DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	4/27/26-5/1/26, 5/4/26-5/6/26, 5/8/26
	FEI NUMBER 2071629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Frank P. Pearson, Medical Center Director

FIRM NAME	STREET ADDRESS
VA San Diego Healthcare Systems	3350 La Jolla Village Dr
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Diego, CA 92161-0002	Producer of Sterile Drug Products

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) (WE) OBSERVED:

OBSERVATION 1

Smoke studies were inadequately performed under dynamic conditions.

Specifically,

Your firm did not conduct smoke studies under dynamic conditions, simulating worst-case production activities, including all components, materials, and equipment present during actual or routine aseptic operations, to demonstrate unidirectional airflow within the ISO 5 area(s) for the following equipment:

04/08/2026 - Hazardous ((b) (4) - Biologic Safety Cabinets (BSC) - SN: (b) (4)
03/11/2026 - Non-Hazardous ((b) (4)) - Laminar Flow Hood (LAFH) - SN: (b) (4), and (b) (4)
04/23/2026 - Operating Room (OR) Segregated ((b) (4)) - Compounding Aseptic (b) (4) ((b) (4) - SN:(b) (4)
04/23/2026 - Intensive Care Unit (ICU) Segregated (b) (4)) - Compounding Aseptic (b) (4) (b) (4) - SN: (b) (4)

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A) For example, your smoke study of the sterile hazardous room (room (b) (4) did not introduce smoke to visualize airflow at the equipment and workflow management system containing the scale and camera for production operations. Your smoke study from 04/08/2026 did not include materials staged during aseptic operations including but not limited to a sterile prep mat, syringes, sterile wipes, (b) (4) prep tray for materials, closed transfer device, and (b) (4) plate and washer over the ISO 5 grille. The smoke study videos for BSC SN(b) (4) and SN(b) (4) (hazardous room (b) (4)) were 58 seconds and 57 seconds in duration, respectively, and did not span the entire hood workspace, providing incomplete visualization of airflow throughout the critical zone.

B) The smoke study conducted on 03/11/2026 for the non-hazardous LAFH ((b) (4)(b) (4)) in room (b) (4) did not include equipment and materials staged during normal operations including but not limited to the equipment and workflow management system with protocol for drug production, scale, camera, and for production operations, hanging IV bags, (b) (4) vial reconstitution mixer, vials, beaker, handheld scanner with base, and printing of labels. The smoke study videos for non-hazardous LAFH (b) (4) were 16 seconds, 29 seconds, and 17 seconds in duration, respectively. Only half of the hood workspace was captured in the video, and the operator's positioning blocked visualization of aseptic connections receiving first air.

C) The smoke study conducted on 04/23/2026 for the segregated (b) (4) in the ICU (room (b) (4)) demonstrated that there was activity being performed outside where the smoke was introduced. Therefore, the aseptic critical sites and open product containers received unidirectional first air as required during routine aseptic operations was obscured.

D) The smoke study videos did not demonstrate that non-ISO 5 air was not introduced into the critical zone, namely BSCs.

We observed the sterile production of bortezomib 2.7mg, label #(b) (4) (produced in BSC (b) (4) in the hazardous room (b) (4)) and ertapenem 1 gram in normal saline mini-bag 50 mL, label #(b) (4) (produced in LAFH (b) (4) in the non-hazardous room (b) (4)) on (b) (4) without conducting smoke studies under dynamic conditions.

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OBSERVATION 2

Beta-lactam drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

Beta-Lactam drug products are produced in the same ISO 5 hoods as non-beta-lactam drug products intended to be sterile. The following beta-lactam drugs were observed being produced in your LAFH hood include, but are not limited to:

- ceftaroline fosamil 300 mg in D5W 100 mL
- ampicillin 2 gm in Normal Saline Mini-Bag 100 mL
- ampicillin/sulbactam 3 gm in Normal Saline Mini-Bag 100 mL
- ertapenem 1 gm in Normal Saline Mini-Bag 50 mL
- meropenem 1000 mg in Normal Saline Mini-Bag 50 mL
- meropenem 2000 mg in Normal Saline 100 mL

Your firm performs cleaning with only (b) (4) between the production of beta-lactam and non-beta lactam drug products intended to be sterile in the same ISO 5 area and uses (b) (4), with a (b) (4) (b) (4) time, as the cleaning/sanitizing agent to inactivate beta-lactam residues only (b) (4) on (b) (4) in the non-hazardous production area. This frequency is inadequate to prevent cross-contamination.

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OBSERVATION 3

Contamination was observed in your production area.

Specifically,

On 04/29/2026, unidentified brown staining was observed on the HEPA filter in the ISO 5 non-hazardous LAFH production hood (SN: (b) (4) Your firm was unable to identify the source of the staining or confirm whether it affected filter integrity, air quality, or aseptic conditions in the ISO 5 area. The duration of this condition is unknown.

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OBSERVATION 4

Lack of disinfection of supplies at each transition from areas of lower quality air to areas of higher quality air.

Specifically,

A) On 04/27/2026, 04/28/2026, and 04/29/2026, (b) (4) operators in both the hazardous and non-hazardous production rooms failed to wipe down materials with an appropriate disinfectant (e.g., (b) (4) when transitioning those materials from the ISO 7 buffer room environment into the ISO 5 critical zone during the production of luspatercept aamt 50mg, label #(b) (4) .

B) On 04/28/2026, a re-purposed (b) (4) bottle, labeled "(b) (4) used to discard leftover fluid generated during aseptic processing operations, was observed used within the ISO 5 critical zone without observed disinfection upon transfer from the ISO 7 buffer room after being emptied. The bottle was reused and stored in the ISO 5 hood over multiple days. During aseptic processing activities, the cap has to be removed by the technician, and the bottle handled each time liquid is deposited inside. The operator was observed discarding liquid into the reused bottle. On (b) (4) bortezomib 2.7mg, label #(b) (4) was produced with the re-used fluid discard bottle present in the ISO 5 critical area.

C) The wearable, (b) (4) communication device is inconsistently worn by operators entering the ISO 5 environment during aseptic processing of sterile drug products, with some operators wearing the device over their gown and others wearing it under their gown, resulting in direct or potential exposure of the device to the ISO 5 environment. These devices are used throughout the hospital, including in patient care areas; however, they are only cleaned with (b) (4) prior to being worn into the cleanroom. No sporicidal agent is used to clean these devices, and no environmental monitoring is performed to assess the contamination risk they may introduce.

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OBSERVATION 5

An operator rested their arms on the work surface of the hood during aseptic production. This practice may introduce contamination into the ISO 5 work area.

Specifically,

A) In the non-hazardous production room (b) (4) operators were observed resting their hands directly on the ISO 5 workbench surface on 04/29/2026 during the production of micafungin 100mg in normal saline 100mL.

B) On 04/28/2026, the operator's elbows were observed resting on the edge of the front grille of the ISO 5 Biological Safety Cabinet (BSC).

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OBSERVATION 6

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically,

On 04/28/2026 during the production of bortezomib 2.7mg, label #(b) (4) an operator failed to sanitize or change their gloved hands with (b) (4) after touching the computer keyboard and mouse within the ISO 7 buffer room prior to going back into the ISO 5 critical area to continue aseptically processing drug product intended to be sterile.

Your SOP only specifies (b) (4) surfaces. We did not observe your third party cleaners cleaning and sanitizing your keyboards, mouse, and handheld scanner.

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OBSERVATION 7

Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow.

Specifically,

An operator was observed spraying their gloved hands with (b) (4) under the ISO 5 hood and then rapidly moved their hands to dry within the critical area, causing disruption of unidirectional airflow on 04/28/2026 during the production of bortezomib 2.7mg, label #(b) (4) The operator's hands moved rapidly over materials and components used during production.

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OBSERVATION 8

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically,

A) The (b) (4) plate and washer located on the front grille of BSC SN: (b) (4) and (b) (4) (hazardous room (b) (4)) are difficult to clean and may harbor and shed particulates and microbial contamination into the ISO 5 environment. This screw and washer were left by the firm's engineering to the BSC grill and not part of the smoke studies, therefore there is no assurance that this is not interfering in the functionality or causing turbulence in the BSC.

B) On 04/30/2026, during the production of doxorubicin 48mg in normal saline 250 mL, chipped and protruding paint was observed on the walls of the ISO 7 buffer room.

C) At least (b) (4) protruding fire sprinklers located in the ISO 7 ante and buffer rooms were observed not cleaned since around 2020. Additionally, the screw, cameras, and WiFi device on the ceilings of the buffer rooms (room (b) (4) were not documented as cleaned. The buffer rooms contain the ISO 5 areas that are used to produce drug products intended to be sterile.

D) On 04/28/2026, Bluetooth speakers were observed on the workbench of the ISO 7 buffer room, across from the ISO 5 laminar airflow hood (LAFH) used for hazardous sterile production (room (b) (4)

E) On 04/28/2026 and 04/29/2026, the electronic workflow equipment located within each non-hazardous ISO 5 LAFH (room (b) (4) was observed to not be wiped down with an appropriate disinfectant (e.g., (b) (4) between individual batches. The electronic workflow equipment within each hazardous BSC (room (b) (4)) was observed to not be wiped down with an appropriate disinfectant (e.g., (b) (4) between individual batches.

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OBSERVATION 9

Personnel performed aseptic manipulations with exposed hair or skin.

Specifically,

A) On 04/27/2026 and 04/29/2026, multiple operators were observed aseptically processing drug products intended to be sterile in the ISO 5 laminar airflow hood (LAFH) with exposed hair, including during the production of daptomycin 670 mg in sodium chloride 0.9%, 36.6 mL, label #(b) (4) in room (b) (4)

B) On 04/29/2026, one operator was observed inserting their head, including the exposed skin of their forehead, and eyeglasses into the ISO 5 critical zone during the production of luspatercept-aamt 50mg, label #(b) (4) . These eyeglasses are only cleaned with (b) (4) before being brought into the ISO 7 buffer area and are worn throughout the hospital and patient care areas. No sporicidal agent was used to clean these items and no environmental monitoring was performed to assess the contamination risk they may introduce.

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OBSERVATION 10

Materials were exposed to lower than ISO 5 quality air.

Specifically,

A) Sterile, lint-free wipes stored in an exposed, open condition were observed on the wall of the ISO 7 buffer rooms. At least (b) (4) of the transparent boxes on the wall had broken hinges and were left open during production. The wipes, which were difficult to pull from the box, were sprayed with sterile (b) (4) in the ISO 7 buffer and then used to clean the ISO 5 workbench surface and to wipe materials transitioning from areas of lower quality air into the ISO 5 critical areas.

B) Sterile, lint-free wipes were observed on the wall of the unclassified areas of the segregated ICU room ((b) (4) by the sink.

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OBSERVATION 11

Personnel engaged in aseptic processing were observed wearing non-sterile gloves.

Specifically,

Operators were observed using expired sterile gloves (manufactured in 01/2022) during aseptic production of bortezomib 2.7mg, label #(b) (4) on 04/28/2026. There is no assurance that the gloves are intact and remain sterile.

Your sterile glove manufacturer suggested that the gloves be used within (b) (4) of the manufacturer date.

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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 judgement, 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."