

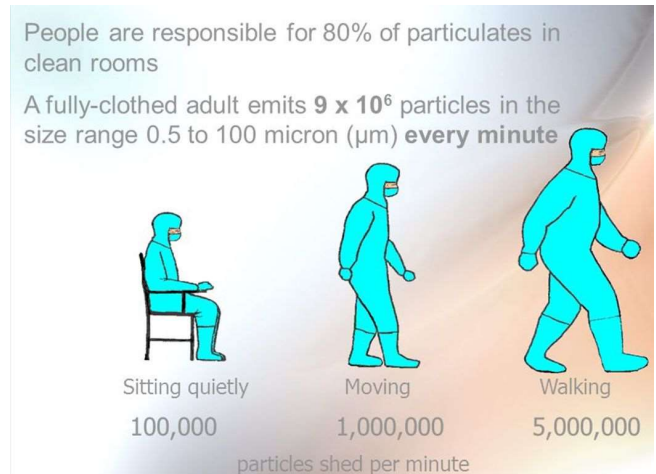
Aseptic Manufacturing Practices!

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People are the biggest source of contamination

Studies have shown that even when wearing standard clean clothing, people are still the biggest source of contamination in cleanrooms

- Human-induced contamination is for **80%** of cleanroom contamination
- Production Tools & Equipment: **15%**
- Cleanroom itself and filter program defects: **5%**
- Even with the dress code, people in a cleanroom can still produce **100,000 particles/min** when they sit still or stand on their own
- Walking, **1,000,000 particles/min** can be generated
- Run: **5,000,000/min**
- Cough: **700,000 dust particles/time**
- Sneezing: **1,400,000 dust particles/time**
- Conversation: **15,000~20,000 dust particles /min**



When entering the aseptic area, the following health problems should be controlled

- Injuries or burns of large openings
- Cold sores (in the case of cold and fever)
- Severe dandruff
- Dermatitis, eczema
- Sunburn (peeling)
- Acne
- Fungal/bacterial infections
- Cough
- Runny nose or sneezing conjunctivitis

Gown

- The right size for your clothes
- Do not confuse the category of clothing (single-use and multi-use)
- Wear undamaged clothing
- No jewellery (including wedding rings)
- No makeup
- Do not wear nail polish (including fake nails) or watches

Gloves

- Spray your hands (regularly)
- Spray wash before/after touching (any) object
- Allow your hands to dry (about 10 seconds) before proceeding
- Do not sanitize gloves before performing microbiological monitoring of fingers
- Damaged gloves must be replaced immediately outside the aseptic area

Goggles

- Sterilization is required, not disinfection (sanitization)
- Goggles should be worn in the aseptic area (almost) at all times, not on the head, and at angles
- Defog the goggles (surfactants are effective in defogging) or use anti-fog goggles
- Nearsighted/farsighted glasses are allowed under goggles

Personnel posture

- Do not lean against the surface
- Do not squeeze overalls
- Keep the body away from the product
- Stand up straight to minimize disruption of airflow
- Keep your arms at (or above) your waistline

Operational action

- Thoughtful, slow, smooth
- Don't run
- Avoid unnecessary movements and think about them before doing them
- When not involved in process operations, the operator should stand or sit

Speak

- No unnecessary conversations
- Don't shout loudly unless you really need to
- Communication takes place without openings, entrances/exits, or airlocks
- If sneezing, stay away from the product

Behavior

- Do not touch the floor. When an item is dropped, if it does not pose a risk, it can be removed at the end of the daily cleaning
- Equipment in critical areas, which needs to be re-sterilized or re-cleaned (if necessary) when re-entering production after leaving the area
- Use sterilized tools (if necessary)

Common deficiencies of aseptic procedures (From US FDA)

- During the aseptic filling of vials, an operator used restricted access barrier system (RABS) (b)(4) to remove a jammed stopper by reaching over exposed sterile stoppers in the stopper bowl. The RABS (b)(4) disrupted the unidirectional airflow over the stopper bowl, creating a risk for microbial contamination. After the operator removed the jammed stopper, the filling line was restarted, but the affected stoppers were not cleared.
- There is no sanitisation of hands after each individual garment is touched and put on.
- Operators wore outdoor clothes under aseptic gowns in the Grade B zone.

- Gowning procedures required operators to remove their shoes when entering grade D and C areas. The nature of the foot coverings used would not prevent microbial contamination passing from the operator's feet onto the clean room floors.
- In the main office of Block B manufacturing operators appeared to be allowed to wear flip flops, shoes with over-shoes or socks.
- During gowning into the manufacturing area the bench was not sanitised prior to sitting on it.
- While donning sterile gloves prior to entering a grade B area an operator was observed touching the outside of sterile gloves on several occasions.
- The wipes used for sanitisation did not appear to be wetted sufficiently as only the area in the centre appeared to be wet rather than the whole area to ensure effective surface coverage.
- A gap between the hood and mask was seen for some operators resulting in exposed skin at the side of the face with the potential for product contamination especially when working in a LAF cabinet.
- There are currently no drawings or diagrams which define the positioning of components in the laminar air flow (LAF) cabinet or isolators to ensure that unidirectional airflow is maintained.
- Operators do not wear goggles even though compounding is conducted in an open LAF cabinet and ampoules may be used in the compounding process which is an open rather than a closed manipulation.
- Sanitised rather than sterile goggles were permitted to be worn in EU Grade B areas.
- The sequence of installing the filling needles and connecting tubing did not minimise contamination risks; the sequence used resulted in contact between fingers of the restricted access barrier system (RABS) glove and the exposed tops of needles on several occasions.

Source: [無菌生產操作規範！\(qq.com\)](http://qq.com)