



Developing a Cleaning Program - Sterile Compounding

Definitions

Cleaning agents – remove residue that may harbor microbes and inactivate sanitizing agents.

Sanitizing agents – cause a 99.99% reduction of bacteria but require pre-cleaning.

Disinfectants – kills 100% of vegetative bacteria, target viruses and target fungi.

Sporicidal agents – kills all vegetative, fungal and bacterial spores.

Classes of Disinfectants

Chemical	Classification
Alcohol	General purpose disinfectant
Phenolics	General purpose disinfectant, sanitizer, cleaning agent
Quaternary Ammonium	General purpose disinfectant, sanitizer, cleaning agent
Chlorine (sodium hypochlorite)	Sporicidal agent
Hydrogen Peroxide	Sporicidal agent

Use of Disinfectants

- Prepare dilution and document – or use RTU formulas
- Ensure adequate contact time – critical
- Store properly
- Check Expiration dates before use
- Rotate agents for full coverage (e.g. Sporicidal agent at least monthly)
- Follow manufacturer's instructions for use
- Make sure SDS (MSDS) is on file and readily retrievable

Materials and Equipment

- Cleaning, disinfectant and sporicidal agents
- Mops and bucket – dedicated to the area
- Non-shedding wipes – pre-sat available
- Cleaning tools (mops) for isolators – disposable or autoclavable covers

Mops

- Bucket-less systems may be beneficial
- Disposable heads and covers stay cleaner
- Should be clean room grade and resistant to disinfectant breakdown
- Clean and rinse before storing
- Proper storage is important

Key Points

- Clean from cleanest to dirtiest and top to bottom
- Use unidirectional motion – not circular

- Replace wipes and– use quarter fold method for wipes, refold after every surface wipe
- Rewet mop often
- Change solution in bucket often or use two buckets
- Contact time is critical
- Perform cleaning separate of operations
- Establish clear policies and procedures for cleaning and disinfection and review frequently
- Follow a schedule
- Document the operator, agent used, date and time – follow up if not performed on schedule
- Consider using task tracking systems to document

USP <797> Cleaning Schedule

Area	Frequency	Notes
LAFWs, BSCs, CAIs and CAIS	Beginning of each shift, before each batch is started, every 30 minutes during compounding, after spills, and when surface contamination is known or suspected.	Only by trained compounding personnel according to SOPs. Clean area, remove loose material, residue. Use residue free agent (e.g. sterile IPA 70% - allow to dry).
Work surfaces in ISO Class 7 & 8 and segregated compounding areas	Daily	Cleaned at least daily
Floors in ISO Class 7 & 8 areas	Daily	When no compounding occurs
Emptied shelving, walls, ceilings	Monthly	Clean and disinfect
Storage sites for ingredients & supplies	When necessary	Remove dust and debris in a method that does not degrade ISO Class 7 or 8 air quality

Sources:

USP Chapters <797>, <1072> Current with USP-38-NF 33
www.texwipe.com
<http://www.contechealthcare.com/>
<http://www.cemag.us/articles/2009/11/cleaning-protocols-usp-797-compliance>