DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	8/20/2019-8/28/2019* FEI NUMBER 1972829

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Timothy C. Roettger, Regional Vice President, Pharmacy Services

FIRM NAME	STREET ADDRESS
SSM Health Care St. Louis DBA SSM St. Clare Health Center	1015 Bowles Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fenton, MO 63026-2394	Outsourcing Facility

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 I OBSERVED:

OBSERVATION 1

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

Specifically,

(A) Operators were observed contacting surfaces such as the handles to the (b) (4) doors in the ISO 7 non-hazardous cleanroom with gloved and ungloved hands. Operators also contacted surfaces in the ISO 7 anteroom with gloved and ungloved hands.

(B) Smoke studies performed in the ISO 5 hoods under dynamic conditions were not representative of normal production operations using the repeater pump and did not simulate the production of total parenteral nutrition (TPN). The smoke studies were conducted in empty hoods, and only basic manipulations were simulated.

(C) During production, the lid of the trash can was observed to be up blocking the path of air exiting of ISO 5 laminar airflow hood (Hood Left) , which has the potential to create turbulent airflow within the ISO 5 hood.

(D) The firm has not conducted media fills simulating the TPN production process.

OBSERVATION 2

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

Specifically,

(A) The firm does not routinely perform viable and nonviable environmental sampling in classified rooms or hoods during the production of drug products prepared pursuant to patient-specific prescriptions.

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	Mindy M Chou, Investigator	X Mindy M Chou Investigator Signed By 2000648922 Date Signed 08-28-2019 12 02 54	8/28/2019

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Additionally, the door handles of the cleanroom, the handles of the (b) (4) door, and the computer keyboards in the anteroom and (b) (4) room, which are frequently touched with gloved and ungloved hands during operations, are not included in the firm's environmental monitoring program without justification.

(B) The firm's personnel monitoring program does not include an appropriate schedule for monitoring the gloves and gowns of the operators involved in the production of patient-specific products during or immediately after completion of aseptic operations.

(C) Large (b) (4) between ISO 7 anteroom and unclassified area are not interlocked and both doors can be opened at the same time.

OBSERVATION 3

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet appropriate statistical quality control criteria as a condition for their approval and release.

Specifically, your firm's product inspection process is deficient in that you do not always perform 100% visual checks against a contrasting background of your sterile drug preparations and repackaged drug products prior to release. For example, the following lots of product were released by your Quality Unit without 100% visual inspection:

Product Name	Lot #	Exp. Date	Batch Size	# of Units Inspected	% Visually Inspected
Norepinephrine Bitartrate 8 mg in Dextrose 5% 250 mL	190619-004	09/17/2019	(b) (4)	(b) (4)	22%
Oxytocin 30 Units in 0.9% Sodium Chloride 500 mL	190626-015	09/24/2019	(b) (4)	(b) (4)	25%
Phenylephrine HCl 1000 mcg in 0.9% Sodium Chloride 10 mL	190617-011	09/15/2019	(b) (4)	(b) (4)	25%
Succinylcholine Chloride 100 mg in 5 mL Syringe	181022-013	01/20/2019	(b) (4)	(b) (4)	20%

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Additionally, visual inspection of the drug products packaged into cassettes (Hydromorphone HCl 10 mg in 0.9% Sodium Chloride 50 mL PCA (0.2 mg/mL); Morphine Sulfate 50 mg in 0.9% Sodium Chloride 50 mL PCA) were inspected with labels covering two faces of the cassettes.

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, the batch release testing for drug products with large batch sizes are only tested for potency, sterility, and endotoxin. The firm does not routinely test for pH and subvisible particulates as part of batch release testing.

OBSERVATION 5

Written specifications for laboratory controls do not include a description of the sampling and testing procedures used.

Specifically,

(A) The firm does not have an established procedure on collection of personnel monitoring samples. On 8/20/2019, the pharmacist was observed swabbing different locations of the operator's gown using (b) (4) cotton swabs, and then streaking the samples on (b) (4) plates.

(B) The firm does not have an established procedure describing how culture media plates should be read. On 8/22/2019, the pharmacist reported no growth for all (b) (4) plates of personnel monitoring and environmental monitoring samples collected on 8/20/2019 during Oxytocin 30 Units in 0.9% Sodium Chloride 500 mL (Lot # 190820-010) production. However, one (1) colony was observed on the edge of the (b) (4) plate for the sample collected from the (b) (4) area of the operator's gown.

OBSERVATION 6

Adequate ventilation is not provided.

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Specifically, there is no HEPA filter in the ceiling of the anteroom and non-hazardous buffer room. The air from the air handling unit (AHU[(b)(4)]) travels through a remote HEPA filter located in the ceiling above an unclassified room and then travels along ductwork and enters the ISO 7 non-hazardous cleanroom and ISO 7 anterooms through air supply grills in the ceiling. There is inadequate control, maintenance, and assessment of the cleanliness of the ductwork leading from the remote HEPA filters to the air supplies located in the ceiling of the ISO 7 anteroom and ISO 7 non-hazardous cleanroom.

OBSERVATION 7

Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices and written procedures required by current good manufacturing practice regulations.

Specifically,

(A) The firm's aseptic gowning qualification program does not include assessment of the ability of the cleanroom operator to maintain the quality of the gown after performance of gowning procedures.
(B) The firm does not have a training program for the collection of personnel monitoring samples.
(C) The firm does not have a training program for reading culture media plates.

OBSERVATION 8

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically,

(A) Personnel were observed handling the sterile gown with ungloved hands and donning subsequent gowning components without hand sanitization.
(B) Sterile gowns are reused when operators prepare products pursuant to patient specific prescriptions.

***DATES OF INSPECTION**

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8/20/2019(Tue), 8/21/2019(Wed), 8/22/2019(Thu), 8/23/2019(Fri), 8/26/2019(Mon), 8/27/2019(Tue), 8/28/2019(Wed)

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