DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT 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 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	05/12/2023-05/22/2023
	FEI NUMBER 3002807108

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alessandro Galassini, Site Director

FIRM NAME	STREET ADDRESS
Sanofi S.p.A	Via Valcanello, 4
CITY, STATE, ZIP CODE, COUNTRY Anagni, FR, Italy, 03012	TYPE 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 WE OBSERVED:

OBSERVATION 1

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

a) the setup of the sterilized stopper bowl and parts in the (b) (4) is not performed aseptically. With open (b) (4) each piece of the (b) (4) stopper bowl assembly is exposed to Iso8 air, prior to its installation in the (b) (4) Once the stopper bowl is setup, the equipment is cleaned, the (b) (4) are closed, and the (b) (4) is decontaminated with (b) (4) (b) (4)

b) the process of making an aseptic connection between the (b) (4) and the (b) (4) is performed using non-sterile (b) (4) gloves. In addition, during this operation the (b) (4) gloves were blocking first air on exposed sterile (b) (4)

c) during setup installation of the sterilized (b) (4) I observed the operator touch the sterile unprotected tubing end with (b) (4) gloves both during removal of the (b) (4) from the (b) (4) bag and during its installation.

d) vials that are to be rejected due to an intervention are not immediately discarded/undergo line clearance. Rather, the to be rejected vials are transferred to the (b) (4) and (b) (4) with the acceptable vials. No formal risk assessment of this practice regarding the potential for cross-contamination between acceptable and rejected vials was provided at the start of the inspection.

e) during manufacturing of batch (b) (4) I observed a stopper bowl intervention where the operator blocked first air on sterile stoppers with his (b) (4) gloves.

f) the sterility of sterilized equipment used during setup and manufacturing is not maintained due to handling with (b) (4) gloves.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Richard Ledwidge, Senior Biologist	May 22, 2023 ~~May 21, 2023~~ RL

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OBSERVATON 2

Aseptic process simulations do not fully represent drug product manufacturing in the (b) (4) Specifically,

The firm does not use (b) (4) used in production for any products filled in the (b) (4) Rather, all (b) (4) aseptic simulations are conducted with like-for-like (b) (4) dedicated solely to media fills.

APPEARS THIS WAY ON ORIGINAL

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