DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Zhihao Peter Qiu, Ph.D., Division of Biotechnology Manufacturing Acting Director US Food & Drug Administration, Office of Pharmaceutical Quality, OBM, DBM 10903 New Hampshire Avenue, Bldg. 22, Silver Spring, Maryland 20993 OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	August 27, 28, 31, September 1, 2, 2020
	FEI NUMBER 3005949964

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Denis Johnson, Site General Manager

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

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:

1) Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written and/or followed. Specifically,

A) You do not always follow good aseptic techniques in your (b) (4) located in Plant (b) (4) Room (b) (4) used for the manufacture (b) (4) Drug Product. The following observations were made during setup and fill operations for (b) (4) Drug Product on September 1, 2020.

i. Operators' movement was not always slow, controlled and deliberate as directed in A-SOP-21-01-019, "Aseptic Technique for Parenteral Operations," rev. 15, effective date 02/24/2020, on page 2 of General Information, and on page 5 of (b) (4) step (b) (4)

ii. Operators were observed entering the (b) (4) to perform interventions without sanitizing the (b) (4) (b) (4) as directed in A-SOP-21-01-019, "Aseptic Technique for Parenteral Operations," rev. 15, effective date 02/24/2020; and A-SOP-21-01-042, "Aseptic Interventions in the Vial and (b) (4) " rev. 35, effective date 08/31/2020.

iii. Operator(s) were observed removing (b) (4) from the (b) (4) by putting the (b) (4) (b) (4) and then while removing the (b) (4) the (b) (4) of the (b) (4) was in contact with the soiled (b) (4) Additionally, the storage of the (b) (4) in the (b) (4) during operations was in a rack where its (b) (4) was not protected and it made contact with numerous none (b) (4) items.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Michael R. Shanks	Michael R. Shanks, Biologist	09/02/2020