

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 3/25/2024-4/2/2024* FEI NUMBER 3006942691
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Tetsuya Isono, Plant Manager

FIRM NAME Chugai Pharma Manufacturing Co. Ltd.	STREET ADDRESS 16-3 Utsunomiya Plant, Kiyoharakogyodanchi
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CITY, STATE, ZIP CODE, COUNTRY Utsunomiya, Tochigi, 321-3231 Japan	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer
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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 OBSERVED:**

**OBSERVATION 1**


Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

The most recent smoke study conducted by your firm to validate the (b) (4) installed in Building (b) (4) room (b) (4) which is used to fill (b) (4) finished drug product vials following (b) (4) was not conducted in a manner that accurately simulated actual processing conditions. Multiple video recordings made during the smoke study conducted on this (b) (4) in September 2021 show the operator responsible for holding and positioning the smoke wand during intervention simulations standing inside of the (b) (4). These video recordings also show a second operator using the (b) (4) (b) (4) to perform interventions, such as the changing of environmental monitoring settle plates, while the body of the operator holding the smoke wand was standing within approximately 50 cm or less of the location the intervening operator is working. Per your records, (b) (4) lots of (b) (4) finished drug product, totalling approximately (b) (4) vials, have been filled in this (b) (4) and released for commercial distribution in the U.S. since this smoke study was conducted.

**\*DATES OF INSPECTION**

3/25/2024(Mon), 3/26/2024(Tue), 3/27/2024(Wed), 3/28/2024(Thu), 3/29/2024(Fri), 4/01/2024(Mon), 4/02/2024(Tue)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator	 Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed 04-02-2024 00:36:57	DATE ISSUED 4/2/2024

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EMPLOYEE(S) SIGNATURE  
Christopher R Czajka, Investigator

Christopher R Czajka  
Investigator  
Signed By: Christopher R. Czajka  
-S  
Date Signed 04-02-2024  
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X

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