



Cleanroom Behavior

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2013 GMP Forum

April 9, 2013

Taipei, Taiwan

Outline

- Sources of Contamination 污染的來源
- Impact of Movement and Touch Contamination 移動的影響與觸摸污染
- Proper Clean Room Behavior 正確潔淨室行為/舉止
- Aseptic Technique 無菌操作技術
- Handling Sterile Materials 處理無菌物件/材料
- The Do's and Don'ts in a Clean Room 潔淨室中可為與不可為的事項
- Different Levels of Gowning 不同級別的無菌工作服
- Aseptic Garments 無菌工作服
- Aseptic Gowning Rules 無菌工作服更衣規則
- Habits for Success 成功的習慣

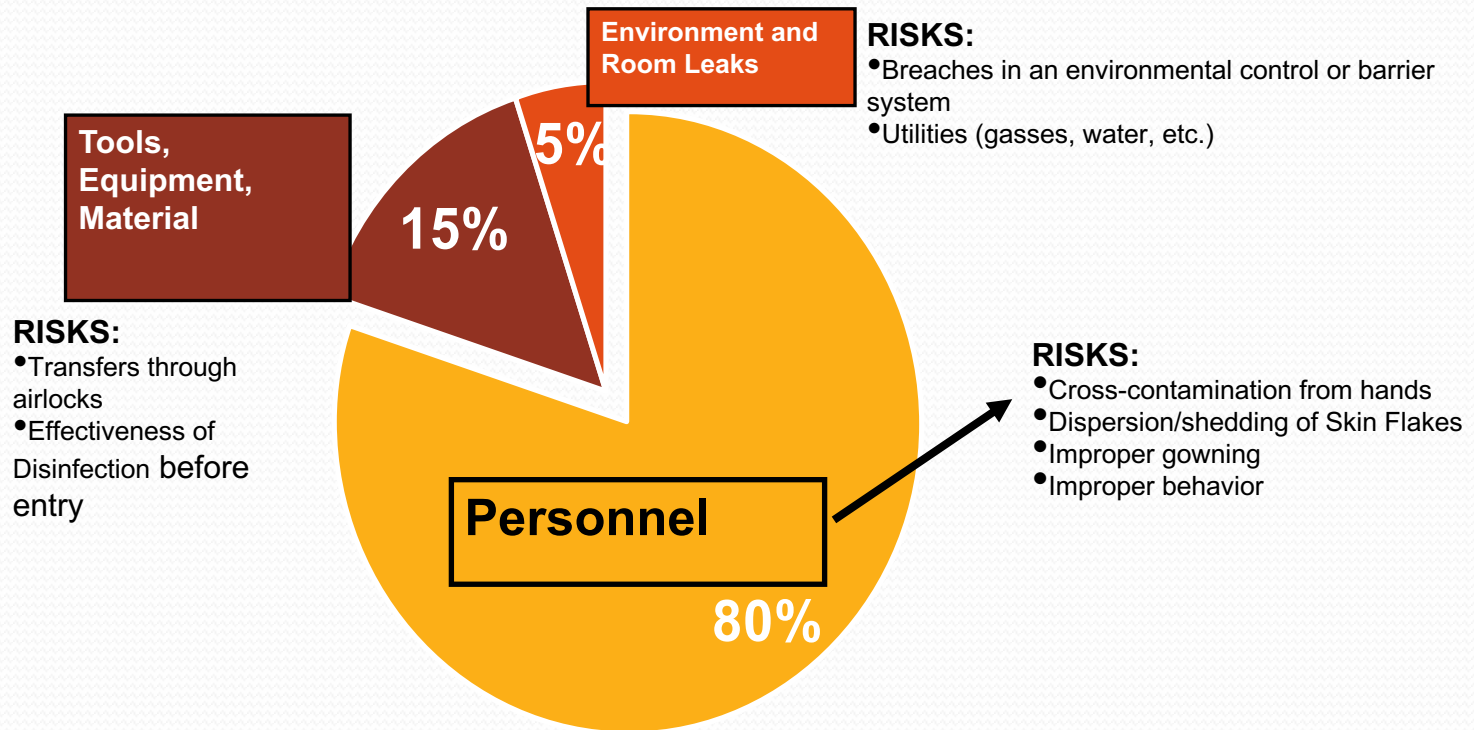
What Should We Consider?

“A well designed aseptic process minimizes personnel intervention. As operator activities increase in an aseptic processing operation, the risk to product sterility also increases. 一個設計良好的無菌工藝生產使人員干預減到最少。如操作員在無菌工藝生產中的活動增加，產品的無菌風險也會相對增加。”

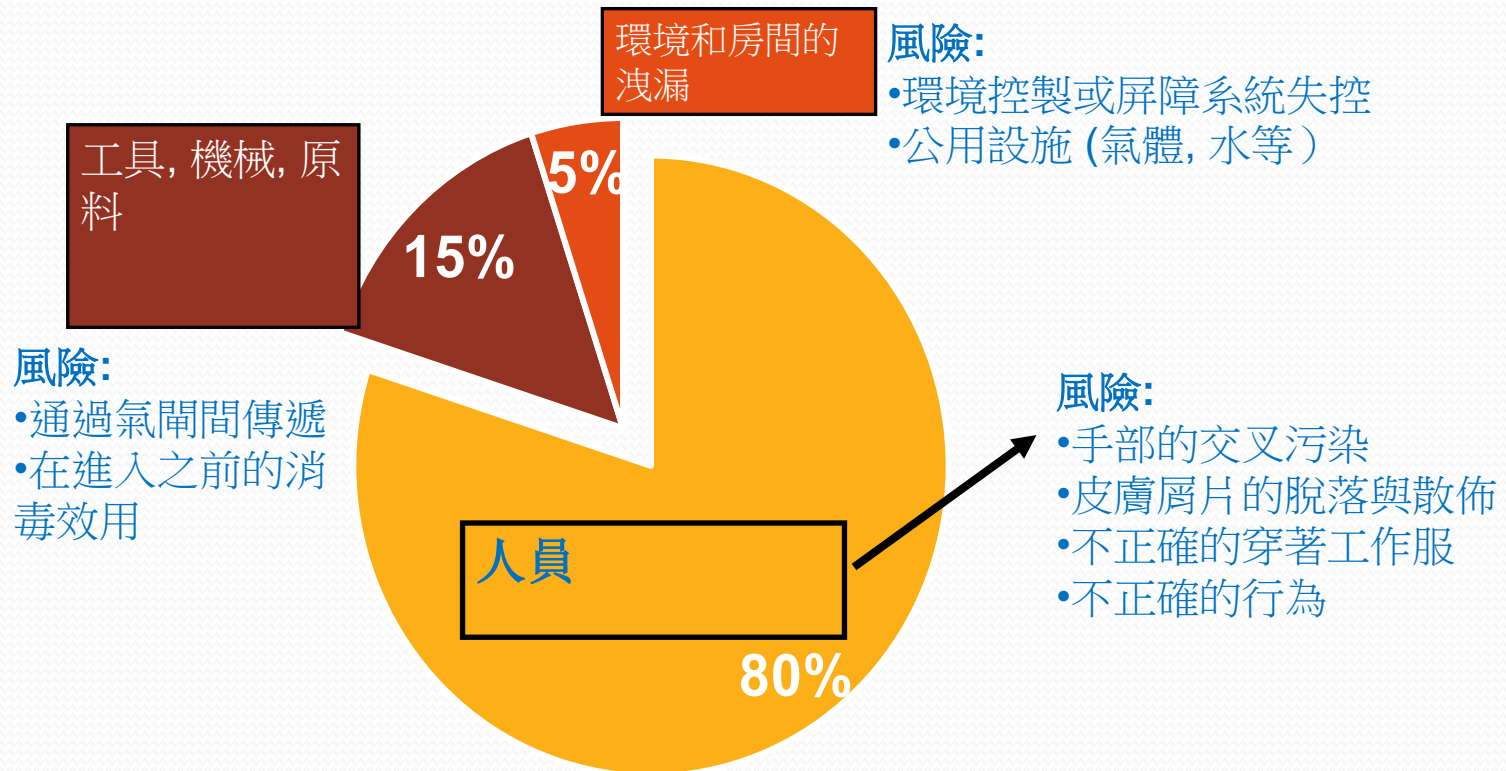
FDA Guidance on Aseptic Processing 2004

來自美國國家食品藥品管理局2004年無菌處理流程指南

Sources of Clean Room Contamination



潔淨室污染的來源



Sources of Clean Room Contamination

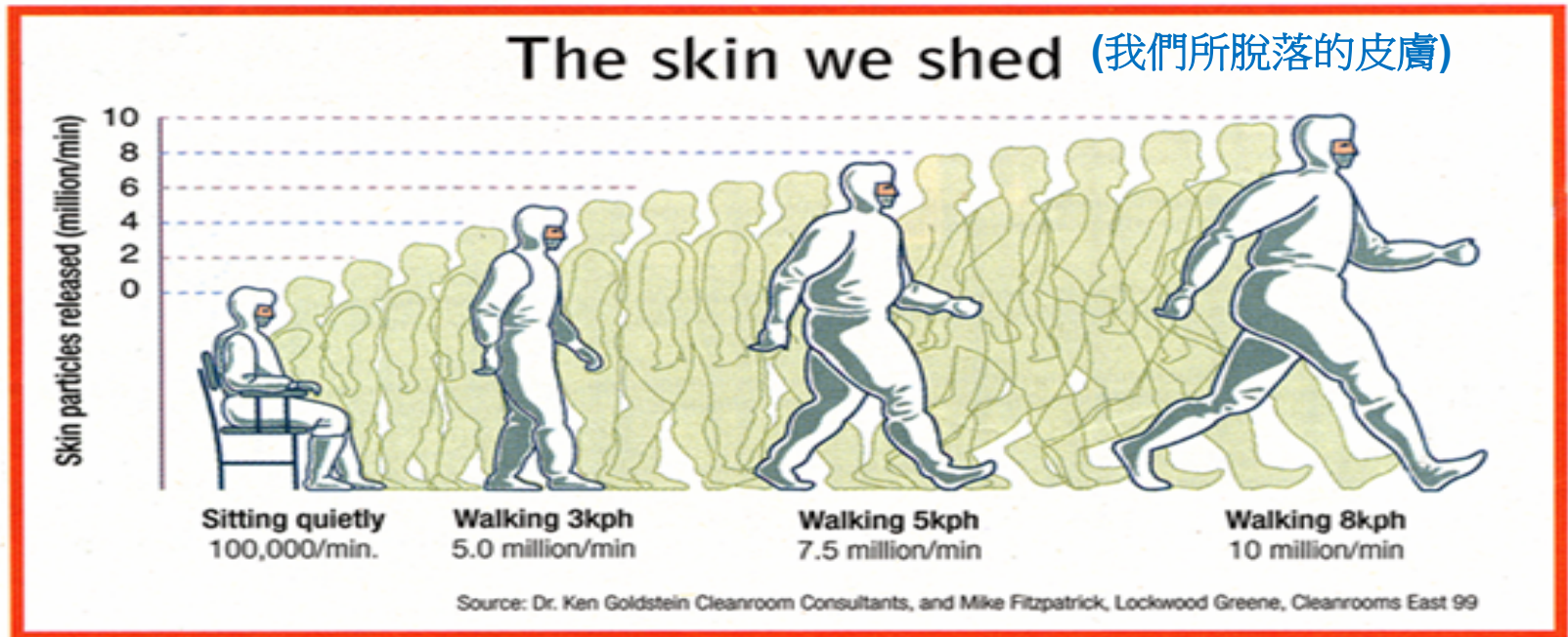
- **MODES OF ENTRY 進入方式**
 - Improper aseptic gowning 不適當的更衣
 - Improper Clean Room behavior 不適當的潔淨室行為
 - Breach in an environmental control or barrier system 環境控制或屏障系統的失控
- **DISPERSAL 散播**
 - Touch contamination 觸摸的污染
 - Air turbulence 空氣的流動

Bioburden Sources

- 皮膚
- 頭髮
- 衣服
- 鞋
- 指甲和指甲油
- 珠寶
- 化妝



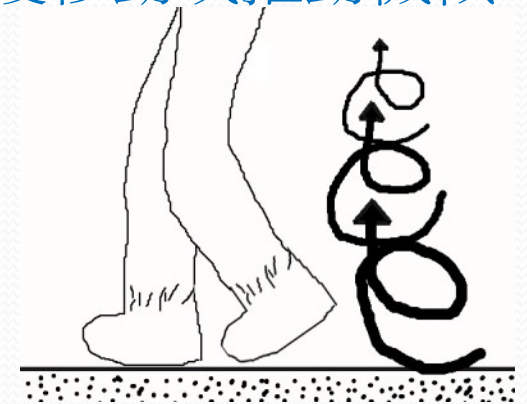
General information on People and Garments



- People are the #1 source of contamination. 人類是第一的(主要)污染源。
- Airborne micro organisms are normally dispersed into the cleanroom from people on skin cells. 空氣傳播的微生物通常會從人類的皮膚細胞散落到潔淨室中。
- People shed one outermost layer of epithelial cells every 24 hours. This amounts to 10^9 cells per day. 人們每24小時就會脫落皮膚表面上最外層的皮細胞。這等於每天高達 10^9 個細胞的數量。

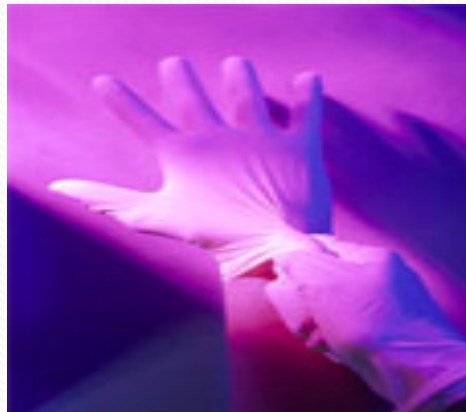
Impact of Movement

- Slow movements 緩慢移動
 - Walk slowly 慢慢走
 - Don't swing or flap your arms 不要搖擺你的手臂
 - Limit gestures 限制過多的手勢
 - Turn slowly to address the person next to you 與你身邊的人講話時, 請慢慢轉身
 - Move or push equipment slowly 請慢慢移動或推動機械裝備



Touch Contamination

- Gloved hands 戴着手套：
 - Change outer pair of gloves whenever contact is made with an object which is less clean or when the integrity of the glove is compromised. 每當與比手套不干淨物體接觸後或手套的完整性受到損害時，請更換外部手套。

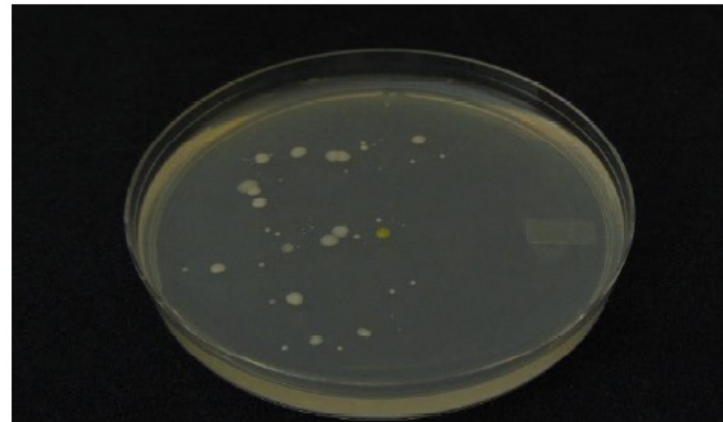


Touch Contamination



Microorganisms from the
refrigerator door handle

微生物來自電冰箱門手柄



Microorganisms from gloved
hand that touched the handle

微生物來自觸摸電冰箱門手柄的手套

Touch Contamination

- Changing gloves 更換手套
 - Tears or cuts in the outer glove 當外面手套被撕開或損傷後
 - Before and after set-up activities 在開始工作設置活動之前和後
 - After touching materials/equipment in the airlock or pass-through 在氣閘間或傳遞箱內觸摸到材料或設備後
 - After performing surface sampling of the floors 在地板表面取樣本後

Touch Contamination

- Sanitize hands with sterile 70% Alcohol during processing 在工作過程中，請使用70% 消毒酒精來消毒手套
 - Upon entry into any Grade A area 進入任何 A 級區域前
 - Following contact with any equipment, parts, tools, etc. in the Grade A area 在A 級區內接觸過任何設備, 零/配件, 工具等
 - Prior to and after any intervention 在任何干預之前和後
 - Before and after using the phone/walkie-talkie 在使用電話或對講機之前和後
 - Every 10-15 minutes of normal processing 在正常操作中每 10 至 15 分鐘

Proper Clean Room Behavior

- Follow the established traffic patterns 按照既定的物流來往格局
- Minimize communication 把信息連絡減到最少
 - No excessive talking 不過多說話
 - No shouting 不呼喊或大聲叫喚
 - No talking between pass-throughs, through the door or mouse holes 在通過傳遞箱時, 不要透過門口或小孔講話
- Use the flush mounted phone system 使用安裝在牆壁上的電話系統
- Use walkie-talkies sealed in plastic bag that have been surface disinfected 使用密封在膠袋中和表面已被消毒的對講機

Proper Clean Room Behavior

- Sitting, standing and working 坐著, 站立和工作時
 - Standing is preferable to sitting 站立比坐著好
 - Proper clean room stance 正確的潔淨室姿勢
 - Leaning on counters, walls, carts, etc. is unacceptable 倚靠在櫃檯, 牆壁, 或手推車等是不正確和不能接受的
 - If sitting is allowed 如果允許坐著:
 - Gloves cannot touch legs or chair/stool 手套不能觸碰腿或凳椅
 - Forearms cannot contact legs 前臂不能觸碰腿
 - Cannot hang arms over control panel 手臂不能倚靠在控制板面上
 - Continuous maintenance of sterile gloves 要經常維護滅菌手套

Proper Clean Room Behavior

- Grade A (class 100) activities **A級區域中工作**:
 - All equipment and materials delivered/set up in Grade A zone **所有在 A 級區域中傳遞或啟始工作的設備與原料**
 - Operators perform Grade A aseptic activities only **工作人員只能從事 A 級區域中的活動**
 - “Aseptic” and “support” operator concept works well **“無菌” 和 “支持” 的經營理念運作良好**

Proper Clean Room Behavior

- Minimal intervention into the Grade A area
減少在 A 級區域中的干預
- Grade A activities completed as one continuous operation
把 A 級區中的活動當作一項連續性工作完成
- Frequent disinfection or change out of sterile gloves
頻繁消毒或更換滅菌手套

Aseptic Technique

- Definition 定義
 - Using methods or techniques to protect against contamination by microorganisms
用來防止被微生物污染的方法或技術

Aseptic Technique

- Good aseptic technique 良好的無菌技術
 - Keep critical components & exposed product in “First Air” 把關鍵/重要組件和暴露的產品放在“第一空氣”內
 - Human intervention kept to a minimum 把人員的干預減至最低
 - When necessary, intervene only with sterile tools 有必要干預時，只使用滅菌過的工具
 - Maintain sterile tools in the Grade A environment 滅菌過的工具應維持在 A 級區域中
 - **Never** touch product contact parts 不要觸摸與產品有接觸的部分
 - Restrict entry into and out of the Grade A area during processing 在操作過程中，限制進出入 A 級區域

Handling Sterile Materials

- Never touch or pick up anything off the floor
永遠不要觸及或撿起任何在地上的東西
- Don't allow hoses, tubing, etc. to rest on floor
不要把水龍帶或管類等東西放在地上
- Don't hold items against your gown
不要把東西放在您的工作服上

Handling Sterile Materials

- Always carry materials outward above waist level with a space between the item and your chest
永遠把物件攜帶在腰部以上並與胸部有空間距離
- Restrict entry into the Aseptic Processing Area (APA) during processing
在操作過程中, 限制進出入無菌區域
- Always remove primary wrap in the Grade A area
永遠在A 級區域中才脫掉主(第一)層包裝

Do's and Don'ts in the Clean Room

- No pounding on windows or doors 不要敲打窗或門
- No feet on chairs, benches, work stations or equipment 不要把腳放在椅凳, 工作台, 或設備上
- Never block or restrict air returns 不要阻隔或限制空氣回流
- No writing on equipment or sterile garments 不要在設備或無菌工作服上寫字
- No removing items from under the sterile garment 不要從無菌工作服內取東西

Do's and Don'ts

- No eating, gum, or hard candy/lozenges
不准進食，吃口香糖，硬糖或止咳糖
- No contact with any body part or goggles
不准接觸身體的任何部分或護目鏡
- No contact with another person
不准與另一人有身體接觸

Do's and Don'ts

- No talking in the airlock/pass-through with someone who is on the non-aseptic side
在氣閘間或傳遞箱內, 不能與在非無菌區域內的人說話
- If you sneeze, you must exit the Clean Room and regown
如果你打噴嚏, 必須退出潔淨室及更衣

Do's and Don'ts

- Use sterile forceps to remove sterile components (cartridges, plungers, and lined seals) from the filling line 在灌裝線上, 使用滅菌鉗去移動滅菌的組件(如盒, 針桿/活塞和密封件)
- Utilize only pre-sterilized writing instruments and pre-sterilized, non-shedding paper inside the APA 在無菌區域內, 僅使用已滅菌的書寫文具和已滅菌而不脫屑的紙張
- If your gown is compromised (i.e. torn or wet) you must change it immediately 如果你的衣服受到損壞(即破裂或弄濕), 您必須立即更換

Different Levels of Gowning

- The wearing of clean room clothing outside the clean room areas is prohibited. 在潔淨區外禁止穿著潔淨區域的工作服。
- The wearing of damaged or dirty clean room clothing is prohibited. 在潔淨區域禁止穿著損壞或已臟的工作服。

Gowning in CRC D



Gowning in CRC C



Gowning in CRC A/B



Aseptic Garments

- Garments constructed of sterile, non-linting, synthetic materials designed to protect the APA environment and sterile product from people 衣服是由無菌，不掉纖維，合成物質設計用來保護無菌生產環境和產品從人員帶來的影響
- Typically includes 通常包括:
 - Hood 頭套
 - Mask 口罩
 - Goggles 護目鏡
 - Coverall 連體衣服
 - Boots 靴子
 - Gloves 手套

Aseptic Garments

- Disposable vs. Reusable
一次性與可重複使用
- Autoclave vs. Gamma Irradiation
高壓滅菌與伽馬輻照
- In-house laundry vs. outsource
內部洗衣房與外包

Aseptic Gowning Rules

- Remove all makeup and jewelry 除去所有的化妝品和珠寶
- Ensure all hair, including facial hair, is covered 確保所有的毛髮, 包括面部的毛髮被覆蓋
- Hand sanitization must include all parts of the fingers, palm, wrist, and forearm 手部的消毒應包括所有的手指, 手掌, 手腕和前臂
- Do not talk while gowning 在更衣的過程中不要講話
- Minimize contact with the outer surfaces of the sterile packages 盡量減少與無菌包裝外表面的接觸
- Avoid contact with shoes, shoe covers, and socks when putting on the boots 在穿靴子的過程中盡量減少與鞋, 鞋套和襪子的接觸

Aseptic Gowning Rules

- Avoid direct contact with nose and facial skin when putting on the mask 在穿戴口罩時, 應盡量減少與鼻子和面部肌膚的直接接觸
- Handle sterile garments only from the inside as much as possible 在處理無菌衣服時應從盡可能從裡面拿起
- Sanitize hands following each step – let dry !!!! 在每一個步驟後請消毒雙手 - 讓雙手乾透!!!!
- Ensure the sterile garments do not touch the floor or any other non-sterile surface 確保無菌衣服不與地板或其他非無菌表面接觸

Habits for Success

- Be aware of how contamination spreads 要注意污染是如何傳播
- Always follow the gowning procedures 永遠遵循“更衣”手則
- Move slowly in the controlled and aseptic processing areas 在管制和無菌工藝生產區域, 請緩慢地移動
- Practice good hygiene and personal cleanliness 實踐良好衛生和個人清潔習慣
- If you have a question or aren't sure – ASK 如果有問題或不能確定 – 請詢問



Questions & Answers

Thanks

謝謝

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