MSHP 2015
Compounding CE Event

Practical Pearls on USP <797> and Sterile Compounding

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Learning Objectives

- Provide a history on sterile compounding from the 1930’s to present, including the inception of USP<797> and other regulatory chapters
- Review relevant USP<797> regulations and how to meet the standards
- Review risk levels and extended beyond-use dating
- Discuss environmental monitoring programs and remediation scenarios
- Review personnel training requirements and competency assessments
- Discuss the optimal use of policies, procedures and sterility/stability charts

History of sterile and non-sterile compounding

- In the 1930’s and 1940’s, 60% of medications were compounded (majority were non-sterile)
- According to the International Academy of Compounding Pharmacies (IACP), in 2009 there were 5000 compounding pharmacies
- By 2012, there were 7500 compounding pharmacies

The breakdown of sterile vs non-sterile is unknown

History of sterile compounding

- Evolved primarily in the hospitals, with customized injections and a few ophthalmics and inhalations
- In 1926, the Pharmacopoeia of the United States (USP) only listed two injections and the National Formulary only listed seven injections
- Today, the majority of sterile products are in the form of either large or small volume parenterals
- In 2013, the USP listed 566 injections

- Until 1933, hospitals compounded their own sterile products
- In 1933, the first large volume parenteral was manufactured for purchase
- In 1964, The American Society of Hospital Pharmacists (ASHP) published a report that documented major deficiencies in compounded sterile preparations
- It noted that a large percentage of sterile products where not coming from the pharmacies, but from central sterile services and nurses were compounding the vast majority of the compounded sterile products in the patient care areas
- This posed a huge concern!
History of sterile compounding

- In 1967, the first successful parenteral nutrition solution was launched (more additives and a greater potential for contamination)
- In 1969, in-line filters were available for patient administration
- In 1971, in-line membrane filters could be attached to syringes
- In 1975, lipid emulsion was introduced
- In 1977, Medicare began paying for home infusions of sterile products.
  Hence, more compounding pharmacies were popping up.

History of sterile compounding
Morbidity and Mortality

- It is likely that many contaminated compounded sterile products have not been recognized over time
- Some examples include:
  - In 1971, 100 patients died from septicemia from LVPs manufactured by Abbott Labs due to a flaw in the glass screw-cap closure
  - In 1977, drug related hospital deaths were documented to occur in 1.2 per 1000 patients (largely from LVPs)
  - In 1986, 1 death occurred from cardioplegia solution from a pharmacy compounding with an automated device

History of sterile compounding
Morbidity and Mortality

- In 1990, 4 deaths and several infections occurred from cardioplegia solution compounded in pharmacies and 2 cases of blindness occurred from contaminated eyedrops
- In 1994, many injuries and 2 deaths occurred from calcium and phosphate precipitation in TPN
- In 1998, 11 children received drug from hospital contaminated IV syringes
- In 2001, 3 deaths and 4 infections occurred which were linked to contaminated injections

History of sterile compounding
Morbidity and Mortality

- In 2003, bacteria was found in pharmacy compounded inhalations effecting 19,000 patients
- In 2004, 36 patients developed infections from compounded sterile products
- In 2005, 11 patients developed infections after cardiac surgery and 4 of these patients died due to contaminated sterile products
- In 2006, a death occurred from a decimal error in compounding and another death occurred from an overly concentrated injection being administer to a patient

As a result, ISMP recommended that Boards of Pharmacy require compounding pharmacies to be compliant with all aspects of USP <797>. They stated that “partial compliance will not even partially protect patients from the risk of infection from contaminated CSPs.”
History of sterile compounding
Morbidity and Mortality

- In 2012, New England Compounding Center (NECC) compounded three products (methylprednisolone, betamethasone and cardioplegia solution) that tested positive for bacteria and fungi in March of 2013.
- Over 750 patients have been harmed with meningitis, strokes, para-spinal infection, joint infections and 64 deaths over the span of 20 states.
- The predominant fungi identified in patients were Exserohilum rostratum and Aspergillus fumigatus. These fungi are commonly found in the environment. Fungal infections are not transmitted from person to person.

USP <797>

Have we taken it seriously?

Massachusetts Chapter 159

- Applies to compounded sterile products in hospital pharmacy settings and other practice settings
- Sets new requirements
- Changes the composition of the Board of Pharmacy
- Creates new pharmacy license categories
- Gives the Board of Pharmacy the ability to set monetary penalties

History USP <797>

- USP Chapter 797: Compounding Sterile Preparations was published on January 1, 2004
- Details procedures and requirements for compounding sterile preparations
- Each chapter of USP is assigned a number which appears in brackets along with the chapter name (ie: <797>)

What is the significance of the USP/ NF chapter numbering system?

- Chapters over 1000 are legally binding and it is up to each state to inspect for proper compliance
- Chapters 1-999 are legally binding and pharmacies may be inspected for compliance by the board of Pharmacy, FDA, and accreditation organizations
- Chapters 1-999 are legally binding and pharmacies may be inspected for compliance by the board of Pharmacy, FDA, DEA and accreditation organizations
- All chapters, regardless of the number, are recommendations for best practice and it is up to each compounding facility to audit its compliance

History USP <797>

- Chapters 1-999 are requirements and official monographs and standards of USP
- Chapter 797 is considered a requirement and pharmacies may be inspected for compliance with these standards by:
  - State boards of pharmacy
  - FDA
  - Accreditation organizations such as The Joint Commission (TJC)
- USP Chapters are reviewed documents
- On June 1, 2008: USP Chapter 797 was revised
What is the significance of the USP/NF chapter numbering system?

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- All chapters, regardless of the number, are recommendations for best practice and it is up to each compounding facility to audit its compliance.

Our cleanrooms...

- Should prevent turbulence and stagnant air from entering our primary engineering controls (PEC).
- Always work from clean to dirty.
- Finished surfaces: walls, floors, fixtures, and ceilings.
- Seamless flooring.
- “Cleanroom grade” ceiling tiles.
- Metal racks.
- All surfaces must be cleanable and able to withstand chemical cleaning.

ISO Classification of Particulate Matter

<table>
<thead>
<tr>
<th>ISO CLASS</th>
<th>Maximum # of Particles of 0.5 micron and larger per cubic meter</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>3,520 (hoods, glove boxes)</td>
</tr>
<tr>
<td>7</td>
<td>352,000 (cleanroom/buffer area)</td>
</tr>
<tr>
<td>8</td>
<td>3,520,000 (anteroom)</td>
</tr>
</tbody>
</table>

USP <797>

What is our goal?

- To prepare a sterile product.
- If we start sterile, we need to end sterile.
- If we start with a non-sterile product, such as high risk product, we must make it sterile before it is administered to the patient.

Where do we do this?

- In a clean air environment under a laminar airflow workbench or biologic safety cabinet (hood).
- In HEPA filtered rooms (cleanrooms) which remove particles.

Facilities and placement of PEC

- PEC
- Buffer Area
- Ante Area

How large are bacteria and viruses?
Positive pressure (non-hazardous)

- Different pressures are used to maintain sterility
- All non-hazardous preparations must be prepared in a positive pressure environment
- For rooms that are physically separated by walls and/or doors, a minimum differential positive pressure of 0.02 to 0.05 inch water column is required
- Buffer area shall be 0.02 inch water column greater than the anteroom
- The anteroom shall be 0.02 inch water column greater than the scrub area
- The scrub area shall be 0.02 inch water column greater than outside area

Room air exchange

- Expressed as: Air Changes Per Hour - ACPH
- ISO 7 buffer area and anteroom shall receive not less than an ACPH of 30
- More air exchanges may be required depending on the processes and the number of personnel in the room
- Additional air may also be needed to balance the room

Working facts about the hood: Horizontal flow hoods

- Air drawn in is cycled though a pre-filter intended to eliminate coarse particles and particulates
- Airflow then proceeds through the HEPA filter and is blown horizontally across the work surface
- HEPA filter removes 99.97% of particles that are 0.3 microns or larger

Working facts about the hood: Vertical flow hoods

- Air is drawn in and cycled through the pre-filter with the intention of eliminating coarse particles and particulates
- Airflow then proceeds through the HEPA filter and is blown vertically onto the work surface
- Some air is recycled into the hood while the rest is exhausted externally and 100% vented to the outside
- HEPA removes 99.97% of particles that are 0.3 microns or larger

Working facts about the hood: Vertical flow hoods

- Product must be 15 cm from the sides and the front of the grate and at least 5 cm away from the back of the hood
- Products having critical sites must remain in the airflow and must not have their airflow obstructed
- Avoid any rapid or sweeping movements while in the hood
- Do not place hands or supplies over product
- Do not over clutter
- Chemotherapy and hazardous products MUST be made in a vertical flow hood
Working facts about the hood:

- It is important to know the type of hood you are working in and the direction of the airflow: horizontal or vertical
- NEVER block airflow
- Perform your aseptic manipulations at least six inches inside the hood
- Keep air vents clear and do not block with objects
- Minimize your garbage
- Minimize turbulence
- Work in a very orderly fashion

Cleaning and Sanitizing our PECs

- Two solutions are used: sterile water for injection and sterile 70% isopropyl alcohol
- First use sterile water for injection or irrigation (water bottle must be emptied and rinsed with sterile 70% isopropyl alcohol daily)
- Cleaning order: top to bottom, back to front
- Spray water on all surfaces of the hood. Be careful not to spray liquid directly into the filter. Using a lint free cloth with a long sweeping motion.
- Wipe the water (long strokes)
- Do not go back over the surfaces that were done
- Spray sterile 70% isopropyl alcohol on each surface of the hood being careful not to spray into the filter
- Allow to air dry

What is BUD?

- **Beyond-Use Date**
  - The date or time after which the CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.
- Several factors are critical in establishing BUDs for CSPs:
  - Chemical stability
  - Sterility based on risk level based on the complexity of the manipulation
  - Environmental conditions where compounding is performed

Risk Levels...

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Use</td>
<td>No Primary Engineering Control.</td>
<td>Compounding procedure does not exceed 1 hour. Administration begins not more than 1 hour after compounding. If the preparer does not administer the CSP, the CSP shall bear a label w/ patient ID, names of all ingredients, initials of the person who prepared the CSP, and the exact 1-hour BUD and time. Compounding takes place on a cleaned surface free of clutter.</td>
</tr>
</tbody>
</table>

What about certification?

- Rooms must be certified by qualified personnel every six months
- Air sampling must be done every six months
- Hoods must be certified by qualified personnel every six months or anytime they are repaired or moved
Risk Levels...

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low with 12 hour or less BUD</td>
<td>Low risk product. No hazardous compounding. The Primary Engineering Control (ISO 5 hood) is located in an ISO 7 buffer area.</td>
<td>The segregated area shall be located in a location that has sealed windows and doors that are not connected to the outside. No sinks or food are allowed in the area. There is no high volume traffic. Personnel shall get appropriately. Area shall be clean and disinfected accordingly. Media fill tests should mimic the manipulations and be done annually.</td>
</tr>
<tr>
<td>Medium</td>
<td>The Primary Engineering Control (ISO 5 hood) is located in an ISO 7 buffer area. Multiple individual doses of CSPs or packed CSPs that will be administered to several patients or 1 patient several times. Compounding process that is complex or that requires a long duration.</td>
<td>Media fill tests should mimic the manipulations and be done annually. Examples include batching, TPN, transfer of volumes from multiple amp vials to 1 or more containers, long reconstructions, filling reservoirs with more than 3 sterile products and evacuating air before dispensing (intrathecal, epidural).</td>
</tr>
<tr>
<td>High</td>
<td>The Primary Engineering Control (ISO 5 hood) is located in an ISO 7 buffer area. Compounding involves transfers and mixing of not more than 3 manufactured CSPs.</td>
<td>Media fill tests should mimic the manipulations and be done semi-annually.</td>
</tr>
</tbody>
</table>

What are the Risk Levels and the BUD?

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Controlled Room Temperature 20 to 25 degrees C or 68 - 77 degrees F</th>
<th>Refrigerated 2 to 8 degrees C or 36-46 degrees F</th>
<th>Frozen -25 to -10 degrees C or -13 to 14 degrees F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Use</td>
<td>1 hour</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Low with 12 hour or less BUD</td>
<td>12 hours</td>
<td>12 hours</td>
<td>N/A</td>
</tr>
<tr>
<td>Low</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Medium</td>
<td>30 hours</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

All of the following factors must be taken into consideration when assigning a beyond-use date (BUD) except:

- Chemical stability
- Sterility based on the risk level of the complexity of the manipulation
- Environmental conditions where compounding is performed
- Number of personnel in the cleanroom when compounding is being performed
All of the following factors must be taken into consideration when assigning a beyond-use date (BUD) except?

- Chemical stability
- Sterility based on the risk level of the complexity of the manipulation
- Environmental conditions where compounding is performed
- Number of personnel in the cleanroom when compounding is being performed

Which statement is TRUE when assigning a 12 hour or less beyond-use date (BUD) to a compounded sterile product?

- The compounded sterile product is low risk and the Primary Engineering Control (ISO 5 hood) is located outside of an ISO 7 buffer area
- The compounding may involve a hazardous medication as long as a closed-system transfer device is utilized
- Medium and high risk compounding may be involved as long as batching involves units of less than 25
- Examples include cardiopulmonary events and emergency treatment where compounding must be done outside of an ISO 5 hood

Batching and Process Validation: USP <71>

- Media
  - (1) Fluid Thioglycollate Medium for primarily anaerobic bacteria
  - (2) Soybean-Casein Digest Medium suitable for both fungi and aerobic bacteria
- Must use both mediums and quarantine product

Batching and Process Validation (Provided the products have valid stability data)

<table>
<thead>
<tr>
<th>Number of items in a batch</th>
<th>Minimum number of items to be tested in each medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not more than 100</td>
<td>10% or 4 containers, whichever is greater</td>
</tr>
<tr>
<td>More than 100 but less than 500</td>
<td>10 containers</td>
</tr>
<tr>
<td>More than 500</td>
<td>2% or 20 containers whichever is less</td>
</tr>
<tr>
<td>More than 500 large volume parenterals</td>
<td>2% or 10 containers whichever is less</td>
</tr>
</tbody>
</table>

Batching and Process Validation

- Thioglycollate Medium incubation:
  - 32.5 degrees +/- 2.5 degrees centigrade
- Soybean-Casein Digest Medium incubation:
  - 22.5 degrees +/- 2.5 degrees centigrade
- Incubate for 14 days
Batching and Process Validation

- “Good to go” after 14 days of no growth in both media
- Release product and dispense
- Process MUST be done with every batch
- If there is growth anywhere along the way...back to the drawing board!

Which statement is TRUE when performing process validation testing on batched sterile preparation?

- Product cannot be released until 14 days of incubation in Thioglycollate Medium and Soybean-Casein Digest Medium with ZERO CFUs
- Product cannot be released until 14 days of incubation in Thioglycollate Medium and Soybean-Casein Digest Medium with <5 CFUs
- The quarantine and incubation process must be done initially and then every THREE months thereafter as long as the initial 14 days of incubation in Thioglycollate Medium and Soybean-Casein Digest Medium yields zero CFUs
- The quarantine and incubation process must be done initially and then every SIX months thereafter as long as the initial 14 days of incubation in Thioglycollate Medium and Soybean-Casein Digest Medium yields zero CFUs

Multiple-Dose Vials

- The beyond-use date for MDVs, after needle puncture, is 28 days unless stated otherwise by the manufacturer
- The date you open the vial should be placed on the vial label

Single Dose Vials

- Single dose vials, once needle punctured in an ISO class 5 environment, shall be sealed with an IVA seal and used within 6 hours of the needle puncture if kept in the hood
- Once removed from the hood, the vial MUST be DISPOSED of within 1 hour of puncture

What poses the biggest threat to our cleanrooms and ultimately our products?
Facts about us!

- Human pathogen microbes are everywhere
- There are 150-200 different classes of bacteria (this does not include viruses and fungi) in/on the human body
- Peoples’ hands have approximately 100,000 organism per square millimeter
- We release 5 grams of skin particles in a day - 40 pounds in a life time!
- Theses particles act as a vector for bacteria as well as our clothes
- Humans are the dirtiest things in our cleanrooms and we need to protect our products from us!

Import rules about our rooms:

- No eating, drinking, gum chewing or smoking
- No visible jewelry is to be worn
- No makeup…liquid or otherwise
- No artificial nails and nails must be kept short
- No nail polish

Personal Scrubbing: a review

- **Water scrub**: Used when entering the cleanroom at the beginning of the shift or coming back from breakfast-lunch-dinner or when hands are soiled
- **Waterless scrub**: Can be used after the initial water scrub as long as hands are free of dirt
- MUST be completed every time you enter the buffer area

Bugs are everywhere!
Aerobic and anaerobic bacterial load on food samples

<table>
<thead>
<tr>
<th>Food Sample</th>
<th>Aerobic Load</th>
<th>Anaerobic Load</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banana</td>
<td>8x10^2 CFU/g</td>
<td>3 CFU/g</td>
</tr>
<tr>
<td>Bagel</td>
<td>3.9x10^2 CFU/g</td>
<td>Below detection limit</td>
</tr>
<tr>
<td>Breakfast Burrito</td>
<td>3.5x10^2 CFU/g</td>
<td>6.0x10^5 CFU/g</td>
</tr>
<tr>
<td>Coffee</td>
<td>1.7x10^1 CFU/mL</td>
<td>3.3x10^1 CFU/mL</td>
</tr>
<tr>
<td>Salad</td>
<td>6.8x10^1 CFU/g</td>
<td>5.3x10^1 CFU/g</td>
</tr>
<tr>
<td>Burger</td>
<td>3.5x10^1 CFU/g</td>
<td>8.8x10^1 CFU/g</td>
</tr>
<tr>
<td>Fries</td>
<td>3.0x10^1 CFU/g</td>
<td>3.0x10^1 CFU/g</td>
</tr>
<tr>
<td>Sandwich</td>
<td>1.1x10^1 CFU/g</td>
<td>2.8x10^1 CFU/g</td>
</tr>
</tbody>
</table>

Garbing: a review

- Scrubs must be donned at the workplace
- Scrubs MUST be tucked in
- If you leave the building, put on a new set of scrubs before entering the IV room
- A clean, knee length lab coat MUST be worn outside of the cleanroom
- Don from top to bottom:
  - Beard cover (for beards and sideburns)
  - Mask (soft or molded)
  - Boots over shoes or shoes that are only worn in the cleanroom
- *Discuss dirtiest to cleanest: booties, bouffant, beard cover and mask according to USP <797>*

Hand washing: a review

- Scrub from top to bottom
- Cleanser: chlorhexidine or betadine scrub brush
- From fingertips to elbows
- Apply soap on one arm and then on the other arm
- Rinse the first side and then the other.
- Contact time is important
- Between the fingers and under the nails
- 30 seconds on each side - we say 1 minute
- Dry well
- Once hands are clean do not re-contaminate
- Put on sterile procedure gown
- Proceed to anteroom
Once in the buffer area:

- Apply alcohol
- Put on sterile gloves before entering the inside of the hood

Minimizing Particles and Sanitizing!

- Activities that generate particles should never be performed in the buffer and anterooms
- No corrugated boxes are allowed
- Items that are being introduced in the anteroom need to be sprayed down with sterile 70% isopropyl alcohol
- Some items may need to be introduced into the anteroom by placing them in plastic bags and spraying the outside with sterile 70% isopropyl alcohol

Cleaning and disinfecting the work area

- MUST be clean
- Must be done by trained personnel
- Areas included are: primary engineering area, work surfaces, shelving, floors, walls, ceiling, storage bins and their contents in both the buffer and ante areas
- Cleaning solutions used to clean walls and floors should be rotated every other week to deter bacterial resistance
- Goggles MUST be worn for mixing and application
- Follow manufacturer's instructions for diluting solutions

Cleaning and Sanitizing Primary Engineering Controls (our hoods)

- At the beginning of each shift
- Before batching
- At least very 30 mins during compounding
- When surfaces are soiled or there is suspected contamination

Cleaning and Sanitizing the Primary Engineering Controls

- Two solutions are used: sterile water for injection and sterile 70% isopropyl alcohol
- First use sterile water for injection
- Cleaning order: top to bottom, back to front
- Spray water on all surfaces of the hood. Be careful not to spray liquid directly into the filter. Using a lint free cloth with a long sweeping motion.
- Wipe the water
- Do not go back over the surfaces that were done
- Spray sterile 70% isopropyl alcohol on each surface of the hood being careful not to spray into the filter
- Allow to air dry

Remember...

- All items must be cleaned and sanitized before entering the buffer and anteroom areas!
Daily: Buffer Area Duties

- Work surfaces are cleaned and sanitized
- Trash is removed
- Air pressure recorded
- Remember: Mops, wipes, and sponges must be made of non-shedding material
- The floors are mopped while no aseptic operations are in progress
- Allow solution to air dry for 10 minutes
- Apply cleaning solution inside the buffer area and proceed outward to the perimeter of the anteroom

Daily: Anteroom Duties

- The same floor mop may be used in both the buffer and anteroom areas, but only in that order
- Remember to begin inside the buffer area and proceed outward to the perimeter of the anteroom.
- Mop heads must be changed daily
- All work surfaces must be cleaned and sanitized
- Record refrigerator and freezer temperatures
- Remove trash
- Record air pressure
- Change the tacky mat, if applicable

Monthly: Buffer Area and Anteroom Cleaning:

- Cleaning must occur while no aseptic operations are in progress
- All items are removed from storage shelving and all bins are emptied of all supplies
- Bins are cleaned with sterile 70% isopropyl alcohol and supplies are returned to bins
- Be sure to clean computer and printer area
- Clean and sanitize the chairs, glass surfaces, pass-thru, walls, ledges, trash bins, ceilings, ceiling fixtures, ventilation ducts

Supplies in the Anteroom Area:

- Supplies and equipment are removed from shipping cartons
- Wipe down with sterile 70% isopropyl alcohol
- Supplies that are contained in sealed pouches can be removed as they are introduced into the anteroom
- No cartons may be taken into the anteroom area

Documentation!

- All cleaning and sanitizing must be documented, including all hood & room cleaning
- All cleanroom areas should have SOPs and a daily workflow sheet which directs the staff to complete the duties of the day
- Must be completed daily

Example of Cleanroom Documentation
Why document and clean?
The results of all our hard work:

- Microbial air sampling is completed monthly in our cleanrooms.
- The current USP <797> states semi-annually (this is not without its issues!)
- The results allow us to determine how clean our working environment is
- Action is warranted when there is an increasing trend above baseline

Microbial Air Sampling

- We noticed an increased trend in CFUs in one of our cleanrooms
- Possible reasons for an increasing trend above baseline include: poor cleaning, operator technique variability, and the number of people circulating in the IV room during the sampling.
- Placement is consistent (air sampling maps in each IV area)
Correction of counts...

- We were able to correct this with two super cleanings
- Another explanation: Our HEPA filtration was turned off in our buffer area
- Looking at our increased counts helped us to identify this problem

According to USP <797>, how frequently must microbial air sampling be conducted?

- Every 6 months or when remediation is necessary
- Monthly for cleanrooms which compound low/medium risk products and weekly for cleanrooms which compound high risk products
- Every month or when remediation is necessary
- Not less than annually and up to the institution’s discretion

Process: for set-up, compounding, and checking

- MANY SETS OF EYES MAKE SAFE WORK!
- Anteroom set-up: done by technician or pharmacist. Should NOT be done by the person doing the compounding
- Set-up person: Fill out all the documentation except for the checking piece
- Compounding person: Always initial the label
- ALL calculations and writing should be done in the anteroom, NOT in the cleanroom

Checking compounded sterile preparations

- The pharmacist must visually inspect the CSP for particulate matter
- Must confirm accuracy of ingredients
- Check the label and all expiration dates and match lot #’s
- Document everything!
Documentation of compounded products must include:

- Set-up technician’s initials
- Compounding technician’s initials
- Checking pharmacist’s initials
- Drug lot number and expiration date
- Diluent(s) lot number and expiration date
- BUD

Documentation of a compounded sterile product should include all of the following except?

- Initials of technician setting up ingredients
- Initials of pharmacist checking the sterile product
- ISO Classification of the hood and cleanroom at the time of compounding
- Diluent lot numbers and expiration dates

Training new employees

- Shall be trained by expert personnel, using multimedia instructional resources and professional publications incorporating:
  1. the areas of garbing procedures
  2. aseptic work practices
  3. maintaining an ISO 5 & ISO 7 environment
  4. Cleaning and disinfection procedures for both personnel and surfaces

Competency

- Pass written test of basic compounding knowledge
- Garb and scrub appropriately
- Demonstrate cleaning, including surface sampling techniques
- Demonstrate proper equipment use
- Low/medium risk media-fill (annually)
- High risk media-fill (semi-annually)
- Demonstrate gloved fingertips are not contaminated

Training new employees

- Compounding personnel shall complete:
  1. didactic training
  2. written competency assessment
  3. observational audit tools
  4. media-fill testing and fingertip sampling
- Any employee that fails testing must be retrained and retested
- Training, media-fill test and fingertip sampling shall be completed, passed and documented before employees can make sterile products for patients
Update by: Holly Creveling  Date: March 6, 2015
Reviewed by: Peggy Stephan  Date: September 2, 2005
Written by: Denise Arena  Date: August 30, 2005

Avoid Freezing
Refrigerated:

STABILITY/STERILITY INFORMATION
***FOR IM USE***

Prep: Campus (W/E) today's date batch (B)
12 mg /2 mL *SHAKE WELL

(Brand Name if applies)
Betamethasone

PROCEDURE:
Fluid Dispensing Connector (Braun) 1
Luer tip caps 10
3 mL Syringes 10
30 mL Syringe 1
Betamethasone 6mg/mL; 5mL vial 4

MATERIALS:

LABEL REQUIREMENTS
6. Place syringes in a plastic bag.
5. Label with bar code label.
4. Repeat step 3 until all the suspension has been used.

Average
Starting
Study
Provide
Give
Create
Provide
Provide
Provide

To pop or to peel? You decide!
Study done by Eric Kastango and Jim Wagner published in Am J Health –Sysm Pharm, 2006;65:1443-50
Average Particle Count for Two Methods of Needle and Syringe Package Opening. Particles per cubic foot=ppcf
BD 18g needle: 471 ppcf Peel- 2,472 ppcf Pop
BD 1 mL syringe: 269 ppcf Peel- 2,397 ppcf Pop
BD 10 mL syringe: 582 ppcf Peel- 4,512 ppcf Pop
Terumo 18g needle: 938 ppcf Peel: 17,937 ppcf Pop
Tyco 1 mL syringe: 6,230 ppcf Peel- 34,243 ppcf Pop
Tyco 10 mL syringe: 5,713 ppcf Peel- 17,222 ppcf Pop

NOW...
Who wants to be a <797> expert?

<QUESTIONS?>