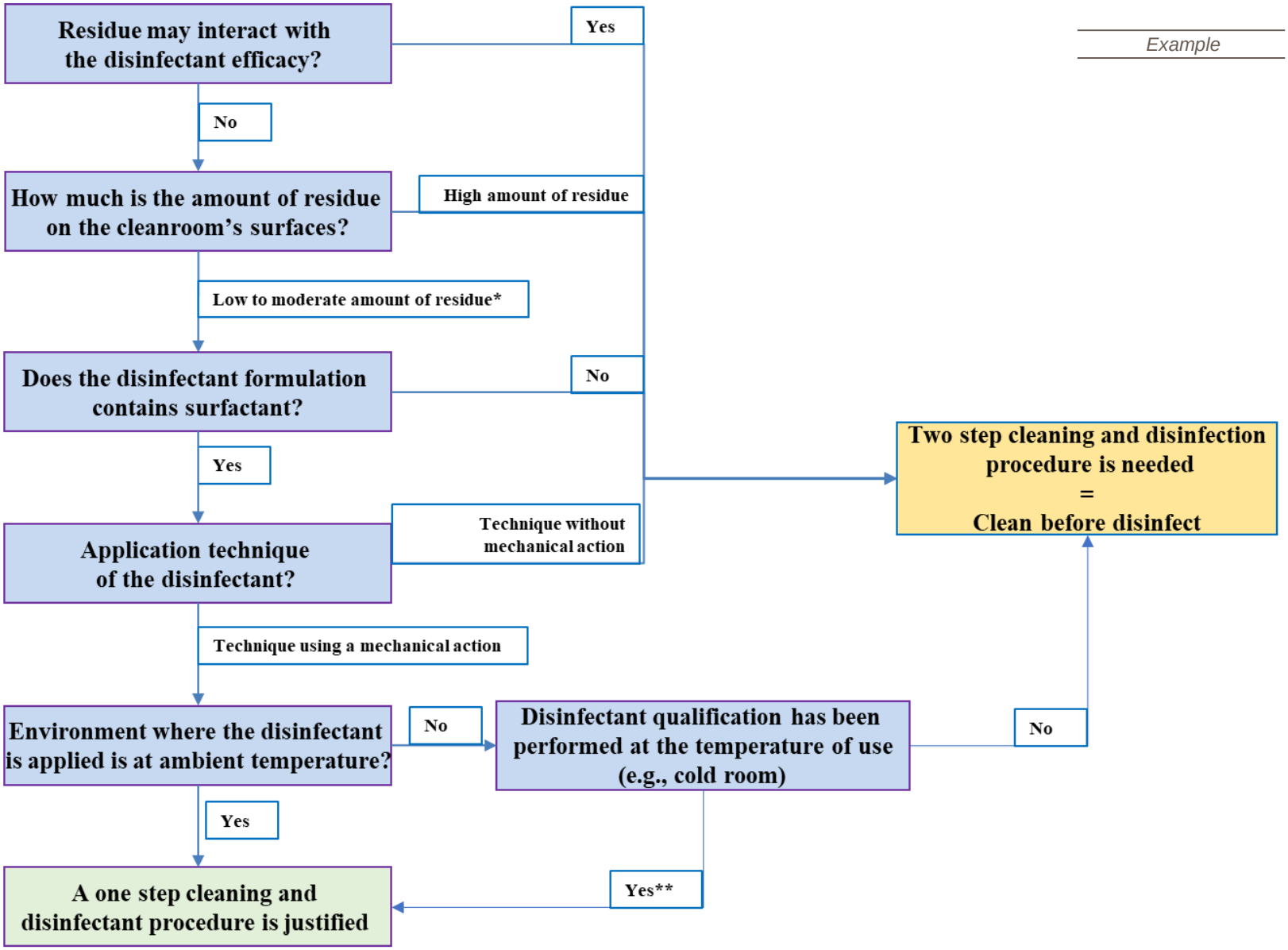

Example

Source: *El Azab W., Cleaning and disinfection – a one or a two steps process or scientifically justified?, cleanroom technology, edition March 2019*

Possible options for cleaning and disinfection procedure

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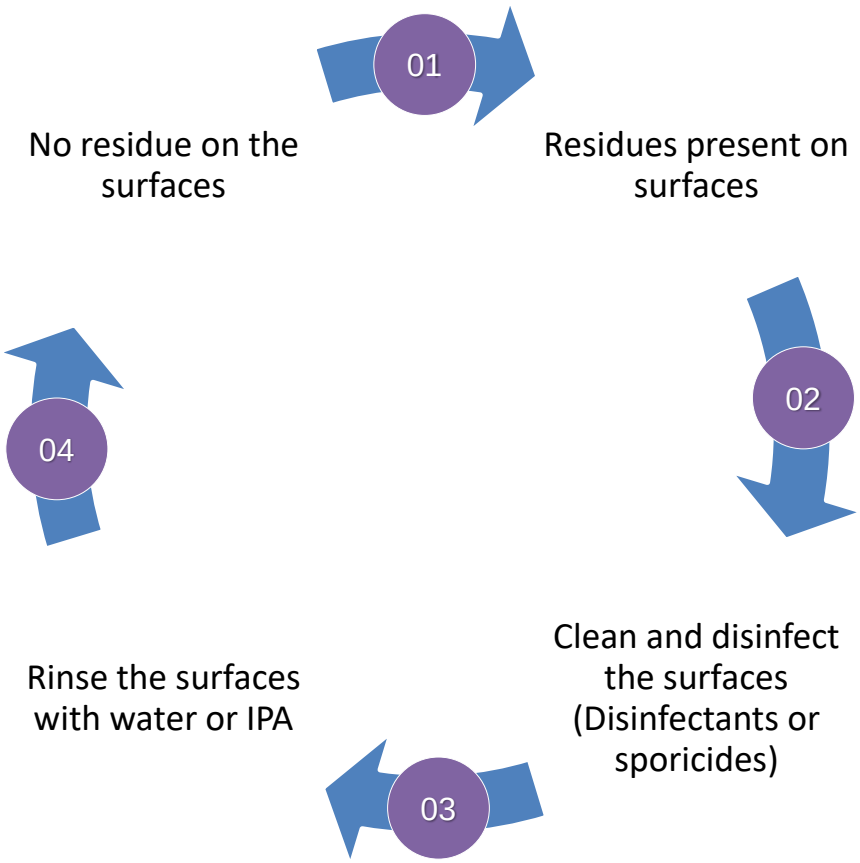
Option 1



Possible options for cleaning and disinfection procedure

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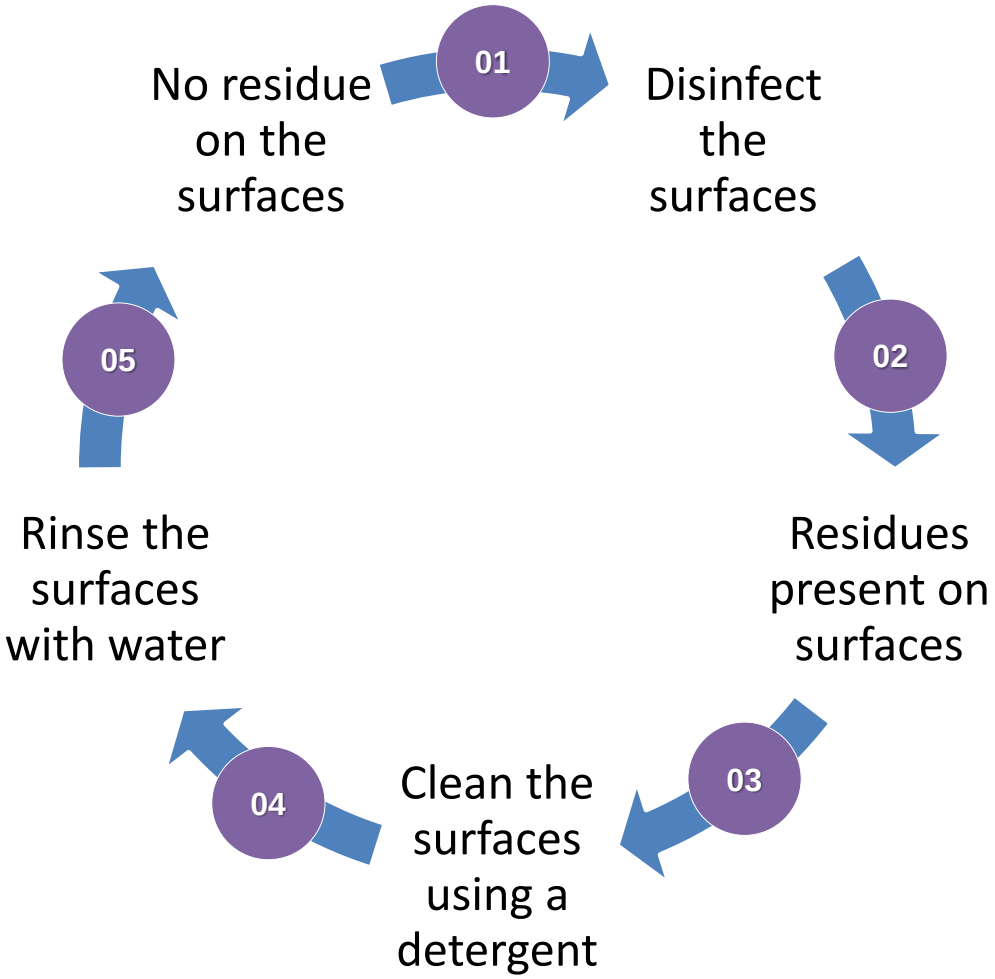
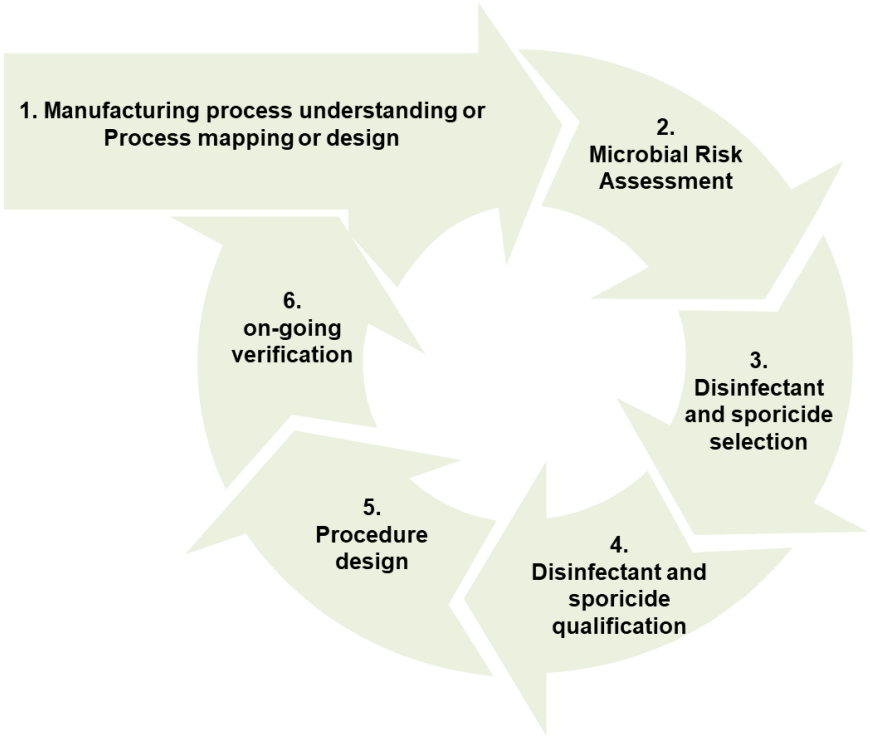
Option 2



Conclusion and Q&A



Keep it simple :

Understand your processes and sources of contamination and interaction to develop robust cleaning and disinfection procedures.

Thank You

For your listening

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References

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Note: This is not a complete listing, just a guidance to literature the speaker has found to be interesting/beneficial.