DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	3/18/2019-3/22/2019
	FEI NUMBER 3014539004

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael R. Molby, PharmD, Pharmacy Manager

FIRM NAME	STREET ADDRESS
CMC Enterprise Pharmacy	4400 Golf Acres Dr
CITY, STATE, ZIP CODE, COUNTRY Charlotte, NC 28208-5968	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Nonsterile Drugs

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

The ISO 5 classified aseptic processing areas had difficult to clean, particle-generating and visibly dirty equipment or surface.

Specifically,

We observed the following in the ISO 5 sterile production area:

A.) Difficult to clean surfaces such as drywall; power strip ledges and open outlets; computer keyboard, mouse, and mouse pad; an apparent paper towel folded up and taped to the underside of the keyboard; binders filled with pages; common office supplies such as pens, calculators, and scissors; and anti-fatigue mats.

B.) Particle-generating surfaces such as crumbling drywall, peeling paint, paper, and apparent rust on HEPA filter covers, IV bag hanging racks above the work tables, table legs, cart legs, and office chairs.

C.) Over the course of consecutive days, a white residue was observed in streaks on the tops of repeater pumps, the inside of the observation window, a trash can, a table leg, the side edge of a work table, and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Adam R Cooke, Investigator Rachael L Cook, Investigator	X Adam R Cooke Investigator Signed By: 2001332542 Date Signed: 03-22-2019 12:05:34	3/22/2019

multiple chair seats. Additionally, debris was observed on HVAC return vents in the sterile production area as well as the gowning area on multiple days.

OBSERVATION 2

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, we observed:

There are no controls which prevent the (b) (4) doors leading to the gowning room and the ISO 5 sterile production area from being opened at the same time. This seemingly led to numerous and repeated observed pressure reversals over the course of the multiple day inspection. Pressure reversals led to lower classified air entering the ISO 5 sterile production area while sterile drug production was ongoing.

OBSERVATION 3

Your facility was designed and/or operated in a way that permits poor flow of personnel and materials.

Specifically:

The gowning room is used for gowning and to transfer supplies in and out of the ISO 5 classified sterile production area. The gowning room does not provide adequate space for gowning and does not contain adequate space to hold supplies during transfer. For example:

A. Firm personnel were repeatedly observed to disregard the line of demarcation in the gowning room as shoe covers were not always donned prior to stepping over the demarcation line and personnel were observed stepping back and forth over the line of demarcation after donning shoe covers and returning to the ISO 5 classified sterile production area without first changing their shoe covers.

B. Empty IV bags were observed piled in the hand-washing sink in the gowning room.

OBSERVATION 4

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, we observed:

IV bags are not individually sanitized and wiped down prior to entry into the ISO 5 sterile production area. Instead, they are piled on (b) (4), stacked as high as nine bags deep, or more, and only the outermost surfaces of the pile are sprayed with (b) (4).

OBSERVATION 5

Personnel engaged in aseptic processing were observed with exposed hair.

Specifically,

We observed at least one operator with hair escaping their hair net. Moreover, none of the operators were observed using the gowning mirror, which is not easily visible from the line of demarcation, and no operator appeared to assist any other operator with ensuring their gowning was appropriate. Finally, the eyebrows, eyelashes, eyes, cheeks, forehead, and neck were not covered in the ISO 5 sterile production area.

OBSERVATION 6

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Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically,

During the (b) (4) cleaning, the (b) (4) was only allowed to remain on the work surfaces in the ISO 5 sterile processing area for approximately eight minutes before being wiped off; firm management stated that (b) (4) of contact time is required for the (b) (4) to be efficacious as a sporicidal agent.

OBSERVATION 7

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

The sleeves of the full-body suit for at least three operators touched the floor during gowning for both cleaning and sterile drug production operations.

OBSERVATION 8

You had inadequate HEPA filter airflow over the area to which sterile product was exposed.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Adam R Cooke, Investigator Rachael L Cook, Investigator	X Adam R Cooke Investigator Signed By: 2001332542 Date Signed: 03-22-2019 12:05:34	3/22/2019

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The HEPA filter directly above work table (b) (4) in the ISO 5 sterile processing area was not moving air during the smoke study that was performed in 2018. No corrective action was documented, no leak testing, or replacement of HEPA filters has occurred, and we observed sterile drug production occurring at table (b) (4).

OBSERVATION 9

Media fills (aseptic process simulations) were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities, representative volume, and conditions that provide a challenge to aseptic operations. Additionally, environmental monitoring performed on work surfaces is performed immediately after sanitizing the surface. This leads to a negative bias in your verification process and can provide misleading data as to the cleanliness of your facility post operations.

X Rachael L Cook
Investigator
Signed By: Rachael L. Cook -S
Date Signed: 03-22-2019 12:07:21

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."