Missouri Board
Of
Pharmacy
Sterile Compounding: Aseptic Technique
Skill Assessment & Media Fills
August 25, 2016
Katie DeBold, PharmD
Inspector

Webinar Design

- All participants are muted, “listen only” mode
- Listen by telephone option

Continuing Education

- Board-approved for one hour (0.1 CEU) of live pharmacist continuing education
- Must be officially signed up and logged on via your computer
- CE credit will not be issued to those listening via the phone only
- Complete post survey within 48 hours of the webinar
- Instructions at the end of webinar
- CE credit is not submitted to CPE Monitor
Handouts and Recordings

- Handouts posted on Board’s website
- Recording of webinar
  - Videos/Webinars under “Publications/Resources” on the Board’s website
  - 2015 Legislative and Regulatory Update
  - 2015 OTC Update: White Blood Cell
  - 2015 Demo Tips for Year End Compaction
  - 2015 Medication Administration Regulation Review and Update
  - 2015 RGO Update
- No CE credit for watching recording.

How to Ask a Question

Missouri Board Of Pharmacy
Sterile Compounding: Aseptic Technique Skill Assessment & Media Fills
August 25, 2016
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Webinar Objectives

- Provide guidance on aseptic technique skill assessment and media fill testing
- Answer questions

Why Is Training So Important?

Studies have demonstrated a contamination rate of 5.1% among compounded sterile preparations.

In order to reduce the chance of contamination, our personnel need to be properly trained in all aspects of sterile compounding.

Building a Training Program

- Review of pharmacy policies & procedures
- Review of state/federal regulations (BOP, USP 797)
- Written tests
- Calculations
- Videos
- Online sterile compounding courses
- Shadowing
- Demonstrations
- Ample time to practice and ask questions
- Aseptic technique skill assessment & media fill
- Consistent training among all sterile compounding personnel (regardless of prior experience)
Personnel Education & Training Requirements

- All compounding staff must take and pass an aseptic technique skill assessment that includes a direct visual observation during a process simulation.

When:

- An initial assessment must be completed before allowing personnel to perform sterile compounding at your facility
- A reassessment must occur according to your risk level
  - Risk Level 1 & 2: Reassessment occurs every 12 months
  - Risk Level 3: Reassessment occurs every 6 months

Aseptic Technique Skill Assessment

A direct visual observation that must include the following competencies:

1. Proper aseptic technique, manipulations, and work practices
2. Cleaning and disinfection
3. Hand hygiene, gloving, and garbing
4. Identifying, weighing, and measuring of ingredients
5. Maintaining sterility in ISO Class 5 areas
6. Labelling and inspecting CSPs for quality

Additional competencies for risk level 2 or 3 compounders:

- Use of equipment: automated compounding devices, autoclaves, dry heat ovens etc.
- Sterilisation methods
- Filter integrity testing
- End-preparation testing

Aseptic Technique Skill Assessment: Proper aseptic technique, manipulations and work practices

What to assess during the visual observation:

- Avoiding touch contamination
  - Critical sites that should not be touched include:
    - Needle
    - Syringe tip
    - Vial & Bag ports
    - Needle hub
    - Syringe plunger
    - Tubing & dispensing pin spikes
- Proper use of "air" (see next slide)
- Appropriate disinfection practices
  - Disinfecting items prior to PEC placement
  - Frequent glove disinfection
  - Swabbing vial & bag ports with sterile alcohol pads
- For risk level 3 compounders:
  - Sterilisation of risk level 3 compounds
Proper Use of First Air

- First air: The air exiting the HEPA filter in a unidirectional air stream.
- Primary engineering controls (PEC) provide HEPA-filtered air at velocities sufficient to sweep away particles and microorganisms from critical sites.
- Essential to keep critical sites within first air at all times!
  - Anything that blocks the first air (hands, supplies etc.) will result in turbulent air. Turbulent air is not able to sweep away harmful particles & microorganisms.
- How to determine where the first air comes from?
  - Depends upon your PEC & the location of the HEPA filter
    - Vertical flow PEC (BSC or RABS) – 1st air will come from the ceiling of the unit
    - Horizontal flow PEC (LAFW) – 1st air will come from the back of the unit

Proper Use of First Air in a Horizontal Flow PEC

- First air is coming from the back wall of the unit.

Proper Use of First Air in a Vertical Flow PEC

- First air is coming from the ceiling of the PEC.
All personnel (including non-pharmacy personnel) that perform cleaning in a controlled/buffer area need to be trained and demonstrate cleaning/disinfection competencies.

**What to assess:**
- Proper dilution of cleaning agents
- Knowledge of appropriate contact time for disinfectants
- Proper cleaning tool selection (dedicated tools/buckets)
- Proper cleaning methods (cleanest to dirtiest, overlapping strokes)
- Proper cleaning procedure of primary engineering controls
- Knowledge of proper cleaning frequencies (what’s done daily vs monthly)

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Aseptic Technique Skill Assessment: Cleaning & Disinfection

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Aseptic Technique Skill Assessment: Hand Hygiene, Gloving & Garbing

All personnel (including non-pharmacy personnel) that enter the controlled or buffer area must be able to demonstrate proper hand hygiene, gloving, and garbing procedures.

**What to assess for the hand hygiene competency:**
- Washes hands and forearms for 30 seconds
- Washes all areas of hands (fingertips, thumbs, in-between fingers)
- Dries off hands/arms
- Turns off sink using a hands free procedure

**What to assess for the gloving competency:**
- Chooses the appropriate gloves (sterile, non-sterile, chemo)
- Chooses the appropriate glove size
- Pulls glove over the sleeve of the gown
- Dons sterile gloves appropriately (risk levels 2 & 3)
- If using a RABS, sterile gloves are donned inside the RABS

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Aseptic Technique Skill Assessment: Hand Hygiene, Gloving & Garbing

**What to assess for the garbing competency:**
- Removes outer garments, jewelry, & makeup
- Dons garb in the appropriate area
- Dons garb in the appropriate order
  1. Hair cover & Beard cover if applicable
  2. Face mask
  3. Shoe covers
  4. Wash hands
  5. Non-shedding gown
  6. Best practice: Apply an alcohol based hand rub
  7. Don gloves (Risk levels 2 & 3: sterile gloves are required)
- Garb is not re-used at any time (except gowns)
- If gowns are re-used, they are re-used for sterile compounding only and for 1 shift only
Aseptic Technique Skill Assessment: Identifying, Weighing & Measuring Ingredients

Ensure that personnel are able to select appropriate ingredients/materials:
- Preservative-free (if applicable)
- Sterilized glassware (if applicable)
- Filters (sterilizing filter, if applicable)

Ensure that personnel are able to use equipment properly:
- Scales
- Syringes
- Filters
- Autoclaves
- Dry Heat Ovens
- Automated compounding devices
- Fluid transfer pumps

Aseptic Technique Skill Assessment: Maintaining Sterility in ISO Class 5 Areas

Ensure that personnel maintain sterility throughout the compounding process:
- Maintain proper aseptic technique while compounding
- Frequent disinfection of gloves and work surface
- Proper use/selection of equipment

Aseptic Technique Skill Assessment: Labeling & Inspecting CSPs

Ensure that personnel label preparations appropriately:
- Affixes appropriate label
- Assigns appropriate beyond use date
- Affixes any applicable auxiliary labels

Ensure that personnel inspect preparations for integrity:
- Holes or leaks
- Cores or particulate matter
- Appropriate color, volume, clarity etc.
Reassessments

Additional reassessments must occur in the following situations:

- Quality assurance program yields an unacceptable result
  - Environmental sampling results exceed 797 action levels
  - End preparation testing results out of specification
- Unacceptable techniques are observed
  - If an individual fails the visual observation of hand hygiene, garbing or aseptic technique, they must be re-trained and pass 3 successive re-evaluations in the deficient area before they can resume sterile compounding
- Changes in risk level
- Changes in compounding methods

Media Fills

Media fill testing shall comply with USP Chapter 797 procedures

- Media Fill Test: A test used to qualify your technique of compounding personnel. During this test, a microbiological growth media is substituted for the actual drug product to simulate admixture compounding

- Media Fill tests are required as part of the aseptic technique skill assessment
  - A reassessment must occur according to your risk level
    - Risk Level 1 & 2: Every 12 months
    - Risk Level 3: Every 6 months
    - A minimum of 3 media fill tests must be completed during initial media fill testing
  - A reassessment must occur for any failed media fill tests
  - Personnel must pass 3 media fill tests before they can resume sterile compounding

Media Fill Procedures

- Media fill tests must be conducted using the most challenging or stressful conditions that a person encounters while compounding
- Design the procedure to closely simulate your pharmacy’s compounding activities
  - Utilize automated compounding devices or other equipment if applicable
  - If compounding risk level 3 preparations, utilize a non-sterile media and incorporate your sterilization method into the test
- If using media fill kits, evaluate their recommended procedure. Do the manufacturer’s instructions simulate a compounding process that your pharmacy currently employs?
  - If not, create your own procedure!
Types of Media
- Must use a sterile soybean casein digest media. Otherwise known as trypticase soy agar (TSA) or trypticase soy broth
- For risk level 3 compounders, use a non-sterile TSA powder. The media will then be diluted and sterilized as part of the media fill test.
- Do NOT dilute any growth media unless specifically directed by the manufacturer
- A certificate of analysis should accompany all media
- Media can be purchased as part of a kit or purchased as individual components
- Positive controls are useful in evaluating the ability of the media to support microbial colonization
- Media is purposely contaminated and incubated to show that it is capable of growth
- Risk level 3 compounders must have positive controls to prove that the initial preparation was non-sterile at the beginning of the test
- After diluting the non-sterile media (according to the manufacturer), transfer some fluid to empty vials and incubate them along with the media fill test. These samples should demonstrate positive growth.

Media Fill Incubation
- All media fills need to be incubated at 20-25 degrees C or at 30-35 degrees C for a minimum of 14 days.
- If two temperatures are used for incubation, then the containers should be incubated for 7 days at each temperature
- Media cannot be incubated at room temperature or for less than 14 days! (Even if recommended by the manufacturer)

How to Read & Document Media Fills
- How often to inspect them?
  - Best to review them everyday, but at a minimum review them on day 7 and day 14
- Failure is indicated by visible turbidity in any of the containers on or before 14 days
- Microbial growth can appear as cloudy, stringy or clumpy
  - When reading the media fill tests, try not to disturb the container. Shaking the bag/vial may interfere with the visualization of microbial growth
- Document the following information on your media fill test log:
  - Date the test was completed
  - Dates that the test was inspected
  - Incubation temperature
  - Incubation period
  - Lot number, manufacturer, & expiration date of the media
  - Result of test (growth/no growth, pass/fail)
  - Results of positive controls, if applicable
Policies & Procedures

Must have a policy and procedure for media fill testing and staff training/assessment

Media fill policy and procedure should include:

- Frequency of media fill tests
- Step by step process of media fill test
- Incubation of media fill tests
- Inspection of media fill tests
- Procedure for dealing with failed media fill tests

Staff training/assessment policy and procedure should include all aspects of training

Questions
Continuing Education

- Post Webinar Survey
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