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Hands-on Exercise 1

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Contents:

- Gowning and personnel requirements



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FDA Guidance on Sterile Drug Products Produced by Aseptic Processing

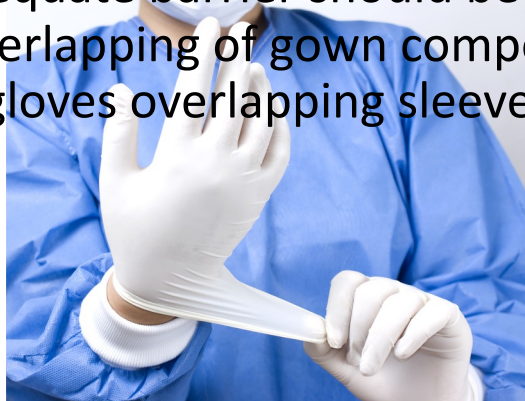
- PERSONNEL TRAINING, QUALIFICATION & MONITORING (Section V)



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FDA Guidance

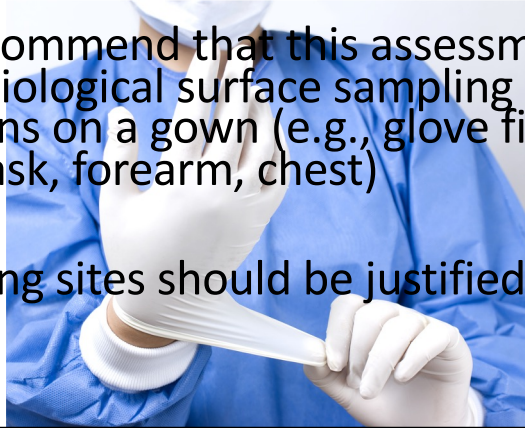
- Written procedures should detail the methods used to don each gown component in an aseptic manner
- An adequate barrier should be created by the overlapping of gown components (e.g., gloves overlapping sleeves)



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FDA Guidance

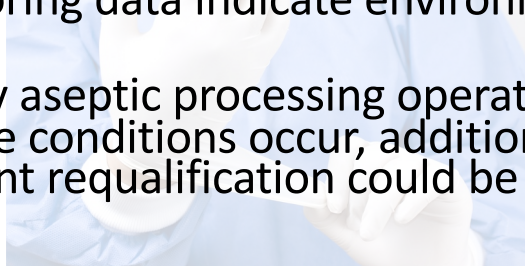
- An aseptic gowning qualification program should assess the ability of a cleanroom operator to maintain the quality of the gown after performance of gowning procedures
- We recommend that this assessment include microbiological surface sampling of several locations on a gown (e.g., glove fingers, facemask, forearm, chest)
- Sampling sites should be justified



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FDA Guidance

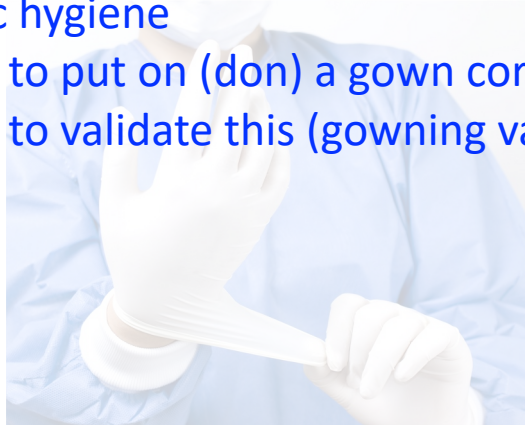
- Following an initial assessment of gowning, periodic requalification will provide for the monitoring of various gowning locations over a suitable period to ensure consistent acceptability of aseptic gowning techniques
- Annual requalification is normally sufficient for those automated operations where 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



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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)



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Basic hygiene

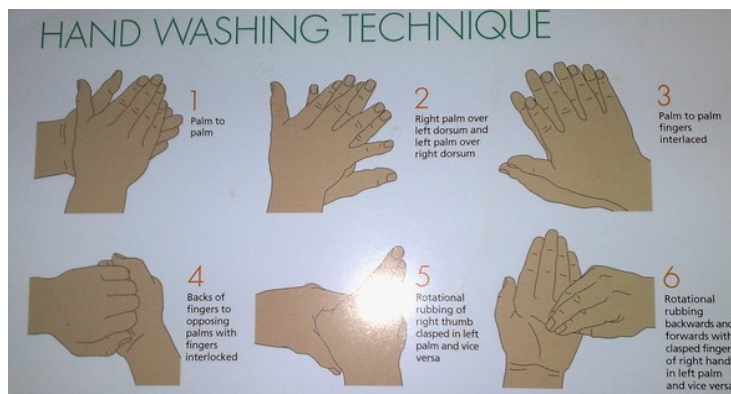
- Personal hygiene practices
- Medical assessment
 - **Medical condition**
- Procedures in place
 - **Illness or unusual condition**
 - **Restrict the individual**
 - **Infection, particularly if contagious**
 - **Skin conditions**
 - **Open wounds**



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Hand washing

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



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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 with gloves on “inside” surfaces
- Packed and donned to reduce contamination from operator and floor



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How to put on (don) a gown correctly



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Gowning validation

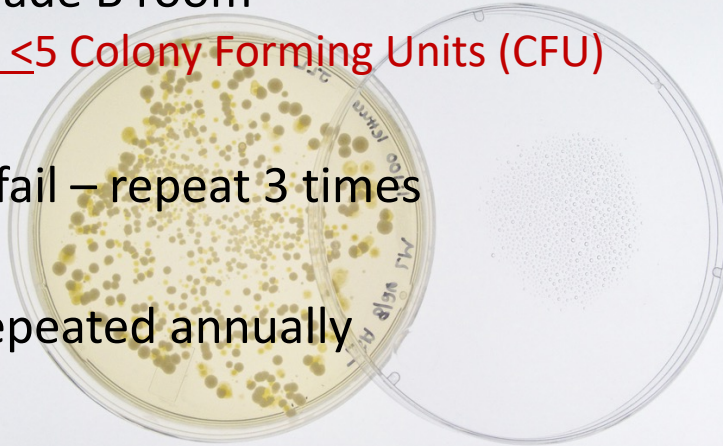
- Operator dons sterile gowns in changing room
- Dabbed by QA/QC using contact (raised surface) plates
- Typical sites:
 - Neck
 - Wrists
 - Waist
 - Gloves (using larger settle plates)



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Gowning validation

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



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Any questions?



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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>

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