Hands-on Exercise 1

Contents:

- Advantages and disadvantages of SUS
- Gowning and personnel requirements

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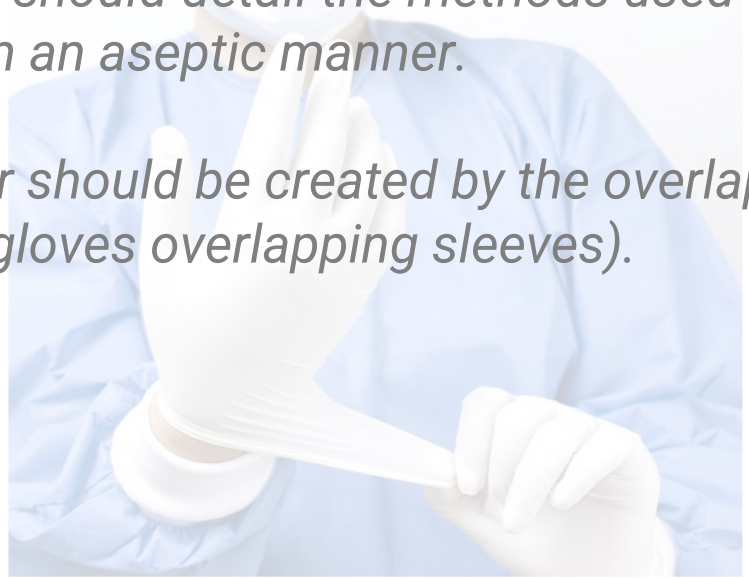
- **Gowning and personnel requirements**

FDA Guidance on Sterile Drug Products Produced by Aseptic Processing

- PERSONNEL TRAINING, QUALIFICATION & MONITORING (Section V)

- *Written procedures should detail the methods used to don each gown component in an aseptic manner.*

- *An adequate barrier should be created by the overlapping of gown components (e.g., gloves overlapping sleeves).*



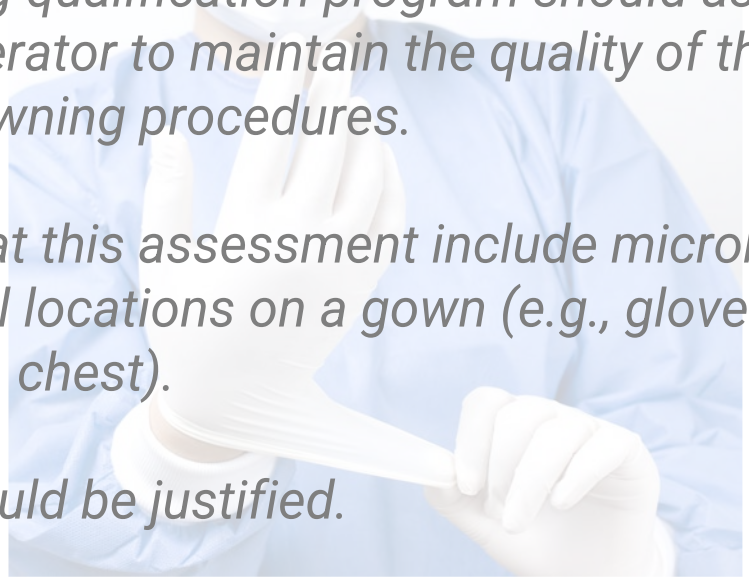
FDA Guidance on Sterile Drug Products Produced by Aseptic Processing

- PERSONNEL TRAINING, QUALIFICATION & MONITORING (Section V)

- *An aseptic gowning qualification program should assess the ability of a cleanroom operator to maintain the quality of the gown after performance of gowning procedures.*

- *We recommend that this assessment include microbiological surface sampling of several locations on a gown (e.g., glove fingers, facemask, forearm, chest).*

- *Sampling sites should be justified.*



FDA Guidance on Sterile Drug Products Produced by Aseptic Processing

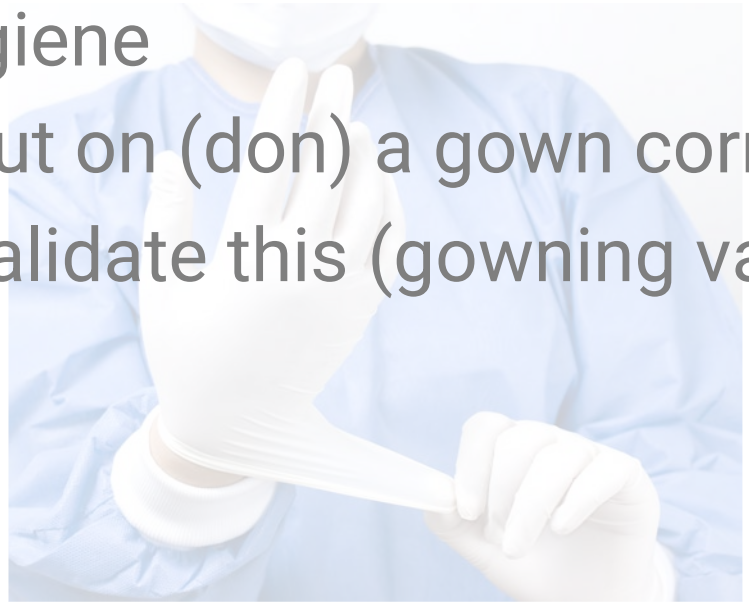
- PERSONNEL TRAINING, QUALIFICATION & MONITORING (Section V)
- *Following an initial assessment of gowning, periodic requalification will provide for the monitoring of various gowning locations over a suitable period to ensure consistent acceptability of aseptic gowning techniques.*

- *Annual requalification is normally sufficient for those automated operations where personnel involvement is minimized and monitoring data indicate environmental control.*

- *For any aseptic processing operation, if adverse conditions occur, additional or more frequent requalification could be indicated.*

What we can do with people:

- Train them in **basic microbiology** and **aseptic manufacture**
- This can include:
  - Basic hygiene
  - How to put on (don) a gown correctly
  - How to validate this (gowning validation)

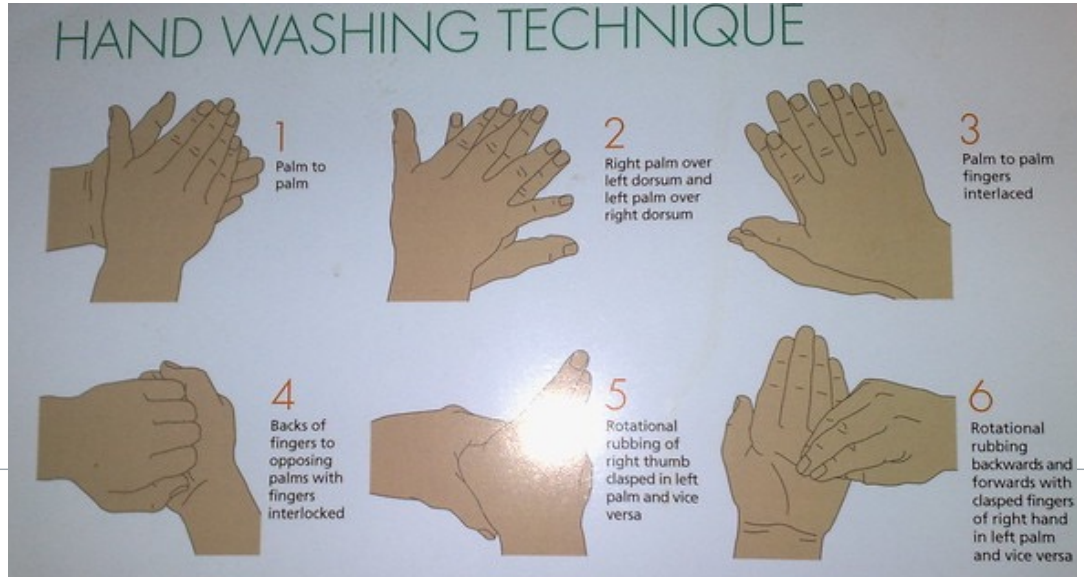


Basic hygiene

- Personal hygiene practices
- Medical assessment
  - –Medical condition
- Procedures in place
  - –Illness or unusual condition
  - –Restrict the individual
  - –Infection, particularly if contagious
  - –Skin conditions
  - –Open wounds

Hand washing

- Removal of dirt, debris and microorganisms
- Documented process
  - –How to wash and dry hands
  - –Including what soap is used



How to put on (don) a gown correctly

- Documented and trained
- No outdoor clothing entering change rooms
- Clothing contamination risks
  - –Turnover
  - –Dirty surfaces
  - –Aseptic handling
- Ensure all clothing is fitted correctly
- Handle gloves on “inside” surfaces and with sterile surfaces and sanitise

1 Don bouffant hair cover and a pair of disposable shoe covers prior to entering the controlled environment or outer corridor.

2 Enter the change room across tacky mat or other debris control mat taking at least three steps with each foot.

3 Don two pairs of cleanroom gloves, placing the second pair over the first pair.

4 Select proper size garments (hood, boots, coverall & goggles)

5 Remove hood from packaging making sure that the I.D. label is on the inside. Don hood. Adjust the hood for a comfortable, yet snug fit using the adjusting snaps.

6 Remove coverall from package. Grasp coverall by the garment to unfold, yet not to touch the ground. Unzip coverall.

7 Grasp right cuff to bottom right of zipper and left cuff to bottom left of zipper.Gather coveralls upper torso and step into the coverall.

8 Tuck in the hood. Completely zip up all zippers. Snap the collar and anklets of coverall (if applicable).

9 Roll down donning gloves slightly to expose cuff. Snap cuffs of coverall (if applicable). Place cleanroom working gloves over or under the cuff depending on your

10 Remove boots from package and don the first boot. Snap upper leg and buckle straps as needed. Swivel that leg to the clean zone without making contact with the top of the bench (if applicable). Don second the second boot. Swivel that leg to the clean zone without making contact with the

11 Don goggles. Place goggles so they cover the exposed eye area.

12 Use a mirror to check proper gowning. Discard donning gloves and enter the cleanroom

Gowning validation

- Operator dons sterile gowns in changing room
- Dabbed by QA/QC using contact (raised surface) plates
- Typical sites:
  - Neck
  - Wrists
  - Waist
  - Gloves (using larger settle plates)

Gowning validation

- Limits for Gowning Monitoring in an EU Grade B room
  - ≤5 Colony Forming Units (CFU)
- If fail – repeat 3 times
- Repeated annually

References

- EU GMP Directives and Guidelines:
- https://ec.europa.eu/health/documents/eudralex/vol-4_en
- USA GMP – FDA Guidance Documents
- https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs