DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	05/04/2023 - 05/12/2023
	FEI NUMBER 3005949964

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Scott Gunther, Senior Vice President of Quality Assurance & Regulatory Affairs

FIRM NAME	STREET ADDRESS
Catalent Indiana, LLC	1300 S. Patterson Dr.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bloomington, IN 47403	Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM I (WE) OBSERVED:

Observation 1:

Written production and process control procedures are not followed or established in the execution of production and process control functions. Specifically,

a. I (WS) observed the sanitization of gloved hands not adhered to during the setup of the (b) (4) Flexible Fill Line stopper bowl according to A-SOP-21-01-019, "Aseptic Technique for Parenteral Operations", v22, Effective date 2023-01-03, where (b) (4) setup includes disinfection of gloved hands with (b) (4) before (b) (4) connection and touching non-sterile items/surfaces. Furthermore, I (WS) observed the following:

i. The (b) (4) bagged stopper bowl transitions from Grade C space into the Grade A air (b) (4) with (b) (4) covers removed within the (b) (4) Observed was the lack of good aseptic technique, where the (b) (4) bag should be removed in Grade C space, with the (b) (4) bag containing the stopper bowl transitioning to Grade A space for assembly.

ii. The complete removal of the stopper bowl (b) (4) covering was conducted during assembly within the Grade A (b) (4) I (WS) observed a fill technician breaking (b) (4) air, exposed face skin directly over the uncovered stopper bowl, stopper contact surface.

b. On 10 May 2023, I (WS) observed on the (b) (4) Flexible Fill Line for batch (b) (4), lot (b) (4) an (b) (4) used in a stopper jam dislodge placed below the stopper (b) (4) out of (b) (4) air and onto a sanitized surface. According to Document No.: A-SOP-21-01-042, "Aseptic Interventions in the Vial and (b) (4) (b) (4) ", v50, Effective date 2023-04-03, Section 4.49.1, Use forceps (b) (4) Guide/remove stoppers through bowl (b) (4) without glove moving over open containers. Document No.: A-SOP-21-01-019, "Aseptic Technique for Parenteral Operations", v22, Effective date 2023-01-03, Step (b) (4) implies for the (b) (4) component contact end not to touch anything within the (b) (4) The procedure was not followed.

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	Wayne Scifert Hyung-yul Lee	Wayne Scifert, Consumer Safety Officer Hyung-yul Lee, Pharmaceutical Scientist Esther C. Broner, Pharmaceutical Scientist	05/12/2023

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c. You (b) (4) sterilize equipment within an (b) (4) for docking to the Flexible Fill Line (b) (4) with the (b) (4) including a (b) (4) . The (b) (4) is not integrity tested post manufacture in assurance of (b) (4) sterility. Your risk assessment RA-21-05-001, "Risk Assessment for (b) (4) , v0, Effective date 2020-06-30 fails to include and evaluate the (b) (4) for integrity test.

d. The direct product contact (b) (4) ank for the Flexible Fill Line (b) (4) ill is supplied with (b) (4) (b) (4) (sterile (b) (4) The integrity of the (b) (4) conducted on a (b) (4) basis is not considered in batch release. Although you identified the deficiency through a gap assessment 17 November 2022, with corrective action due 26 May 2023 for (b) (4) integrity test, the time-period for correction action is not commensurate with the level of risk to product quality.

e. The (b) (4) Flexible Fill Line for (b) (4) manufacture is cleaned with sterile (b) (4) pending fill line machine assembly. You failed to establish a maximum clean hold time limit, where after a period-of-time based on validation or risk assessment, (b) (4) cleaning would be repeated prior to fill line machine assembly and (b) (4)

Furthermore, during filling line assembly for manufacture, the cleaned (b) (4) are opened into Grade C space, followed by closure back into Grade A space. The (b) (4) prior to closure into Grade A space are not cleaned.

You failed to implement a maximum hold time limit for post machine assembly pending (b) (4)

f. On 10 May 2023, I (WS) observed (b) (4) not visually inspected for multiple interventions on the Vial Filling Line, Fill Line (b) (4) According to Document No.: SOP-21-01-019, "Aseptic Technique for Parenteral Operations", v22, Effective date 2023-01-03, Step (b) (4) an operator shall perform a visual inspection of the (b) (4) (b) (4) for (b) (4) intervention per A-SOP-21-01-042, "Aseptic Interventions in the Vial and (b) (4) The procedure was not followed.

g. According to Document No.: A-SOP-09-02-002, "Gowning Qualification", v23, Effective date 2023-02-20,

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Section 3.6.2.1, a non-conformance in aseptic practice, the employee shall receive feedback at the time of the incident and meet with their Manager and the Classified Area Owning Department Manager or a member of QC Microbiology Management prior to re-entering the classified area unescorted. The conversation should be documented on A-FRM-09-02-011, "Classified Area Non-Conformance Observation", v7, Effective date 2022-07-11. For Observation 1.a and 1.f, documentation of the non-conforming aseptic event by form was not conducted.

h. You indicate that the sterile hold of equipment and materials at (b) (4) is incorporated into the media fills at a frequency of (b) (4) Your procedure A-POL-06-01-001, "Aseptic Process Simulation Policy", v33 and A-SOP-06-01-015, "Periodic Qualification Evaluation", v20, Effective date 2021-12-20 fails to include the sterile equipment and component hold time requirement and frequency, with the frequency not supported by risk assessment.

Observation 2:

Equipment revalidation in support of the manufacture is inadequate. Specifically,

(b) (4) 2101 and 2102 are used in (b) (4) sterilization of equipment for manufacture. The (b) (4) (b) (4) is not physical and biological evaluated at any frequency in assurance the validated state is maintained.

Observation 3:

Equipment and facilities are not adequately maintained or cleaned in support of manufacture. Specifically,

a. On 09 May 2023, I (WS) observed the (b) (4) Filter with dents in the filter (b) (4) The integrity of the filter was not known.

b. On 04 May 2023, manufacturing Suite (b) (4) used in the formulation of products (b) (4) (b) (4) was observed with analytical balance BLA-2005-11 in a deteriorated state, tape peeling from a (b) (4) wall surface, ceiling HEPA filter F-2212-05 with discoloration, and a cart with a rusty wheel mechanism. An (b) (4) section separating Grade C space from Grade C floor scale space was observed

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with two detached (b) (4) egments. A (b) (4) surface under elevated (b) (4) balance slabs was observed unclean.

c. MMC Receiving Dock, Door 151, leading to the outside was observed with an inadequate door frame seal.

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