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Gowning, Personnel Monitoring and Beyond

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 **2023 Annex 1 Workshop Series (Singapore)** 

 **2023 Annex 1 Workshop Series (Singapore)** 2

Aspects of... Gowning, Monitoring & beyond

People & Barriers as per Annex 1 (Reference Section 7-Personnel)


Socks, Gowns, Goggles, Gloves

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3

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Annex 1: Going Beyond Gowning & Monitoring?



- Gowns
- Gloves
- Goggles
- People-Minimum vs Maximum
- Process of Gowning for all crew
- Process of De-gowning for all crew
- Training on various disciplines for all crew

Attributes

Abilities

Quality

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4

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Annex 1 enlists details for Gowning & Personnel Monitoring

| Reference | Topic | Requirement |
|-----------|----------|--|
| Page 55 | Glossary | Gowning qualification – A programme that establishes, both initially and on a periodic basis, the capability of an individual to don the complete gown. |

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| Maximum Action Limits for viable particle contamination; Annex 1 | | SPECIFICATION | | | |
|--|---|-----------------------|---|--|---|
| GRADE | ACTIVITIES | Air sample CFU /m3 | Settle plates (diam. 90 mm) CFU /4 hours(a) | Contact plates (diam. 55mm) CFU / plate(b) | Glove print Including 5 fingers on both hands CFU / glove |
| Grade A | Aseptic assembly of filling equipment. | No growth(c) | | | |
| | Connections made under aseptic conditions (where sterilised product contact surfaces are exposed) that are post the final sterilising grade filter. These connections should be sterilised by steam-in-place whenever possible. | | | | |
| | Aseptic compounding and mixing. | | | | |
| | Replenishment of sterile bulk product, containers and closures. | | | | |
| | Removal and cooling of unprotected (e.g. with no packaging) items from sterilisers. | | | | |
| | Staging and conveying of sterile primary packaging components in the aseptic filling line while not wrapped. | | | | |
| | Aseptic filling, sealing of containers such as ampoules, vial closure, transfer of open or partially stoppered vials. | | | | |
| | Loading of a lyophilizer. | | | | |

LEGEND

(b) Contact plate limits apply to equipment, room and gown surfaces within the grade A and grade B areas. Routine gown monitoring is not normally required for grade C and D areas, depending on their function.

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| Maximum Action Limits for viable particle contamination; Annex 1 | | SPECIFICATION | | | |
|--|--|-----------------------|---|--|---|
| GRADE | ACTIVITIES | Air sample CFU /m3 | Settle plates (diam. 90 mm) CFU /4 hours(a) | Contact plates (diam. 55mm) CFU / plate(b) | Glove print Including 5 fingers on both hands CFU / glove |
| Grade B | Background support for grade A (when not in an isolator). Conveying or staging, while protected from the surrounding environment, of equipment, components and ancillary items for introduction into grade A. | 10 | 5 | 5 | 5 |
| Grade C | Preparation of solutions to be filtered including sampling and dispensing. | 100 | 50 | 25 | - |
| Grade D | Cleaning of equipment. | 200 | 100 | 50 | - |
| | Handling of components, equipment and accessories after cleaning. | | | | |
| | Assembly under HEPA filtered airflow of cleaned components, equipment and accessories prior to sterilisation. Assembly of closed and sterilised SUS using intrinsic sterile connection devices. | | | | |


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7

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Annex 1 enlists details for Gowning & Personnel Monitoring

| Reference | Topic | Requirement |
|-----------|-----------|---|
| 7.4 | Personnel | Compliance with aseptic gowning procedures should be confirmed by assessment and periodic reassessment at least annually , and should involve both visual and microbial assessment (using monitoring locations such as gloved fingers, forearms, chest and hood (facemask / forehead)). |



Gowns

Attributes

Abilities

Quality


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8

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HUMAN BODY SITES AND TYPICAL NUMBERS OF MICROORGANISMS WITHIN AREA



| AREA | NUMBER OF MICROORGANISMS/cm ² |
|------------------------|--|
| Scalp | 1 million |
| Saliva and nasal fluid | 10 million/gram |
| Back | 100 |
| Groin | 1 – 20 million |
| Forehead | 100 – 1000 |
| Hand | 10,000 – 100,000 |
| Armpit | 1 – 10 million |
| Feet | 1 million |



Ref: IVT- Dec 2014- Dr.T.Sandle People in Cleanrooms: Understanding and Monitoring the Personnel Factor;

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|--|--|--|
| Gowning requirements/Grade | | |
| Grade C: | Grade D: | Any other section |
| <p>Hair, beards and moustaches should be covered. A single or two-piece trouser suit gathered at the wrists and with high neck and appropriately disinfected shoes or overshoes should be worn. They should minimize the shedding of fibres and particles.</p> | <p>Hair, beards and moustaches should be covered. A general protective suit and appropriately disinfected shoes or overshoes should be worn. Appropriate measures should be taken to avoid any ingress of contaminants from outside the clean area.</p> | <p>Additional gowning including gloves and facemask may be required in grade C and D areas when performing activities considered to be a contamination risk as defined by the CCS.</p> |
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|---|-----------|---|
| Reference | Topic | Requirement |
| 7.9 | Personnel | <p>Wristwatches, make-up, jewellery, other personal items such as mobile phones and any other non-essential items should not be allowed in clean areas.</p> <p>Electronic devices used in cleanrooms, e.g. mobile phones and tablets, that are supplied by the manufacturer solely for use in the cleanrooms, may be acceptable if suitably designed to permit cleaning and disinfection commensurate with the grade in which they are used.</p> <p>The use and disinfection of such equipment should be included in the CCS.</p> |
| 7.10 | Personnel | <p>Cleanroom gowning and hand washing should follow a written procedure designed to minimize contamination of cleanroom clothing and/or the transfer of contaminants to the clean areas.</p> |
| 7.12 | Personnel | <p>Clothing should be chosen to limit shedding due to operators' movement.</p> |
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11

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Annex 1 enlisting details for Gowning & Personnel Monitoring

| Reference | Topic | Requirement |
|-----------|-----------|--|
| 7.11 | Personnel | <p>The clothing and its quality should be appropriate for the process and the grade of the working area. It should be worn in such a way as to protect the product from contamination. When the type of clothing chosen needs to provide the operator protection from the product, it should not compromise the protection of the product from contamination.</p> <p>Garments should be visually checked for cleanliness and integrity immediately prior to and after gowning. Gown integrity should also be checked upon exit.</p> <p>For sterilised garments and eye coverings, particular attention should be taken to ensure they have been subject to the sterilisation process, are within their specified hold time and that the packaging is visually inspected to ensure it is integral before use. Reusable garments (including eye coverings) should be replaced if damage is identified, or at a set frequency that is determined during qualification studies. The qualification of garments should consider any necessary garment testing requirements, including damage to garments that may not be identified by visual inspection alone.</p> |


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12

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Annex 1 enlists details for Gowning & Personnel Monitoring

| Reference | Topic | Requirement |
|-----------|-----------|---|
| 7.4 | Personnel | <p>The unsupervised access to the grade A and grade B areas where aseptic operations are or will be conducted should be restricted to appropriately qualified personnel, who have passed the gowning assessment and have participated in a successful APS.</p> |




People-
Minimum vs Maximum

Attributes

Abilities


Quality




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13

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Going Beyond **JUST** Gowning & Monitoring?



Process of Gowning *for all crew*


Process of De-gowning *for all crew*

Training on various disciplines *for all crew*

Attributes

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14

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Annex 1 enlists details for Gowning & Personnel Monitoring

| Reference | Topic | Requirement |
|-----------|-----------|---|
| 7.14 | Personnel | <p>Cleanroom gowning should be performed in change rooms of an appropriate cleanliness grade to ensure gown cleanliness is maintained. Outdoor clothing including socks (other than personal underwear) should not be brought into changing rooms leading directly to grade B and C areas.</p> <p>Single or two-piece facility trouser suits, covering the full length of the arms and the legs, and facility socks covering the feet, should be worn before entry to change rooms for grades B and C.</p> <p>Facility suits and socks should not present a risk of contamination to the gowning area or processes.</p> |



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| Reference | Topic | Requirement |
|-----------|-----------|--|
| 7.18 | Personnel | <p>Activities in clean areas that are not critical to the production processes should be kept to a minimum, especially when aseptic operations are in progress. Movement of personnel should be slow, controlled and methodical to avoid excessive shedding of particles and organisms due to over-vigorous activity.</p> <p>Operators performing aseptic operations should adhere to aseptic technique at all times to prevent changes in air currents that may introduce air of lower quality into the critical zone.</p> <p>Movement adjacent to the critical zone should be restricted and the obstruction of the path of the unidirectional (first air) airflow should be avoided.</p> <p>A review of airflow visualisation studies should be considered as part of the training programme.</p> |

| Reference | Topic | Requirement |
|-----------|-----------|--|
| 7.60 | Personnel | <p>There should be systems in place for the disqualification of personnel from working in or given unsupervised entry into cleanrooms that is based on aspects including ongoing assessment and/or identification of an adverse trend from the personnel monitoring programme and/or after being implicated in a failed APS.</p> <p>Once disqualified, retraining and requalification should be completed before permitting the operator to have any further involvement in aseptic practices.</p> <p>For operators entering grade B cleanrooms or performing intervention into grade A, this requalification should include consideration of participation in a successful APS.</p> |



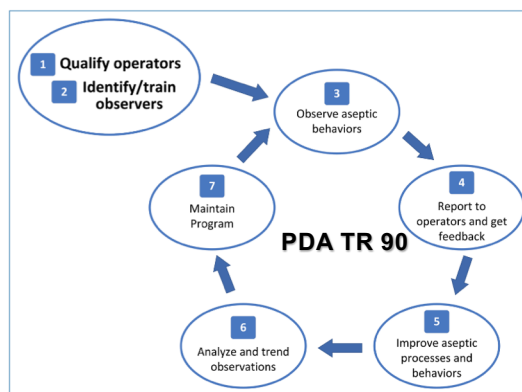


Annex 1 enlisting details for Gowning & Personnel Monitoring

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|-----------|--------------------------------------|--|
| 8.19 | Production and Specific Technologies | Aseptic operations (including APS) should be observed on a regular basis by personnel with specific expertise in aseptic processing to verify the correct performance of operations including operator behaviour in the cleanroom and address inappropriate practices if detected. |



Gowning & PeMo: Qualification Plans & Execution



Aseptic-Operator's Observation 7-Step Program



PDA 2023 Annex 1 Workshop Series (Singapore) 19

Summary

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Thank You

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