The USP <797> Compliance Study: Main Pharmacy

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I. Compliance : 60%

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Action Plan Detail

II. The information contained in this section, Action Plan Detail, lists all of the action plan items within each domain that need to be addressed based on your responses to the gap analysis questions. To view the full detail of each question answered and your response please refer to Section III. Action Plan Detail by Trigger Question.

Demographic Information

A. None.

General Compounding

B. None.

Immediate Use CSPs

C. None.

Develop written SOPs that govern the conditions and procedures for Immediate Use CSPs. CriticalPoint strongly recommends that a list of specific Immediate Use CSPs be created at each entity. SOPs should include compounding conditions, documentation and training for those who may prepare Immediate Use CSPs.

Proprietary Bag and Vial Systems

D. Ensure that nursing staff do not assemble or dock these devices until they plan to administer the dose to the patient. Frequently, nursing staff are not aware of the additional contamination risk to the patient should docking occur in advance of the administration of the dose.

As the medication steward for the organization, CriticalPoint recommends that if nurses dock the devices at the patient unit, that pharmacy educate the nurses about the requirements for all patient care devices in that they may only be docked at the point of care which is at the patient bedside or in a designated area immediately prior to administering the patient dose. Hands must be washed before docking and proper aseptic technique used which are consistent with the manufacturer's instructions for use.

Point of care devices that are docked in advance of administration to patients, must be docked inside the ISO 5 area in either the SCA or cleanroom suite. The BUD assigned may not be longer than those specified by both:

- the manufacturer based on the package insert
- the requirements of the chapter (if in a SCA, the BUD cannot be longer than 12 hours room temperature or 24 hours refrigerated even if manufacturer's instructions say longer; if in an ISO 5 placed inside a cleanroom suite, then BUD is limited to 4 days room temperature or 10 days refrigerated even if manufacturer's instructions say longer).

Make initial and regular observations of the location and state of point of care devices on patient units. If staff observe point of care devices docked in advance by nursing staff (e.g., docking the devices needed for the entire shift), take immediate action by reporting it to the designated person so follow up action can be taken to change this practice.

Personnel Training/Evaluation: General

E. Develop a plan for training that is in a writing and addresses at least the following components:

- Specifically, what training is required at the facility
- CriticalPoint recommends that training needs are assessed every year since training needs can change based on the type of compounding performed, physical plant changes; changes to compounding equipment (PECs and automated compounding devices); different ingredients,
II. Action Plan Detail

The information contained in this section, Action Plan Detail, lists all of the action plan items within each domain that need to be addressed based on your responses to the gap analysis questions. To view the full detail of each question answered and your response please refer to Section III. Action Plan Detail by Trigger Question.

A. Demographic Information

None.

B. General Compounding

None.

C. Immediate Use CSPs

None.

- Develop written SOPs that govern the conditions and procedures for Immediate Use CSPs. CriticalPoint strongly recommends that a list of specific Immediate Use CSPs be created at each entity. SOPs should include compounding conditions, documentation and training for those who may prepare Immediate Use CSPs.

D. Proprietary Bag and Vial Systems

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E. Personnel Training/Evaluation: General

- Develop a plan for training that is in a writing and addresses at least the following components:
  - Specifically, what training is required at the facility
  - CriticalPoint recommends that training needs are assessed every year since training needs can change based on the type of compounding performed, physical plant changes; changes to compounding equipment (PECs and automated compounding devices); different ingredients,
actions which include but may not be limited to:
hand hygiene and garbing
initial gloved fingertip and thumb sampling (GFS)
aseptic technique
media-fill testing
ongoing GFS

Ensure that compounding personnel receive training in the principles and psychomotor skills necessary for performing sterile manipulations as well as how to achieve and maintain required environmental conditions before preparing CSPs independently.

After the training, these individuals also must demonstrate the skills necessary to perform these
actions which include but may not be limited to:

- hand hygiene and garbing
- initial gloved fingertip and thumb sampling (GFS)
- aseptic technique
- media-fill testing
- ongoing GFS

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- hand hygiene and garbing
- initial gloved fingertip and thumb sampling (GFS)
- aseptic technique
- media-fill testing
- ongoing GFS

- The designated person/s are responsible to ensure that anyone who enters the sterile compounding area maintains the quality of the environment. Potential areas to consider include:

  - Establish a visitor policy that delineates who can come inside the compounding area and under what conditions and then ensure staff is trained and the SOP is followed (e.g., remove make-up, jewelry, nail polish; perform garbing and hand hygiene under supervision; enter buffer room with limited activity (define limitations).
  
  - Develop and implement a SOP that details the conditions which prohibit workers from entering the sterile compounding area such as: new tattoo (unhealed), severe sunburn, fever; conditions that cause coughs, sneezes and runny noses. These conditions increase skin shedding, represent transmittable disease or produce sensations that may compromise the environment. Create a log in which the date and employee s name is logged. Document whether or not they were given alternate duty as well as when they are cleared to re-enter the compounding area.
  
  - Ensure that all compounding personnel understand proper conduct in the cleanroom which should include good organization to minimize trips in and out of the buffer room or inside the perimeter of the SCA; walking slowly, minimize talking and do not talk while compounding; aseptic technique; frequent sanitization of gloves, etc.

- Assign a designated person or persons that oversee all training. This does not have to be a single person and can be several people including the person who approves training, develops training, administers and evaluates training as well as those who administer testing and personnel competency verification. Ensure that the responsibility for ensuring that all facets of training required by SOPs is overseen by responsible and competent personnel and that those responsibilities are documented in writing.

F. Personnel Training/Evaluation: Demonstrating Competency in Hand Hygiene and Garbing

- Successful completion of ongoing or subsequent GFS (performed at the conclusion of media-fill unit preparation or compounding) is found by less than or equal to 3 CFUs found on the total of both sampling devices.

  For example: if 2 CFUs are found on the device for the left hand and 2 CFUs are found on the device for the right hand, that equals a total of 4 CFUs and the person would fail subsequent GFS.

- Change SOPs and train employees to reflect the following:

  - sampling devices contain general growth agar supplemented with neutralizing additives (e.g., TSA with lecithin and polysorbate 80) which support the growth of bacteria and fungi.
each sampling device is labeled with a personnel identifier, left/right hand and time of sampling
sampling is not immediately preceded with application of sterile 70% IPA to gloves
a separate sampling device is used for each hand
samples are collected by rolling finger and thumb pads over the agar surface;
media is stored inverted during incubation
devices are incubated in an incubator
incubation occurs at 30 to 35 °C for no less than 48 hours followed immediately by 20 to 25 °C for no less than 5 additional days
the number of CFU observed is recorded for each hand
the results are evaluated to determine if the CFU action level is exceeded by counting the number of CFUs from both hands

- The initial hand hygiene and garbing competency includes:
  - visual observation of hand hygiene and garbing
  - initial gloved fingertip and thumb sampling (GFS) to both hands

USP 797 says the initial GFS must occur no fewer than 3 separate times, each occurring after performing a complete and separate hand hygiene and garbing.

These do not have to done on the same day or they may be. For example: If a new employee will spend time observing operations in the buffer or SCA, they will have to perform hand hygiene and garbing and then instance #1 of the series can take place. If they leave for break and re-enter, then instance #2 can take places and then maybe instance #3 after lunch.

CriticalPoint strongly recommends passing be constituted only when a worker passes 3 consecutive GFS instances. For example: a pass, a pass, a fail and a pass should not constitute pass the initial GFS. We believe that only if workers can pass 3 consecutive times that they have sufficiently demonstrated mastery of the skill.

Initial GFS ONLY verifies the worker’s ability to don sterile gloves without contaminating them. Allow workers (especially those new to compounding) to have the technique demonstrated outside the controlled environment by a master performer. Allow them to practice with the master performer helping to cue them until they understand the procedure. Step by step instructions with pictures will assist greatly. Use videos. Allow workers to practice prior to testing. This is an important skill and takes practice to master.

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  - visual observation of hand hygiene and garbing
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performer. Allow them to practice with the master performer helping to cue them until they understand the procedure. Step by step instructions with pictures will assist greatly. Use videos. Allow workers to practice prior to testing. This is an important skill and takes practice to master.

- USP 797 requires a visual observation of garbing activities for all compounders. This means they must be observed while performing hand hygiene and through all aspects of donning and doffing appropriate PPE initially and every 6 months.

This visual observation must be documented, and the record kept in each worker's file.

CriticalPoint strongly recommends that garbing observation occur when compounders are not aware they are being observed to remove testing bias and ensure that the observation reflects what workers do each day.

Initially, hand hygiene and garbing competencies may be more formally done with a checklist of all required aspects of garbing (those that are specific to your organization and match the information found in your SOPs). Ongoing garbing observations may be captured during normal work so that time is saved, testing bias is eliminated and the observation of performance reflects real performance. The person observing must still document the observation and may use the garbing competency.

- Update written SOPs to specifically state that successful completion of the hand hygiene and garbing competency and the initial/subsequent GFS is indicated by all these:
  - proper hand hygiene and garbing performance (based on SOPs) during visual observation
  - initial GFS results that do not exceed the Action Level of ZERO (0) CFUs
  - subsequent GFS results that do not exceed an Action Level of 3 CFUs for both hands combined

It is NOT unusual to see an occasional CFU or two in an ongoing/subsequent GFS.

- Capture the following information by updating paper or electronic forms:
  - the name of person evaluated
  - evaluation date/time
  - media and components used to include the manufacturer, expiration date and lot number
  - starting temperature for each interval of incubation (temp indication on incubator)
  - the results (observed CFUs)
  - the name identification of the observer/person taking the sample (note: this is a new requirement)
  - the person who reads and documents the results


- USP 797 requires all compounding personnel, regardless of whether they perform Category 1 or 2 compounding, to perform media-fill testing (MFT) initially and at least every 6 months thereafter.

CriticalPoint suggests a more frequent best practice which is to perform MFTs initially and quarterly for those compounders whose compounding is limited to sterile to sterile manipulations. Those who perform Cat 2 compounding with nonsterile ingredients are urged to perform MFTs at more frequent intervals such as monthly.

- Revise your Media-Fill Testing documentation so that it includes at least these elements:
  - the name of person being evaluated
  - evaluation date/time
  - media and components (e.g., syringes, tubing, vials, etc.) used including manufacturer, lot number and expiration date
  - starting temperature of each interval of incubation
  - dates of incubation
  - results
III. Action Plan Detail by Trigger Question

The information contained in this section, Action Plan Detail by Trigger Question, lists each question within each domain that was answered by a NO response and includes a recommended action plan needed to correct the issue.

A. Demographic Information

No negatively-answered questions.

B. General Compounding

No negatively-answered questions.

C. Immediate Use CSPs

1. Does your organization have written standard operating procedures (SOPs) on Immediate Use CSPs?

   No

   • Develop written SOPs that govern the conditions and procedures for Immediate Use CSPs. CriticalPoint strongly recommends that a list of specific Immediate Use CSPs be created at each entity. SOPs should include compounding conditions, documentation and training for those who may prepare Immediate Use CSPs.

D. Proprietary Bag and Vial Systems

1. When using proprietary bag and vial systems, the location handles these devices in either of these two acceptable ways:

   ■ docks them in the pharmacy (following all compounding requirements of the chapter and assigning BUDs not longer than those specified by the manufacturer) for future activation by nursing OR
   ■ nursing docks and activates the devices at the point of use for immediate administration to an individual patient

   No

   • Ensure that nursing staff do not assemble or dock these devices until they plan to administer the dose to the patient. Frequently, nursing staff are not aware of the additional contamination risk to the patient should docking occur in advance of the administration of the dose.

   As the medication steward for the organization, CriticalPoint recommends that if nurses dock the devices at the patient unit, that pharmacy educate the nurses about the requirements for all patient care devices in that they may only be docked at the point of care which is at the patient bedside or in a designated area immediately prior to administering the patient dose. Hands must be washed before docking and proper aseptic technique used which are consistent with the manufacturer’s instructions for use.

   • Point of care devices that are docked in advance of administration to patients, must be docked inside the ISO 5 area in either the SCA or cleanroom suite. The BUD assigned may not be longer than those specified by both:

     ■ the manufacturer based on the package insert
     ■ the requirements of the chapter (if in a SCA, the BUD cannot be longer than 12 hours room temperature or 24 hours refrigerated even if manufacturer’s instructions say longer; if in an ISO 5 placed inside a cleanroom suite, then BUD is limited to 4 days room temperature or 10 days refrigerated even if manufacturer’s instructions say longer).
• Make initial and regular observations of the location and state of point of care devices on patient units. If staff observe point of care devices docked in advance by nursing staff (e.g., docking the devices needed for the entire shift), take immediate action by reporting it to the designated person so follow up action can be taken to change this practice.

E. Personnel Training/Evaluation: General

1. Before beginning to prepare CSPs independently, all compounding personnel complete training and demonstrate knowledge of the principles and proficiency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions.

   No

• Ensure that compounding personnel receive training in the principles and psychomotor skills necessary for performing sterile manipulations as well as how to achieve and maintain required environmental conditions before preparing CSPs independently.

   After the training, these individuals also must demonstrate the skills necessary to perform these actions which include but may not be limited to:

   ■ hand hygiene and garbing
   ■ initial gloved fingertip and thumb sampling (GFS)
   ■ aseptic technique
   ■ media-fill testing
   ■ ongoing GFS

• Develop a plan for training that is in writing and addresses at least the following components:

   ■ Specifically, what training is required at the facility.
   ■ CriticalPoint recommends that training needs are assessed every year since training needs can change based on the type of compounding performed, physical plant changes; changes to compounding equipment (PECs and automated compounding devices); different ingredients, etc.
   ■ Document training, testing and competency verification for all compounding personnel

• The designated person/s are responsible to ensure that anyone who enters the sterile compounding area maintains the quality of the environment. Pote the areas to consider include:

   ■ Establish a visitor policy that delineates who can come inside the compounding area and under what conditions and then ensure staff are trained and the SOP is followed (e.g., remove make-up, jewelry, nail polish; perform garbing and hand hygiene under supervision; enter buffer room with limited activity (define limitations).
   ■ Develop and implement a SOP that details the conditions which prohibit workers from entering the sterile compounding area such as: new tattoo (unhealed), severe sunburn, fever; conditions that cause coughs, sneezes and runny nose, etc. These conditions increase skin shedding, represent transmittable disease or produce secretions that may compromise the environment. Create a log in which the date and employee's name is logged. Document whether or not they were given alternate duty as well as when they are cleared to re-enter the compounding area.
   ■ Ensure that all compounding personnel understand proper conduct in the cleanroom which should include good organization to minimize trips in and out of the buffer room or inside the perimeter of the SCA; walking slowly, minimize talking and do not talk while compounding; aseptic technique; frequent sanitization of gloves, etc.

2. There is a designated person/s to oversee personnel training.

   No

• Assign a designated person or persons that oversee all training. This does not have to be a single person and can be several people including the person who approves training, develops training, administers and evaluates training as well as those who administer testing and personnel competency verification. Ensure that the responsibility for ensuring that all facets of
training required by SOPs is overseen by responsible and competent personnel and that those responsibilities are documented in writing.

3. A written training program describes:

- what training is required
- the frequency of training
- the process for evaluating the performance of individuals involved in preparing CSPs

4. All compounding personnel complete written (or electronic) testing and demonstrate competency in at least the following topics, every 12 months:

- hand hygiene and garbing
- cleaning and disinfection
- performing calculations
- measuring and mixing components
- aseptic technique
- additional measures to achieve or maintain sterility and apyrogenicity
- use of any equipment used (automated compounding devices for parenteral nutrition or volume mixing, scales, samplers, etc.)
- documentation on compounding records
- principles of HEPA-filtered air and use and maintenance of uninterrupted unidirectional first air within the ISO 5 space (specifically the direct compounding area)
- proper use of PECs
- material handling
- conduct of personnel within the compounding area
- proper use of primary engineering controls (PECs)
- principles of movement of materials and personnel within the compounding area

No

- Documentation of ongoing competency in areas other than GFS, garbing and media fill, do not always have to be in the form of checklists. For example, after a staff member has received initial training in math calculations and passed a test, thereafter their ongoing demonstration of competency can be captured during regular work activities. For a specific example, if the employee completes calculations correctly, you can capture that work (make a copy of the compounding record redacting the patient name) and include it the employee's personnel records as an example of annual competency verification. This approach is actually better than what occurs in testing since capturing performance during work eliminates testing bias.

- Ensure that compounding personnel complete testing (on paper or electronic) as well as psychomotor competency verification every 12 months in \textit{at least} the following:
  - hand hygiene and garbing
  - cleaning and disinfection
  - performing calculations
  - measuring and mixing components
  - aseptic technique
  - additional measures to achieve or maintain sterility and pyrogenicity
  - use of any equipment used (automated compounding devices for parenteral nutrition or volume mixing, scales, samplers, etc.)
  - documentation on compounding records
  - principles of HEPA-filtered air and use and maintenance of uninterrupted unidirectional first air within the ISO 5 space (specifically the direct compounding area)
  - proper use of PECs
  - material handling
  - conduct of personnel within the compounding area

\textbf{F. Personnel Training/Evaluation: Demonstrating Competency in Hand Hygiene and Garbing}

1. \textit{All} the following is true for compounding personnel at this location:
   - they are visually observed while performing hand hygiene and garbing initially and at least every 6 months
   - the visual audit is documented
   - documentation of visual audit is maintained for each employee

No

- The initial hand hygiene and garbing competency includes:
  - visual observation of hand hygiene and garbing
  - initial gloved fingertip and thumb sampling (GFS) to both hands

USP 797 says the initial GFS must occur no fewer than 3 separate times, each occurring after performing a complete and separate hand hygiene and garbing. These do not have to done on the same day or they may be. For example: If a new employee will spend time observing operations in the buffer or SCA, they will have to perform hand hygiene and garbing and then instance \#1 of the series can take place. If they leave for break and re-enter, then instance \#2 can take places and then maybe instance \#3 after lunch.

CriticalPoint strongly recommends passing be constituted only when a worker passes 3 \textit{consecutive} GFS instances. For example: a pass, a pass, a fail and a pass should not constitute pass the initial GFS. We believe that only if workers can pass 3 consecutive times that they have sufficiently demonstrated mastery of