

Gowning Commodities and the Gowning Process



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Principles of Gowning

■ Objectives

- Facility Design of Gowning Areas
- General Regulatory Requirements
- Importance of Gowning and Personnel Monitoring
- Sources of Contamination
- Qualification/Re-qualification Requirements
- Discuss Action Limits and Alert Levels
- Qualification of Vendors



Facility Design of the Gowning Areas

- **Placement of HEPA's and air returns**
 - HEPA's should be placed in the ceiling on the clean side of the room
 - Low level air returns should be placed on the dirty side of the room



Facility Design of the Gowning Areas

- **Evaluate Airflow Patterns in the Area**
 - Gowning room should be negatively pressurized to the aseptic processing areas
 - Air should flow from the Clean side with the ceiling HEPA to the Dirty side with the low level air return
 - The gowning room should be positively pressurized to the lesser controlled areas



Facility Design of the Gowning Areas

- **Evaluate Airflow Patterns in the Area**
 - Gowning bench should allow air to flow beneath and/or through it
 - Air must not be allowed to flow from the floor up the gowning bench
 - Bench should have a closed finished underside for easy cleaning/sanitization
 - Recommended material of construction is stainless steel

Facility Design of the Gowning Areas

- Evaluate Airflow Patterns in the Area



Clean → Dirty

Facility Design of the Gowning Areas

- Evaluate Airflow Patterns in the Area



Clean → Dirty



Facility Design

■ **Air Exchange and Area Classification**

- A high number of air exchanges is recommended due to the Clean/Dirty configuration of the room, 30 – 75 air exchanges/hour
- The gowning process generates a high level of particulates
- It is important to remove the particulates and microbial contamination to maintain the area classification



Facility Design

■ **Air Exchange and Area Classification**

- Ensure the velocity of the HEPA filters do not exceed 120 ft./min
- This velocity exceeds the vendor recommendation of 108 ft./min
- At velocity's over 120 ft./min, air entrainment may occur and air can flow along the floor or walls from dirty to clean areas



Facility Design

■ Personnel Flow Pattern

- Gowning room should have a one way flow pattern into the processing areas
- Equipment/commodities should not enter through gowning areas
- Personnel should exit through a defined area/airlock
- If personnel must exit through the gowning room, personnel can not be gowning while people are leaving



General Regulatory Requirements

- **Formalized training systems**
 - Recommend using gowning video
 - Individual training instruction and assessment
- **Defined gowning procedures**
- **Defined qualification, re-qualification and disqualification systems in place**
- **Appropriate failure system in place with cGMP Action and Alert Limits**



General Regulatory Requirements

- **Participate in the following**

- Water fill prior to media fill
- Product fill as a support personnel with no activity in the critical areas
- Media fill as final qualification



General Regulatory Requirements

■ **Types of Contamination**

- Microbial
 - ❖ People, improper gowning, moving too fast, and coughing/sneezing
- Particulate
 - ❖ People, improper gowning, spraying with alcohol and pressure differentials
- Chemical
 - ❖ Contamination from disinfectants
 - ❖ Product cross contamination



General Regulatory Requirements

- **Entering the Aseptic Processing Areas**
 - Do not enter the aseptic processing areas with any of the following conditions
 - ❖ Cold, allergies or respiratory problems
 - ❖ Sunburn, open lesions or skin conditions
 - ❖ Flue symptoms or stomach disorders
 - ❖ Yeast infections or eye infections



General Regulatory Requirements

- **Entering the Aseptic Processing Areas**
 - The following are prohibited
 - ❖ Makeup and jewelry
 - ✓ If a ring can not be removed, company pays to have it removed and re-sized
 - ❖ How long can your finger nails be?
 - ❖ Acrylic nails
 - ❖ Finger nail polish
 - ❖ Perfume and scented deodorants



General Regulatory Requirements

- **Entering the Aseptic Processing Areas**
 - The following are prohibited
 - ❖ Medical alert bands or chains
 - ✓ Operator must notify supervisor and medical personnel of physical conditions
 - ❖ Wet hair
 - ❖ False eye lashes
 - ❖ Contacts (Debatable)
 - ❖ Braces for your teeth/retainer



General Regulatory Requirements

- **Entering the Aseptic Processing Areas**
 - The following are prohibited
 - ❖ Extensions and hair weaves
 - ❖ Sprays, gels or hair products
 - ❖ Socks must cover the ankles
 - ❖ Hands must be visibly clean
 - ❖ Hair accessories
 - ✓ Scrunches or rubber bands
 - ✓ Clips



General Regulatory Requirements

- **Entering the Aseptic Processing Areas**
 - The following are prohibited
 - ❖ New tattoos within 2-3 weeks or if there is visible skin abrasion
 - ❖ Non permanent tattoos
 - ❖ Smoking within a defined period
 - ❖ Rinsing mouth with water after smoking
 - ❖ Nicotine or any type of patches



General Regulatory Requirements

- **Entering the Aseptic Processing Areas**
 - Are these covered in the SOP
 - ❖ Band-Aids
 - ❖ Body odor
 - ❖ Socks are required
 - ❖ Material underwear is made of
 - ❖ Underwear in general
 - ❖ Gender specific underwear



General Regulatory Requirements

■ Gown Rooms

- Employee access/identification card must
 - ❖ Remain with the employee at all times
 - ❖ Not be left on a lab coat
- No personal effects are to be brought into the aseptic processing areas
- Considerations for
 - ❖ Walkie-Talkies
 - ❖ Company cell phones



General Regulatory Requirements

■ Gown Procedure

- Hand wash stations are usually not in the gowning room, but upstream of the process to minimize potable water contamination
- Hands are washed for a defined period of time prior to gowning, 45-60 seconds
- Hands must be dry prior to using a hand sanitizer.
 - ❖ If not, the water will dilute the alcohol concentration and be less effective



General Regulatory Requirements

■ Gown Procedure

- Type of alcohol for hand sanitizer
 - ❖ Ethanol – Concentration 62 – 64 % with emollients to minimize drying
 - ❖ Isopropyl – Concentration 70% with no additives. Dries the skin and therefore can cause flaking of the skin



General Regulatory Requirements

■ Gown Procedure

- Amount of hand sanitizer used is extremely important
 - ❖ Gel – Quarter or half dollar size
 - ❖ Foam – Golf ball
- Sufficient hand sanitizer must be used to provide sufficient contact time



General Regulatory Requirements

- **Gowning Commodities**

- Sterile alcohol/sanitizers
 - ❖ Manual or touch less
 - ❖ Squeeze, pump or propellant
 - ✓ Foaming
 - ✓ Gel
 - ✓ Spray
 - ✓ Liquid stream

General Regulatory Requirements

Hand Sanitizers





General Regulatory Requirements

- **Transfer of Commodities into the Gowning Areas**
 - Prior to handling the gowning packages, non-sterile or sterile gloves are put on
 - ❖ Non-sterile gloves are low in bio-burden
 - ❖ Sanitize non-sterile gloves with alcohol
 - Confirm all commodities are within expiration date
 - Ensure the packages are intact by the squeeze method
 - Verify sterilization indicators have turned



General Regulatory Requirements

- **Transfer of Commodities into the Gowning Areas**
 - At this point, sterile gloves must be used
 - Sanitize the gowning bench/lean bar or plate with 70% sterile isopropyl alcohol
 - Does the SOP say to:
 - ❖ Wipe the bench with alcohol wipe
 - ❖ Spray the bench with alcohol
 - ❖ Spray and wipe the bench
 - How much contact time do you have?
 - Is it sufficient to kill bacteria?



General Regulatory Requirements

- **Transfer of Commodities into the Gowning Areas**
 - Are all the gowning supplies sterile?
 - ❖ It's not they should be, but they must be sterile with at least a single wrap
 - Are the gowning packages sanitized prior to use?
 - If not they should be



General Regulatory Requirements

- **Place gowning packages on the table**

- Sanitize exterior bag with alcohol or remove the outer packaging of a double bagged item prior to placing on sanitized gowning bench

Do you use a self propellant alcohol or a trigger sprayer?

General Regulatory Requirements

- Alcohol types





General Regulatory Requirements

- **Sanitizing gowning commodities**
 - ❖ How much alcohol is applied
 - ✓ Light mist
 - ✓ Medium spray
 - ✓ Dripping wet
 - Does it matter the sequence of sanitization of the commodities?



General Regulatory Requirements

- **Sanitizing gowning commodities**
 - Yes the sanitization sequence is extremely important
 - When sanitizing the items, sanitize in order of use to provide maximum contact time
 - Do you ensure the folds and in between the plastic is sprayed?



General Regulatory Requirements

- **Sanitizing gowning commodities**
 - Yes the sanitization sequence is extremely important
 - When sanitizing the items, sanitize in order of use to provide maximum contact time
 - The question is, in what order do you gown
 - Is it significant?
 - It most definitely is

General Regulatory Requirements

- **Sanitizing gowning commodities**





General Regulatory Requirements

- **Sanitizing gowning commodities**
 - Do you ensure the folds and in between the plastic is sprayed?

General Regulatory Requirements

- **Sanitizing gowning commodities**





General Regulatory Requirements

■ Gowning

- How frequently or after what steps are you required to sanitize the gloves
- Is this even defined in the gowning SOP?
- If it isn't it should be
- At a minimum the operators must sanitize per SOP.
- How much alcohol is applied
 - ❖ Light mist
 - ❖ Medium spray
 - ❖ Dripping wet



General Regulatory Requirements

- **Gowning**

- Do you sanitize after putting on the final pair of gloves?
- Is it necessary?
- If so, why?



General Regulatory Requirements

■ **Gowning Commodities**

- Low shedding and low permeability
- Easy to use and comfortable for operators
- Fits well, durable and easy to put on
- Total body coverage with no exposed skin
- Disposable single use Tyvek gowns
 - ❖ Tend to be hotter and therefore less comfortable
 - ❖ Can be difficult to put on
 - ❖ People can be allergic



General Regulatory Requirements

■ **Gowning Commodities**

- Reusable sterile garments
 - ❖ Dedicated to the company/facility
 - ❖ Double stitched on critical seams of gown
 - ❖ Maximum usage of the gown is determined by
 - ✓ Wash system
 - ✓ Drying cycle
 - ✓ Gamma irradiation/autoclave cycle



General Regulatory Requirements

- Reusable sterile garments
 - ❖ Maximum cycle determined by particulate shedding
 - ❖ Particulate levels are determined after the full cycle, wash, dry, sterilization using the Helmka Drum
 - ❖ Must have a system to track the cycles
 - ✓ Bar codes
 - ✓ Manual writing on some interior surface of the gown



General Regulatory Requirements

■ Evaluation of Garments

➤ Bio-Shield Enclosed System

- ❖ Individual air filtration system with bubble face mask or helmet system
- ❖ Comfortable
- ❖ Cumbersome to gown with many attachments and snaps
- ❖ Uses traditional gowns

General Regulatory Requirements

- **Evaluation of Garments**

- **Bio-Shield Enclosed System**





General Regulatory Requirements

■ Evaluation of Garments

- Traditional
 - ❖ Face mask
 - ❖ Hood
 - ❖ Gown
 - ❖ Boots
 - ❖ Eye covering
 - ❖ Sterile gloves



General Regulatory Requirements

- **Evaluation of Garments**

- Face Masks

- ❖ Standard Mask

- ✓ Pleated

- ✓ Ties or elastic band

- ✓ Metal nose strip

- ✓ With, 5 to 7 inches



General Regulatory Requirements

- Face Masks
 - ❖ Standard with Adhesive
 - ✓ Adhesive associated with the metal nose band
 - ✓ Minimizes fogging
 - ❖ Large Volume
 - ✓ Foam for nose band
 - ✓ Material absorbs moisture to minimize fogging



General Regulatory Requirements

- Face Masks
 - ❖ Duck Bill
 - ✓ Keeps mask off the face/lips
 - ✓ Very comfortable
 - ✓ Reduces fogging

General Regulatory Requirements

➤ Face Masks





General Regulatory Requirements

- Hood
 - ❖ Adjustable with snaps or ties
 - ❖ Can have vendor provide inside out to make adjustments easier
 - ❖ Available in various sizes
 - ❖ Small to large face openings
 - ❖ Companies are starting to use ninja eye openings to minimize exposed skin

General Regulatory Requirements

➤ Hood



- ✓ Medium face opening
- ✓ Snaps
- ✓ Shoulder cut outs
- ✓ Elastic on back of head
- ✓ Bar code

General Regulatory Requirements

➤ Hood



- ✓ Disposable
- ✓ Large face opening
- ✓ Shoulder cut outs small

General Regulatory Requirements

➤ Hood



- ✓ Disposable
- ✓ Large face opening
- ✓ No shoulder cut outs
- ✓ No elastic or ties

General Regulatory Requirements

➤ Hood



- ✓ Disposable
- ✓ Ninja face opening
- ✓ No shoulder cut outs
- ✓ Hood very short
- ✓ Does not stay within gown

General Regulatory Requirements

➤ Hood



- ✓ Disposable
- ✓ Medium face opening
- ✓ No shoulder cut outs
- ✓ Ties to keep hood secure
- ✓ Hood short

General Regulatory Requirements

➤ Hood



- ✓ Disposable
- ✓ Integrated mask
- ✓ Ninja face opening
- ✓ Shoulder cut outs
- ✓ Ties to keep hood down



General Regulatory Requirements

➤ Boots

- ❖ Reusable have adjustments for fit
- ❖ Disposable have various sizes with ties or elastic bands
- ❖ Hard or soft soles
- ❖ Can get a custom fold from vendor to make putting on easier
- ❖ Recommend putting boots on after gown



General Regulatory Requirements

- Gown
 - ❖ Identify proper size
 - ❖ Reusable gowns
 - ✓ Easy to put on
 - ✓ Comfortable
 - ✓ Can define how gown is zipped/folded
 - ✓ Relatively cool to wear



General Regulatory Requirements

- ❖ Disposable gowns
 - ✓ May be difficult to put on
 - ✓ Tend to be hot to wear
 - ✓ No storage area required for used gowns
 - ✓ May tare when gowning
 - ✓ Tends to shed more particulates



General Regulatory Requirements

- Eye Covering
 - ❖ Most can't be autoclaved
 - ❖ UV not a good way to sanitize
 - ❖ Comfort and low fogging
 - ❖ Do not recommend using anti-fog liquid or spray because they are non-sterile
 - ❖ Gamma irradiation to sterilize
 - ✓ Define total number of sterilization cycles. The material will discolor over time and also become tacky



General Regulatory Requirements

- ❖ Types of Eye Covering
 - ✓ Full coverage
 - Straps that adjust easy
 - Straps with cloth weaved into it for comfort
 - Air vents to prevent fogging
 - Do not remove air vents because they leave exposed skin



General Regulatory Requirements

- ❖ Types of Eye Covering
 - ✓ Sterile safety glasses not an option because they leave exposed skin
 - ✓ Visor type do not provide full coverage
 - ✓ Large volume goggles tend to fog less than small volume eye covering

General Regulatory Requirements

- Eye Covering



General Regulatory Requirements

- Eye Covering



General Regulatory Requirements

- Eye Covering



General Regulatory Requirements

- Eye Covering



General Regulatory Requirements

- Eye Covering



General Regulatory Requirements

- Eye Covering



General Regulatory Requirements

- Eye Covering





General Regulatory Requirements

- Gloves
 - ❖ Sterile gloves
 - ✓ Gamma radiation is the method of choice
 - ✓ ETO for gloves wrapped in paper
 - ❖ Single, double or triple wrapped
 - ❖ Wrapped in plastic, synthetic or paper
 - ❖ Easy to open



General Regulatory Requirements

➤ Gloves

- ❖ Fingers are not wrinkled and stuck together
- ❖ Upper glove long enough so it does not pull away from sleeve
- ❖ Powder free
- ❖ Fits well
- ❖ Double glove in critical areas



General Regulatory Requirements

➤ Gloves

- ❖ Latex – Some people are allergic to this material
- ❖ Synthetic – Easier to put on than nitrile but more difficult than latex
- ❖ Nitrile – Non allergenic
 - ✓ Difficult to put on

General Regulatory Requirements

➤ Latex Gloves



General Regulatory Requirements

➤ Nitrile Gloves



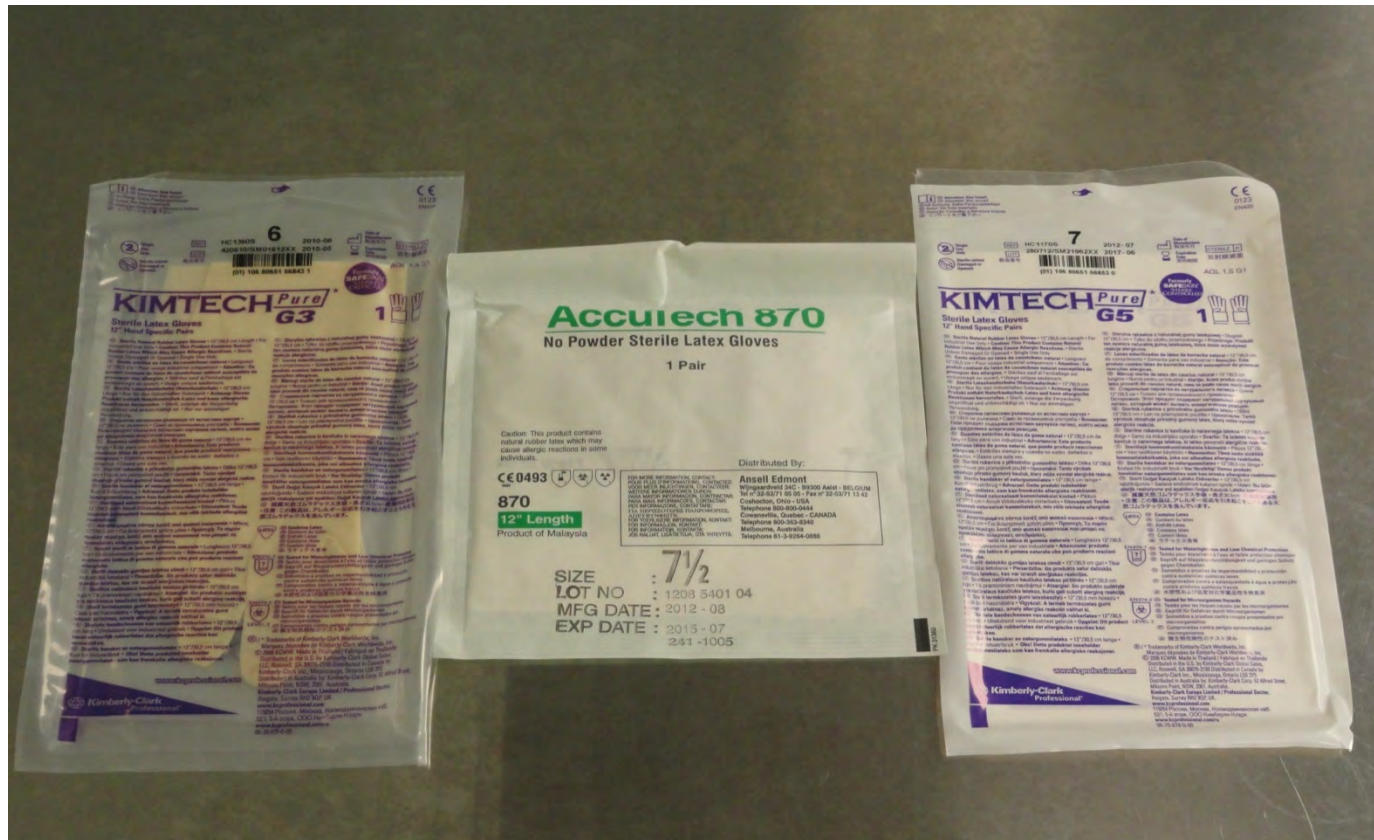
General Regulatory Requirements

➤ Polyisoprene & Neoprene Gloves



General Regulatory Requirements

➤ Various Packaging



General Regulatory Requirements

➤ Packaging



General Regulatory Requirements

➤ Packaging



General Regulatory Requirements

- Quality



General Regulatory Requirements

➤ Easy Opening

