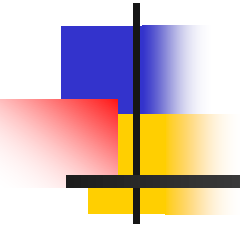


# Principles of Personnel Monitoring



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# Personnel Monitoring

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## ■ Objectives

- The sampling process
- RODAC or TSA plates
- Location of samples
- Number of samples
- Dynamic/Operational qualification



# People as Sources of Clean-room Contamination

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- **This statement is common when talking about aseptic processing; People are a significant source of contamination in cleanrooms, up to 85%**
- **Do you agree with the statement?**
- **If so what is the justification?**



# People as Sources of Clean-room Contamination

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## ■ These can be some reasons

- People shed approximately 4-7 grams of skin particles and hair per day
- Dry skin sheds more particles
- Skin condition/sun burn
- Break through due to moist mask
- Particulates from scrubs
- Perspiration while in the cleanroom
- Incorrect gowning



# General Regulatory Requirements

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## ■ Primary Gowning Requirements

- Recommend scrubs to ensure all personnel wear clean clothes daily
- All hair must be covered with a bouffant and beard cover if applicable
  - ❖ What about eye lashes/brows
  - ❖ Ear and nose hair
  - ❖ Is there a limit on how long a beard and/or moustache can be?
  - ❖ If you have a clean shaven head, do you need to wear a hair net? Why?



# General Regulatory Requirements

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## ■ Primary Gowning Requirements

- Socks must be worn to cover ankles
  - ❖ If socks are customarily not worn, the company must supply them as part of the plant uniform
- Under shirt can be worn under scrubs
- Shoes
  - ❖ Must be dedicated to the facility
  - ❖ Cleaned/Sanitized on a routine bases
- Primary shoe covers are required
- Clear and defined gowning procedures



# People as Sources of Clean-room Contamination

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- **In-proper gowning techniques**
- **Non-compliance to gowning SOP's**
- **Torn garments and/or gloves**
- **Improperly fitting gowns that can cause billowing of the gown**
- **Changing gloves in the clean room**
- **In-proper clean-room behavior**



# Personnel Monitoring

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- **Gowning procedure/sequence will depend on facility design**
- **Routine gown/glove samples must not be taken post gowning prior to work**
- **Gowning qualification requires more samples than routine monitoring**
- **Re-qualification is required once per year**





# Personnel Monitoring

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## ■ **RODAC or TSA Plates**

- Does it depends on what type of samples you are taking?
- Are RODAC plates are used for Finger Impression Plates, (FIP)
  - ❖ Two plates are required, Left and Right
  - ❖ More difficult to hold
  - ❖ Covers can come off accidentally



# Personnel Monitoring

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## ■ RODAC or TSA Plates

- Have you ever seen a finger RODAC plate with growth on the side/edge of the plate?
- Why was there growth on the edge of the plate?
- Is it from the surface of the glove?
- If so, who's glove?
  - ❖ The operators
  - ❖ The person taking the sample

# Personnel Monitoring

- **Personnel monitoring program**
  - What plates do you use to sample your fingers?





# Personnel Monitoring

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## ■ RODAC or TSA Plates

- Based on the growth pattern, is it 1-CFU or multiple colonies
- Is the growth on the area of the plate that the sample was taken?
  - ❖ Can you see finger impressions on the plate?
  - ❖ Is the growth on the areas that the plate was touched?



# Personnel Monitoring

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- **What does this mean**

- What is the ramification of 1-CFU on a FIP plate?
- Is it operator error during sampling?
- Could the samplers glove have touched the edge of the plated?
- Is it possible that the product would be discarded due to this Action Limit?
- Maybe yes, maybe no



# Personnel Monitoring

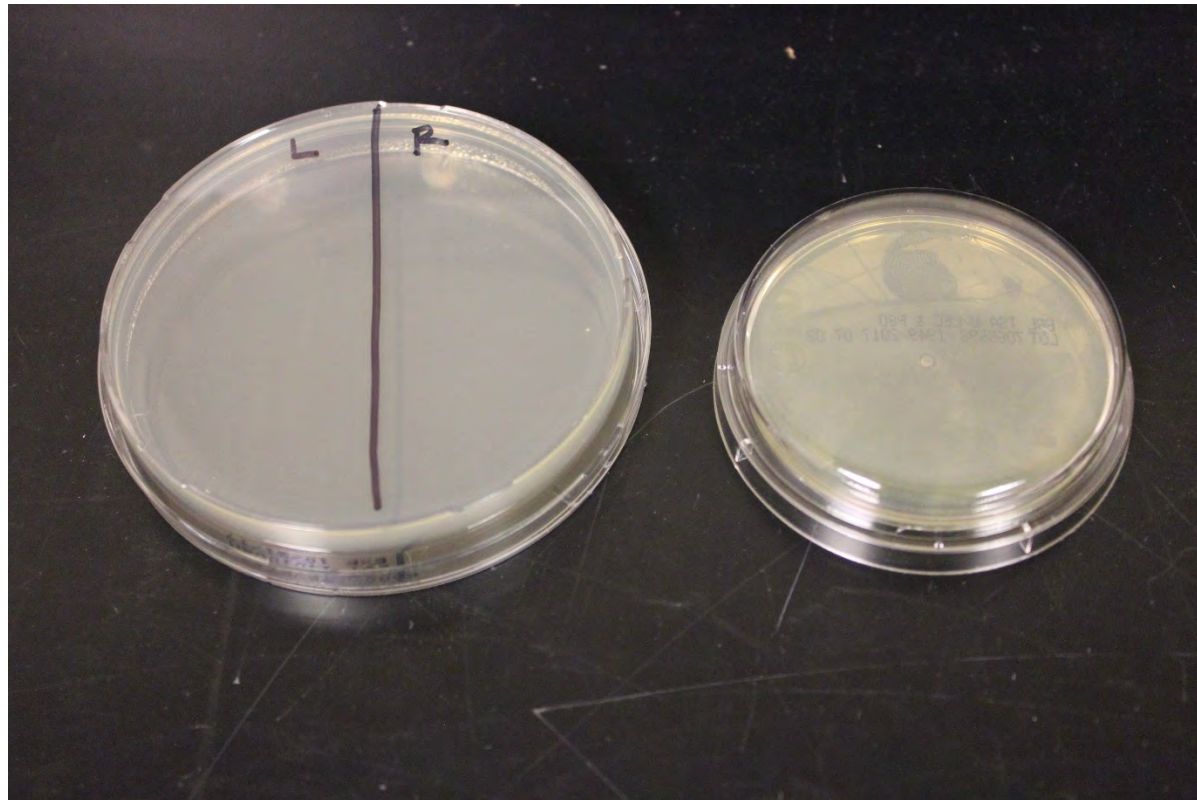
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## ■ What does this mean

- How well did the samplers glove fit?
- Did their gloves fit like a glove?
- Is the RODAC plate the optimum sampling system?
- What other plate could be used?
- How about using a 100 mm TSA plate with a line down the middle to designate Left and Right FIP's

# Personnel Monitoring

- **TSA Plate Verses RODAC Plate**





# Personnel Monitoring

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## ■ Personnel monitoring program

- Do you sample the finger tips or pads?
  - ❖ Tips sample approximately 5 cm<sup>2</sup>
  - ❖ Pads/Finger prints sample approximately 25 cm<sup>2</sup>
- Is there a significance to sampling the tips verses pads?
  - A RODAC plate surface is 25 cm<sup>2</sup>
  - The intent is to use the entire surface of the plate





# Personnel Monitoring

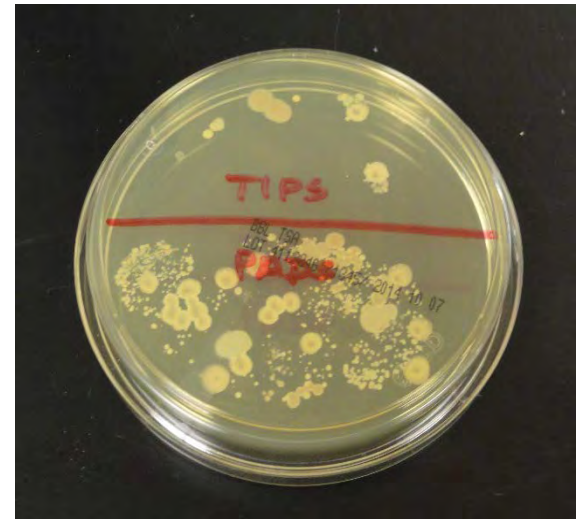
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- **Personnel monitoring program**

- Will the results change significantly?
- Yes since the surface area being sampled is 5 times more
- Since the Action Limit is 1cfu/hand, then it's significant

# Personnel Monitoring

- **Personnel monitoring program**
  - Tips on top and Pads below the line





# Personnel Monitoring

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## ■ Personnel finger sampling

- A single plate means 50% less finger plates
- 50% less labeling and documentation
- 100 mm TSA plates are easier to handle
- Variable of operator touching the sample surface is removed



# Personnel Monitoring

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- **How should the plate be held?**
  - Some companies hold the plate up-side down to prevent contamination
  - Do you think this is a good or bad idea?
  - If you put a settle plate out in the Grade-B Area and sample for 1-hour, what is the likely hood that it will recover  $\geq 1$ -cfu?
  - Extremely unlikely to recover anything
  - Therefore, there is little to no impact on the glove samples



# Personnel Monitoring

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- **How should the plate be held**
  - When holding the plate upside down, does it make it more difficult for the operator to sample their fingers
  - If you sample the tips there is not issue
  - When sampling finger pads, it is significantly more difficult for the operator
    - ❖ Proper pressure applied to the plate
    - ❖ Difficult to roll the finger pads like a finger print



# Personnel Monitoring

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- **Sampling the gown**

- If the sampling process is optimized, what is the recovery rate from the gown surface
  - ❖ 100 – 75%
  - ❖ 75 – 50%
  - ❖ 50 – 25%
  - ❖ 25 – 00%



# Personnel Monitoring

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- **Sampling method for the gown**
  - What sampling information is defined in the SOP?
  - If defined, is it clear and understandable?
  - For most companies, the SOP does not provide sufficient information on the details
  - What are the biggest issues when monitoring on the gown?



# Personnel Monitoring

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- **Personnel monitoring program**

- The **PHANTOM TOUCH**, where insufficient pressure is applied during sampling
- Entire surface area of RODAC plate is contacted
- Sample location differs based on the person taking the sample
  - ❖ Introduces a variable into the process
  - ❖ Therefore, the results may not be reproducible





# Personnel Monitoring

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- **Personnel monitoring program**

- Where are the samples taken for qualification?
- Are the sample locations justified?
- Does it represent worst case scenario?
- Is it representative of the
  - ❖ Gowning process
  - ❖ Manufacturing process
  - ❖ Or a combination of both



# Personnel Monitoring

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- **Locations during qualification**

- Top or back of head at tie/snaps
- Goggles or on the straps
- Mask, on the lips or on the side! @#\$%^&\*
- Hood/Gown interface
  - ❖ Left/Right side or Front/Back
- Shoulders
- Upper arm and/or Elbows
- Forearm at glove interface



# Personnel Monitoring

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- **Locations during qualification**
  - Gloves
    - ❖ Tips or pads
  - Palm of hand
  - Chest
    - ❖ Left, center or right side
    - ❖ On the zipper flap
    - ❖ How many layers are you sampling through



# Personnel Monitoring

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- **Locations during qualification**

- Waist
  - ❖ Left/Right side or Front/Back
- Middle of the back
  - ❖ Upper/Lower
- Thighs and/or Knees
- Interface of gown and boot
- Snaps and tightening system on boot
  - ❖ Left, center or right side



# Personnel Monitoring

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- **Routine sampling locations**

- Hood/Gown interface
- Chest
- Forearms
- FIP's
- Consider
  - ❖ Back based on gowning method
  - ❖ Mask?!\$%^&\*



# Personnel Monitoring

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- **Personnel monitoring program**

- Do personnel spray alcohol on the gown to reduce bioburden
- They should not because of wicking which allows organisms to pass through a moist/wet gown surface



# Personnel Monitoring

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## ■ Sanitization of the gloves

- What is the frequency of sanitization of the gloves in the clean room?
- Frequent? Is frequent defined the SOP?
  - ❖ Usually defined as approximately every 15-minutes
- Does the alcohol contact all areas of the gloves
  - ❖ Between fingers and finger tips/pads
  - ❖ Wrists



# Personnel Monitoring

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## ■ Sanitization of the gloves

- Can an operator sanitize their gloves just prior to sampling their fingers?
- Is it possible for the operator to sanitize their gloves, and not touch anything for 5-10 minutes and then get sampled?
- SOP should define that operators must perform a manufacturing operation prior sampling their fingers
  - ❖ This makes is process driven





# Personnel Monitoring Concepts

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## ■ **Static Personnel Monitoring**

- Evaluates aseptic gowning techniques
- At least 3 sets of qualifications are required and must be observed by a qualified personnel
- Recommend that a check list is used
- Required to be performed on three separate days



# Personnel Monitoring Concepts

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- **Dynamic Personnel Monitoring**
  - Assesses the ability of operator to work in the clean room with little to no contamination on the gown/gloves
  - At a minimum, 1 qualification should be required, however 3 is preferred
  - No risk to media or product
  - Confirms operator is qualified to work in the clean room



# Personnel Monitoring Concepts

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- **Dynamic Personnel Monitoring**
  - This can be accomplished during
    - ❖ A water fill
    - ❖ Support/Noncritical person in product or media fill
    - ❖ During training, after filling and post environmental monitoring
  - Sample locations, same as routine sampling



# Personnel Monitoring Concepts

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## ■ Takeaway Message

- Assess sample locations
- Confirm the locations are justified based on
  - ❖ The gowning process
  - ❖ Manufacturing process
- Are the samples being taken properly
- Dynamic qualification suggested
- Three qualifications are recommended
- Can people sanitize gloves prior to sampling