DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	12/1/2015-1/29/2016*
	FEI NUMBER 3010015551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Carole V. Dupont , Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	27 Village Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wallingford, CT 06492-2426	Producer of Sterile Drug

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A. The firm has not certified the clean rooms (ISO 5, ISO 7 and ISO 8) under dynamic conditions since (b) (4)

B. Two HEPA filters within the ISO 5 area (HEPA (b) (4)) appeared to have black splotchy patches with irregular boundaries. Additionally, all HEPA filters screening were observed to have a "rust" color on the outside within the ISO 5 and ISO 7 areas.

C. The firm uses a Sterile (b) (4) that was specifically designed to be used with (b) (4) (b) (4) containers to (b) (4) a component used in the sterile production of TPN products. The (b) (4) to (b) (4) (b) (4) .

D. The facility is not adequately designed and controlled to prevent influx of contamination from lesser controlled areas. The ceiling light fixtures within "Compounding Room #1" (ISO 7) directly outside the (b) (4) barriers were observed to be lifted up (approximately 1/2 inch space between the light and the ceiling) and not flush with the ceiling.

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OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written and followed .

Specifically,

It was observed that personnel working inside the sterile drug production room (ISO 7) (b) (4) used in producing TPN products with sterile (b) (4) prior to entering the ISO 5 area. (b) (4) The vials are (b) (4) without any physical debridement of the vial (b) (4) The lack of physical debridement does not assure that the vials are fully cleaned of any potential contaminant prior to (b) (4) and producing sterile product for adult and pediatric patients. The firm's written documentation does not require staff to perform this step.

OBSERVATION 3

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between in-process materials and to prevent contamination.

Specifically,

A. On December 8, 2015, an operator was observed beneath the (b) (4) barriers, potentially blocking first air with an exposed face (forehead and eyes), engaging in the (b) (4) manipulation of sterile injectable drug products within the ISO 5 areas.

B. Differential pressure is not adequately monitored and controlled between the controlled manufacturing areas and non-controlled areas. Specifically; there is no continuous monitoring of the pressure differential between the ISO 8 (Prep Room) and warehouse.

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C. Numerous batches of TPN products are produced (b) (4), "Compounding Room #1". This operation requires (b) (4) Additionally, aseptic processing and labeling operations occur within the open sterile drug production room. For example, (b) (4), as observed on December 8, 2015. The room was last certified by air flow pattern analysis (smoke study) under dynamic conditions for (b) (4) in (b) (4). Your firm does not maintain an air flow pattern analysis (smoke study) for "Compounding Room #1" under dynamic conditions for greater than (b) (4)

D. The facility is not adequately designed and controlled (e.g. lack of interlocking doors) to prevent influx of contamination from less controlled areas. Doors accessing the (b) (4) from Prep Room (ISO 8) and "Compounding Room #1" (ISO 7) were observed to have a gap. Materials (b) (4) Prep Room (ISO8) (b) (4) "Compounding Room #1" (ISO 7) are (b) (4) Access to the (b) (4) occurs from unclassified areas of the firm, and manipulation of sterile drug product occurs in "Compounding Room #1"(ISO 7) under the ISO 5 workbenches.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. Production of sterile drug products is performed (b) (4) within ISO 5 laminar flow workbenches; however, the firm conducts environmental monitoring with the following frequencies:

1. Particulate matter air samples are taken on a (b) (4) (b) (4).

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2. Air and surface bioburden samples are taken on a (b) (4) (b) (4) (b) (4) (b) (4) were observed in "Compounding Room #1", where the production of sterile drug product occurs.

3. Personnel glove fingertips sampling is taken (b) (4) (b) (4) in the production of sterile drug products.

4. Personnel sterile sleeve cover sampling is taken (b) (4) (b) (4) in the production of sterile drug products. Moreover, the personnel monitoring fails to include surface sampling on the operators' face mask, forehead and chest.

B. The procedure "CAPS-SOP-Sys Environ Control-Infection Control-ENVIRONMENTAL MONITORING":, SOP - CAPS- 4000172 is not followed during personnel monitoring (fingertips) after (b) (4) in the production of sterile drug products. Fingertips were observed being monitored (b) (4), in contrast with the procedure, as they were (b) (4) to maximize surface evaluation area.

C. The procedure "CAPS-SOP-Sys Environ Control-Infection Control-ENVIRONMENTAL MONITORING":, SOP - CAPS- 4000172 is not followed during personnel monitoring (b) (4) after (b) (4) in the production of sterile drug products (b) (4) were observed being monitored (b) (4) in contrast with the procedure, as they were (b) (4) instead of (b) (4) to ensure full contact is made between the (b) (4) and the media surface.

D. The procedure "CAPS-SOP-Sys Environ Control-Infection Control-ENVIRONMENTAL MONITORING":, SOP - CAPS- 4000172 is not followed during surface bioburden monitoring after (b) (4) in the production of sterile drug products. Surface samples were observed being monitored (b) (4) in contrast with the procedure, as they were (b) (4) (b) (4) instead of (b) (4) to ensure full contact is made between the (b) (4) and the media surface.

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E. The firm's environmental monitoring plan is inadequate due to the fact that no surface samples are taken in the (b) (4) (b) (4) Prep Room (ISO 8), (b) (4) Ante Room (ISO 8) and the Gowning Room (ISO 8). Additionally, surface sampling in "Compounding Room #1" (ISO 7) does not include cart handles, walls, floors, computer printer or cart wheels.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

Cleaning records fail to include cleaning solutions used during the (b) (4) cleaning of the ISO 5 hoods where sterile TPN products are produced for pediatric and adult patients.

OBSERVATION 6

Written records are not made of investigations into unexplained discrepancies .

Specifically,

A. The firm's certification reports document that HEPA Filter (b) (4) located in the ISO 5 area documented variable filter sizes in multiple reports. For example, the (b) (4) report states that HEPA Filter (b) (4) was (b) (4) square feet, on (b) (4) as (b) (4) square feet and on (b) (4) at (b) (4) square feet. The firm performed no investigation into the size variations.

B. The firm performs (b) (4) identification of microbial CFUs found during routine monitoring. The firm identified one (1) CFU from the touchplate in the (b) (4) on December 18, 2014 and sent the plate to the CAPS Laboratory located in California for identification. The laboratory report sent back

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the identification of four (4) isolates from the plate. Additionally, on August 31, 2014 technician (b) (6) had one (1) cfu identified by the pharmacist from (b) (6) fingers on (b) (6) right hand. The labs reports identified two (2) isolates gram-positive rods and gram- positive cocci. No investigation was done to explain the discrepancy.

OBSERVATION 7

Batch production and control records do not include the specific identification of each batch of in-process material used for each batch of drug product produced.

Specifically,

The batch records state that the firm is utilizing the component (b) (4) which is interpreted as (b) (4). It was observed and confirmed during this inspection that the firm is not using this component identified in their batch records and is instead using a component labeled (b) (4)" to produce Total Parenteral Nutrition (TPN) for adults and neonates.

*DATES OF INSPECTION

12/01/2015(Tue),12/02/2015(Wed),12/03/2015(Thu),12/04/2015(Fri),12/08/2015(Tue),12/09/2015(Wed),12/10/2015(Thu),12/11/2015(Fri),1/08/2016(Fri),1/09/2016(Sat),1/12/2016(Tue),1/29/2016(Fri)

1/29/2016

X John P Mistler
John P Mistler
Investigator
Signed by: John Mistler -S

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."