DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place Drive Ste 5900 Detroit, MI 482307 (313) 393-3100	06/23/2025-07/02/2025, 07/14/2025 FEI NUMBER 3005949964
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lars Arnoldsen, Corporate VP and General Manager	
FIRM NAME	STREET ADDRESS
Catalent Indiana LLC	1300 S Patterson Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bloomington, IN 47403 USA	Sterile Drug 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

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. REC 831826 was initiated on January 31, 2024, in response to Lot (b) (4), Project Code (b) (4) being released without identification of two atypical extrinsic particles found during 100% manual visual inspection. One of the particles was identified as cat hair, while the second was not evaluated. You stated that only one representative particle is required to be identified if other similar defects are found, meaning no determination into the source or impact of the second particle was evaluated. Additionally, your investigation failed to determine a root cause for the contamination, assess the potential impact to the rest of the lot, or evaluate whether similar issues may have occurred in upstream batches. The review of related deviations was limited to a one year time frame, and no complaints were assessed. Although components were considered a potential root cause, no corrective or preventative actions were taken to address this. Since this time, approximately 20 additional deviations related to hair contamination during 100% manual visual inspection have occurred. In addition, approximately 14 other deviations were opened as a result of a gap analysis conducted in response to this deviation.

There are approximately (b) (4) batches associated with these deviations. No commercial lots of drug products have been rejected due to hair. These batches span across approximately (b) (4) project codes (including, but not limited to: (b) (4)). One example of a

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recently released lot is project code (b) (4), lot (b) (4), released on or around 29Apr25.

B. You failed to conduct adequate historical reviews during investigations by limiting searches for deviations to one year and by not consistently querying (b) (4) with an appropriate scope. For example, REC 1035680 was opened on April 21, 2025, in response to an extrinsic particle observed during 100% manual inspection of lot (b) (4), project code (b) (4). The particle was identified as "proteinaceous mammalian hair." The recurrence analysis was limited to deviations related to stoppers and only covered the date range of April 14, 2024, to April 14, 2025, rather than encompassing all relevant (b) (4) records (e.g., LIRs, CAPAs, change controls, complaints) involving stoppers. Additionally, your investigations do not consistently include a review of complaints when evaluating deviations. While remediation efforts have begun, this gap has not yet been fully addressed.

C. REC 691329 was initiated on April 9, 2023, for Lot (b) (4), Project Code (b) (4), due to a failed AQL for a critical defect, plunger not seated. You identified root cause as a lack of defined procedures or instructions for inserting the syringes into the trays. However, operators interviewed during this investigation stated that they have long experienced this issue and developed informal methods to package the product in a way that avoids the defect. You failed to capture this feedback in a separate deviation and no action was taken to formally evaluate or address this tribal knowledge.

D. You failed to adequately investigate and implement effective corrective actions to address the presence of foreign material, such as hair, in your sterile drug products. On or around July 2024 you initiated (b) (4) supplier complaint records (SCRs) for your stopper manufacturer, (b) (4), approximately seven months after hair was found during 100% visual inspection of finished product. Since then, approximately 20 additional deviations have been initiated for hair contamination in finished product batches.

Despite an ongoing trend of hair related to stoppers, you have not fully evaluated or implemented additional corrective actions to mitigate this risk. You currently have an open protocol for

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opening one additional bag of stoppers for visual examination, however, this is limited to a predetermined number of lots and applies to stoppers received from one supplier (b) (4), which accounts for approximately (b) (4) of FM complaints. The remaining (b) (4) of complaints associated with other stopper sources have not been investigated or included in the enhanced sampling protocol. Furthermore, you continue to rely on (b) (4) as the primary method of stopper acceptance, without revisiting the adequacy of sensitivity of incoming inspection procedures in response to this contamination trend.

E. You detected Staphylococcus hominis via surface environmental monitoring failure regarding your filling head sample on syringe line (b) dated 8/26/2023 at the end of a (b) (4)-batch campaign via deviation REC 758885. While you rejected batches (b) (4) and (b) (4), your investigation failed to consider various elements including but not limited to:

- Upon detection, you failed to review previously manufactured batches potentially impacted by this root cause on syringe line (b) (4) as well as other syringe line configurations, e.g. Syringe line (b) (4) and (b) (4) filling line(s) (b) and (b) (4) utilizing syringe line configurations to include batch record review, retain review or testing. You identified the root cause as occlusion of equipment part (b) (4) lacking (b) (4)) exposure. This equipment is only used when atypical unbracketed intervention (b) (4) change and insertion rod bar change is employed. You failed to revisit your risk assessment for other potential equipment lacking (b) (4) exposure.
- You also identified man / operator error as a contributing root cause, however, you failed to document any operator interviews. Man / operator error was not addressed by any documented actions.
- You also identified method as a contributing root cause, however, you failed to document actions potentially mitigating this root cause. Filling head installation post (b) (4) is currently consistent with the method utilized during this failure.

F. Deviations completed for pests found in classified areas do not include adequate determination of root cause and applicable corrective actions. For example, deviation REC 723587 stated that

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a pest was discovered in (b) (4) System (b) (4), during teardown activities in room 880. Materials used during filling satisfied Incoming Quality Control standards, however, given the location of the pest found and possible points of ingress for pest entry into the (b) (4), it was determined that materials are a probable root cause for this deviation. Customer (b) (4) procures the syringes used for this product and manages the supplier relationship; therefore, it is recommended by the firm that Customer (b) (4) pursue supplier alert or action as appropriate. Deviation was opened 15-June-2023 and your firm has received no communications from client or supplier to support the material syringes as the root cause.

G. Your firm is not always identifying all root causes and/or documenting the root cause for investigations. In addition, your firm does not always document within the investigation all issues/deficiencies related to the problem being investigated. For example, laboratory Investigation Family Report REC 840570 stated there was an action level result from microbial water monitoring of Building A Drug Product Formulation (b) (4) port (b) (4). A result of 21 Colony Forming Units/100ml was entered which exceeded the action level result of Not More Than (b) (4). Sampling analyst noted that upon arrival, manufacturing had left an undrained hose attached to the (b) (4) port. Hose was removed by analyst and replaced with a new hose to be used for sampling. It was determined that because routine (b) (4) sanitizations of (b) (4) system was maintained and follow-up samples from port (b) (4) had passing results of no growth, that the integrity of the (b) (4) system was not compromised, and the excursion was resolved. Your firm did not adequately investigate that the hose attachment and water left in the hose may have been the potential cause of the microbial growth and a possible root cause. Formulation (b) (4) port (b) (4) was used for formulation activities for MBR# (b) (4)-(b) (4) lot (b) (4) on 13Feb24.

H. You were notified of no less than 8 complaints from 6/2022 through 3/2025 to include Complaint 1021042 for Lot (b) (4) regarding failure of visual inspection / appearance /particles of product (b) (4). This failure originated from a contract testing laboratory during a (b) (4) stability testing interval, dated 2/4/2025. You were not notified of nor did you open the complaint until 3/19/2024. You opened CAPA REC 622043 effective 4/2023 resulting from

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previous failure(s). CAPA action(s) included master batch record changes modifying sample handling to mitigate this failure mode, however, you continued to observed failure(s) to date. Furthermore, your investigations have not included CAPA effectiveness checks.

I. You received Complaint 678118 on 3/13/2023 for product (b) (4), Lot (b) (4) This lot has at least 3 previous complaints and 43 complaints of this nature for the client over the previous two years. The complaint nature of foreign matter was reported by the clinician during removal of product from the vial and into a syringe. Your investigation does not necessarily support foreign matter was caused by coring as the particles observed in the sample range from approximately 400 to 700 microns. You could not confirm the size of the needle used by the clinician. Furthermore, your batch record review documents critical particle counts of approximately 400 Damaged/Deformed Stopper (total critical category limit of (b) (4) with actual of 0.85%) for Sublot (b) (4) and 604 Damaged/Deformed Stopper (total critical category limit of (b) (4) with actual of 1.32%) for Sublot (b) (4) .

J. You detected appearance failure for project (b) (4), Lot (b) (4) on 10/11/2024 for appearance. This was the at least the 5th failure of this nature for this project since approximately 7/2024. You implemented CAPA 919566 as a part of this failure. You failed to implement CAPA effectiveness as a design feature of your CAPA system. No CAPA effectiveness check even after these additional failures observed as evidenced by last (b) (4) lot.

K. You detected stability failure for Lot (b) (4) dated 6/4/2024 for (b) (4) (b) (4) at the (b) (4) interval. Three separate requirements failed, purity at 89.4 with a limit of no less than (b) (4). You performed hypothesis testing in addition to a repeat test all with passing results. You reported the initial failing result as not aligned with previous timepoints as all are above 91.0%, thus warranting an investigation. This product expires at (b) (4) (b) (4). Your root cause was identified as man without scientific support, and you did not implement any CAPA.

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L. You have failed to investigate all critical equipment failures that have the potential to impact drug products.

1. You opened approximately 10 work orders during the period of late February, 2024 to May, 2025 for recurrent leaks and / or other failures of your critical (b) (4) system (b) (4). These work orders document leaks and other failures and do not necessarily include previous occurrences impacting these failures. Furthermore, work order 1032333 documenting leaking (b) (4) system (b) (4) dated 4/23/2025 was not repaired until 5/8/2025. You placed a hold on this (b) (4) system on 5/8/2025 in order to return the system to service upon passing QC test results after performance of maintenance activities. During post maintenance testing, you detected Endotoxin OOS 880348, on 5/8/2025 for failing endotoxin recovery of (b) (4). These corrective action work order events are risk assessed by your firm as not impacting SISPQ. Your written maintenance SOP does not require visual checks of your critical systems.

System	System Descr	WO Asset	Asset Descr	WO #	WO Type	WO Descr	WO LD	Asset Status	Date Created
(b) (4)	(b) (4) Storage and Distribution	YV-2806-504	Automatic Valve	1087818	CM	Hand Valve broken	(b) (4) port pressure valve not turning and has broken off. Will this work require a QA hold tag? No	OPERATING	4/5/2025
(b) (4)	(b) (4) Storage and Distribution	YV-2806-101	Automatic Valve	1084367	CM	Leak at Weep Hole	It was discovered that YV-2806-101 is leaking out of the weep hole. Determined the cause of the leak and repair or replace as required. Date of repair to be determined by Planning and Operations. Will this work require a QA hold tag? Yes	OPERATING	2025-17-04

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(b) (4)	(b) (4) Storage and Distribution	YV-2806-504	Automatic Valve	1075207	CM	Unable to Pull (b) (4)	Unable to adjust pressure to get (b) (4) from port. Repair/replace as needed. Will this work require a QA hold tag? No	OPERATING	10/2/2025
(b) (4)	(b) (4) Storage and Distribution	FCV-(b) (4)	Flow Control Valve	1071565	CM	Investigate check valve		OPERATING	2025-14-01
(b) (4)	(b) (4) Storage and Distribution	FCV-(b) (4)	Flow Control Valve	1071564	CM	Investigate Check Valves	Investigate integrity of FCV-(b) (4) & FCV-(b) (4), repair or replace as needed. Will this work require a QA hold tag? No	OPERATING	2025-14-01
(b) (4)	(b) (4) Storage and Distribution	P-(b) (4)	PUMP	1071489	CM	Pump Leak Investigation	Pump (b) (4) has been repaired more than once and is leaking again. We need to investigate why we continue having issue with this leaking issue. Will this work require a QA hold tag? No	OPERATING	2025-13-01
(b) (4)	(b) (4) Storage and Distribution	AE-(b) (4) (b) (4)	Analytical Element	1067847	CM	Replace (b) (4) lamps	During calibration work order 1065185, (b) (4) bulb was not in stock. Need to replace both (b) (4) bulbs during next calibration due by 31JUL25. Will this work require a QA hold tag? No	OPERATING	2024-19-12
(b) (4)	(b) (4) Storage and Distribution	P-(b) (4)	PUMP	1066225	CM	Pump Replacement	Replace pump on (b) (4) (b) (4) Separate hold work order will be created. Will this work require a QA hold tag? No	OPERATING	2024-27-11
(b) (4)	(b) (4) Storage and Distribution	P-(b) (4)	PUMP	1056422	CM	Investigate coupling	Investigate black debris around (b) (4) coupling. Possible miss-alignment/bearing issue causing excess vibration and degradation of (b) (4) coupling. Repair/replace as	OPERATING	2024-30-09

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							necessary. Will this work require a QA hold tag? No		
(b) (4)	(b) (4) Storage and Distribution	YV-2806-606	Automatic Valve	1052547	CM	Perform Sanitization for QC EM Hit		OPERATING	2024-19-09
(b) (4)	(b) (4) Storage and Distribution	YV-2806-605	Automatic Valve	1052527	CM	Perform Sanitization for QC EM Hit	Perform a (b) (4) sanitization for YV-2806-605 and YV-2806-606. Also perform a POU (b) (4) of both valves.QC EM recovered an objectionable organism See REC 939124. Will this work require a QA hold tag? Yes	OPERATING	2024-18-09
(b) (4)	(b) (4) Storage and Distribution	YV-2806-619	Automatic Valve	1051803	CM	Leak In Sink Piping	drip found in piping leading from sink to the wall. Pipe clamps appear to be turned green. Will this work require a QA hold tag? No	OPERATING	2024-13-09
(b) (4)	(b) (4) Storage and Distribution	P-(b) (4)	PUMP	1047460	CM	Pump Leak, Motor Vibration	Pump (b) (4) leaking at seal. Repair or replace as required. Motor (b) (4) is excessively vibrating & noisy, flexible coupler is deteriorating. Repair or replace as required. Note: This work will compromise the integrity of the system. Once the work is completed allow the system to circulate at operating temperature for a minimum of (b) (4), and perform a POU (b) (4) (b) sanitization on (b) (4) (b) (4). Create a separate QA HOLD work order when a time/date are set for the work to take	OPERATING	2024-14-08

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							place. Will this work require a QA hold tag? No		
(b) (4)	(b) (4) Storage and Distribution	P-(b) (4)	PUMP	1043298	CM	Pump Seal Leaking	The pump seal on P-(b) (4) is leaking. Repair or replace as required.Note: Coordinate with operations on repair. A QA HOLD work order will need to be created separately when a time for repair is determined. Will this work require a QA hold tag? No	OPERATING	3/7/2024
(b) (4)	(b) (4) Storage and Distribution	(b) (4)	(b) (4) Storage and Distribution	1037085	CM	Perform (b) (4) (b) (4) Sanitization at HV-2806-101	Perform (b) (4) sanitization (b) (4)) at HV-2806-101 (Clean (b) (4) Generator 2820) due to an endotoxin monitoring hit from sampling on 08May24. Also verify the sample port slopes to drain and doesn?t hold up any water in the line. Contact (b) (6), (b) (7)(C) in Facility Engineering for further details. Will this work require a QA hold tag? No	OPERATING	2024-30-05
(b) (4)	(b) (4) Storage and Distribution	P-(b) (4)	PUMP	1033903	CM	Pump Seal Leaking	There is a leaking pump seal on system (b) (4) (P-(b) (4)). Repair or replace as required. When performing the work ensure that manufacturers torque specifications are followed.Note: This work will compromise the integrity of the system. Once the work is completed allow the	OPERATING	2024-17-05

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							system to circulate at operating temperature for a minimum of (b) (4), and perform a POU (b) (4) sanitization on (b) (4) (b) (4) Create a separate QA HOLD work order when a time/date are set for the work to take place. Will this work require a QA hold tag? No		
(b) (4)	(b) (4) Storage and Distribution	T-(b) (4)	Tank	1032333	CM	(b) (4) Gasket Leak	The (b) (4) Gasket on T(b) (4) is periodically leaking by. Replace as required.This work will need to be schedule with F&F Building A. A QA HOLD work order will need to be placed separately once a date to complete the work has been scheduled. Will this work require a QA hold tag? No	OPERATING	2024-23-04
(b) (4)	(b) (4) Storage and Distribution	(b) (4)	(b) (4) Storage and Distribution	1032295	CM	(b) (4) Leaking	(b) (4) is leaking replace gasket. Will this work require a QA hold tag? No	OPERATING	2024-22-04
(b) (4)	(b) (4) Storage and Distribution	(b) (4)	(b) (4) Storage and Distribution	1024337	PMF	pump seal repair	PMF to work order 10087522805 pump seal leaking needs repaired or replaced once pump lead is switched confirm that that seal is not leaking as well if there is any leak replace the second seal as wellwork with QA when work is to be completed to apply QA hold tag once the date for work is set Will this work require a QA hold tag? No	OPERATING	12/3/2024

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(b) (4)	(b) (4) Storage and Distribution	(b) (4)	(b) (4) Storage and Distribution	1020036	CM	(b) (4) Not Working in (b) (4)	Ambient (b) (4) will not come on in (b) (4) (flashes green, light will not turn solid). When trying switch closest to washers, hear unusual noise Will this work require a QA hold tag? No	OPERATING	2024-15-02
(b) (4)	(b) (4) Storage and Distribution	YV-(b) (4)	Automatic Valve	1019277	CM	Valve Replacment	Unable to get water released from valve Will this work require a QA hold tag? No	OPERATING	4/2/2024

2. You opened approximately 23 work orders regarding your critical air handling unit systems integral to your (b) (4) from January 2024 through June 2025. Examples of work orders include but are not limited to:

System	System Descr	WO Asset	Asset Descr	WO #	WO Type	WO Descr	WO LD	Asset Status	Date Created
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1018629	CM	(b) (4)	Hole located in the (b) (4) above the Tub outfeed. Will this work require a QA hold tag? No	OPERATING	1/27/2024
(b) (4)	Vial Filling and Capping (b) (4)	(b) (4)	Vial Filling and Capping (b) (4)	1019576	CM	(b) (4) Tensioning screws	(b) (4) in (b) (4) need five tensioning screws replaced. Please replace Item #530646 ***QA hold tag? No	OPERATING	2/8/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1074173	CM	Change Mebrane (b) (4) and check jug	Change Mebrane (b) (4) and check jug. Supervisor permission given by (b) (6), (b) (7). Will this work require a QA hold tag? No	OPERATING	1/22/2025

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place Drive Ste 5900 Detroit, MI 482307 (313) 393-3100	06/23/2025-07/02/2025, 07/14/2025 FEI NUMBER 3005949964

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lars Arnoldsen, Corporate VP and General Manager	
FIRM NAME Catalent Indiana LLC	STREET ADDRESS 1300 S Patterson Dr
CITY, STATE, ZIP CODE, COUNTRY Bloomington, IN 47403 USA	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1028553	CM	Hepa Filter	There is a Hepa Filter with green duct tape on it that QA(b) (4)) has requested to be fixed***QA hold tag? No	OPERATING	3/27/2024
(b) (4)	Air Handler System(b) (4)	AHU-(b) (4)	AIR HANDLING UNIT 25	1071807	CM	High temperature alarm	At 0337, a potential quality impacting alarm occurred. (b) (4)) alarm read 30444 - Limit Value Exceeded Temperature (b) (4) (b) (4) . Verbal approval for submission of work order provided by (b) (6), (b) (manager). ***QA hold tag? No	OPERATING	1/18/2025
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1071721	CM	Hole in Membrane	There is a hole in the membrane above the stopper bowl Will this work require a QA hold tag? No	OPERATING	1/16/2025
(b) (4)	Vial Filling and Capping (b) (4)	(b) (4)	Vial Filling and Capping (b) (4)	1067000	CM	Holes in (b) (4) membrane of (b) (4)	Two holes in a (b) (4) membrane within the (b) (4). Membrane is located near tunnel infeed. ***QA hold tag? No	OPERATING	12/11/2024
(b) (4)	Vial Filling and Capping (b) (4)	(b) (4)	Vial Filling and Capping (b) (4)	1074067	CM	Investigate AHU-(b) (4)	Trend observed in SCADA for high variability of relative humidity (M09101) in (b) (4) (System (b) (4). Air handler (b) (4)) above (b) (4) needs to be inspected for proper functionality. *** QA hold tag? No	OPERATING	1/21/2025
(b) (4)	Air Handler System(b) (4	RHC-(b) (4)	Reheat Coil	1033300	CM	investigate temperature alarm	investigate temperature alarm and repair as needed Will this work require a QA hold tag? No	OPERATING	5/5/2024

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(b) (4)	Syringe & Cartridge Filling (b) (4)	VI-(b) (4) 09101	(b) (4) Air Flow Sensor	1066487	CM	LAF Alarms	The LAF sensor has been dropping below the set point and throwing the alarm "Value below limit value laminar air flow (b) (4) ALL". The (b) (4) still maintains its decontaminated status following the alarm. Sensor needs checked to ensure it is still reading correctly. ***QA hold tag? No	OPERATING	12/2/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1037627	CM	LAF probe alarm	LAF probe wire broke Will this work require a QA hold tag? No	OPERATING	6/7/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1070847	CM	Laminar flow alarms	Please investigate and correct Laminar air flow issues, actively causing issues and alarms***QA hold tag? No	OPERATING	12/29/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	VI-(b) (4) 09101	(b) (4) Air Flow Sensor	1015697	CM	Limit value exceeded laminar air flow (b) (4)	Investigate root cause for alarm Limit value exceeded laminar air flow (b) (4) Create child UCAL to perform a calibration check on VI-(b) (4) -09101 ***QA hold tag? Yes	OPERATING	1/17/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1043918	CM	Membrane	Membrane above (b) (4) tank has a hole in it. Will this work require a QA hold tag? No	OPERATING	7/17/2024
(b) (4)	Vial Filling and Capping (b) (4)	(b) (4)	Vial Filling and Capping (b) (4)	1088120	CM	Membrane	Large slice observed in the membrane above door (b) (4) Will this work require a QA hold tag? No	OPERATING	5/7/2025
(b) (4)	Vial Filling and Capping (b) (4)	(b) (4)	Vial Filling and Capping (b) (4)	1088119	CM	Membrane	small holes observed in the membrane located above door (b) (4) Will this work require a QA hold tag? No	OPERATING	5/7/2025

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FIRM NAME Catalent Indiana LLC	STREET ADDRESS 1300 S Patterson Dr
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(b) (4)	Vial Filling and Capping (b) (4)	(b) (4)	Vial Filling and Capping (b) (4)	1050589	CM	Membrane	Membrane in Vial (b) above door (b) was removed to be sent to labs for testing Rec# 888909 ***QA hold tag? Yes	OPERATING	8/26/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1019102	CM	membrane on door (b) has hole in it	membrane on door (b) has hole in it. The hole is above the outfeed hole and stopper track/bowl of the (b) (4). It is right above the 10 high hook. *** QA hold tag? No	OPERATING	2/1/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1043976	CM	P04102 air flow way below limit	P04102 PV is at 74 M3/h and AHH is 3800, and ALL is 1500 Will this work require a QA hold tag? No	OPERATING	7/18/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1063998	CM	Replace (b) (b) (4)	Replace (b) (b) (4) with IMN T112864.Verbal approval given by (b) (6), (b) (7). *** QA hold tag? No	OPERATING	11/21/2024
(b) (4)	Vial Filling and Capping (b) (4)	(b) (4) 40002	(b) (4)	1074981	CM	replace (b) (4) membrane	membrane needs replaced *** QA hold tag? No	OPERATING	2/5/2025
(b) (4)	Vial Filling and Capping (b) (4)	(b) (4) 40002	(b) (4)	1032341	CM	Replace (b) (4) membrane F-40002	Replace (b) (4) membrane on (b) (4)-4002 *** QA hold tag? No	OPERATING	4/23/2024
(b) (4)	Syringe & Cartridge Filling (b) (4)	(b) (4)	Syringe & Cartridge Filling (b) (4)	1084100	CM	(b) (4) failure	Alarm 30450 Value below limit value differential pressure (b) (4)(b) (4) (b) (4) Please investigate and correct as needed. ***QA hold tag? No	OPERATING	4/12/2025

These events did not result in deviations.

M. You failed to initiate a timely and thorough investigation into unexplained batch termination. For example:

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lars Arnoldsen, Corporate VP and General Manager	
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REC 1068477 was opened on July 2, 2025, in response to a failure to initiate a deviation for terminated media fill batches. Lot (b) (4) was terminated due to mechanical stoppering issues. No deviation or investigation was initiated at the time of failure. The issue was only discovered during review of Summary Report A-VPPQ-00334 in December 2023.

Lot (b) (4) was terminated due to a non-intrinsic particle, yet no deviation was opened. This was noted during review of Summary Report A-VPPQ-00288 in September 2022.

This is a repeat observation.

OBSERVATION 2

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

Specifically,

A. Your media fill program does not include all high risk or critical interventions frequently observed. You categorize high risk or critical interventions, in part, via atypical unbracketed and atypical bracketed interventions. Your written media fill procedures do not require you to track and trend previous occurrences of these types of interventions for future inclusion into your media fill program.

1. You documented approximately 20 atypical unbracketed interventions of (b) (4) change from 6/2023 through 6/2024. You failed to include this intervention into your media fill program. This intervention was documented as the root cause of a failing filling head surface EM sample dated 8/26/2023.
2. You documented approximately eight atypical unbracketed interventions of rod bar assembly replacement. You failed to simulate this intervention into your media fill program. This

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intervention was documented as the root cause of a failing surface glove EM sample as REC 895205, and presented, in part, with an occluded surface and rouging of machine parts above open product.

3. During 2024 Q4 Intervention Frequency Summary Report – Q4 2024, you observed typical high risk intervention type (b) (4) or (b) (4) occur approximately 9 times whereby your previous media fill(s) only included this intervention (b) (4). You have not documented any deviation investigating this event and historical risk.
4. You observed atypical bracketed intervention described in part as outfeed transfer arm during 2025 Q1 Intervention Frequency Summary Report – Q1 2025. You characterized this intervention as bracketed via interventions (b) (4)" and (b) (4) given the similarity in nature of the interventions. You did not have documented evidence to support the inclusion of this intervention into either group of interventions (b) (4)" or (b) (4)" for appropriate count and risk into media fills.

B. Your written procedure for media fills is inadequately designed regarding filling times. Syringe line (b)(4 media fill was reviewed which limits filling times to (b) (4) while units are only open for approximately (b) (4).

C. During setup activities inside Syringe Line (b)((SL(b)(4), multiple surfaces of both equipment and isolator floors were observed to have visible scratches and abrasions.

D. Multiple instances of first air violations were observed during aseptic setup activities and smoke studies.

- During setup of SL(b)(4 an operator was observed breaking first air while using the (b) (4) (b) (4) to install the filling needles into the fill head.
- During setup of (b)(4) Fill Line ((b)(FL), an operator was observed leaning into the (b) (4), appearing the hug the equipment in order to install components.

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You acknowledged awareness of this issue and stated that design constraints may impact aseptic technique. You indicated that alternative approaches, such as use of sterile tools, could reduce risk but have not been assessed.

E. Your written procedure fails to provide instructions on proper hand placement or installation technique for the stopper chute leading to inconsistent installation practices amongst operators. During both in person observation and review of smoke studies for (b)(FL we noted variability in how the chute was installed. Operators were seen placing their hands in different positions underneath the chute, and instances where (b) (4) cover was partially removed or repositioned during installation were also noted.

F. You do not directly monitor (b) (4)) concentration within your (b) (4) during routine decontamination cycles. (b) (4) is used to sterilize the (b) (4) and is a critical process parameter. Although you monitor injection rate, humidity, and temperature during the (b) (4) cycle, these parameters do not provide a direct measurement of (b) (4) concentration within the (b) (4) during use.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. You do not perform direct surface monitoring of all of your filling heads. Instead, your written procedure specifically precludes direct contact of your filling head tips as it may render interpretation of results difficult. Furthermore, only (b) (4) is utilized for sampling. Syringe line (b)(is not currently affected by this gap as you performed change control 982857 migrating from (b) (4) sampling to (b) (4) sampling May, 2025. This change was

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initiated due to filling head failure, 758885 deviation, dated 8/26/2023.

1. You have not documented a scientifically justified microbiological sampling recovery study to support filling head sampling activities provide accurate and reliable results under actual conditions. This method gap affects lines Syringe line (b) (4) Vial line (b) (and (b) (4) fill line.

B. You do not perform scientifically justified sampling regarding your aseptic connections. Specifically, surface contact sampling of aseptic connections is not performed. Aseptic connections are employed on Syringe line (b) (4) Syringe line (b) (4) Vial line (b) (and (b) (4) fill line (b) (where (b) (4) filling mechanism is employed.

OBSERVATION 4

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

A. Limits are not currently established for individual defects found during 100% visual inspection operations; currently, they are only established for overall defect criticality categories (critical defects, major defects, minor defects). A-SOP-22-05-001, *Manual Visual Inspection Using a* (b) (4), requires action only if the overall category defect rate is exceeded; meaning, atypical or otherwise unexplained increases of an individual defect type are not required to be investigated so long as the overall defect category rate remains below limits.

B. Your automated visual inspection (AVI) system categorizes defects as "cosmetic" or "particulate" and does not identify individual defect types (e.g., hair, glass, fiber). Defect

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characterization is only performed when the overall reject count exceeds your defect control limit, at which point (b) (4) . This method fails to provide sufficient visibility into specific critical defects. Approximately 20 deviations have been documented for hair found in finished product during 100% manual visual inspection, but the AVI system does not allow for detection or trending of such defects unless they appear in the limited manual sample. Additionally, you have not evaluated or modified your AVI process or re-examined previously inspected products to assess the potential for similar contamination.

This is a repeat observation.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. You do not document sterility samples counts when taken during interventions via your intervention forms.

B. The firm's UV-vis spectrophotometer is a legacy device that is not capable of saving and retaining electronic data. You have not established written procedures for electronic data review and data backup of your UV-vis spectrophotometer, and you have never backed up data from this stand-alone equipment.

C. Your quality unit does not review audit trails on test results for UV-vis to ensure data integrity. The UV-vis is used to perform protein assay testing and release testing of finished products such as (b) (4) , and (b) (4)

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D. Your (b) (4) equipment "user login" feature within the (b) (4) software is disabled or inaccessible hence the device goes to collection mode once powered on. No audit trail is captured, and your quality unit does not review electronic raw data to ensure data integrity.

E. Your firm's Data Integrity Assessment and Remediation Plan Summary document dated 12/02/2024 only lists two systems (b) (4) and (b) (4)) with recorded DI gaps. During the inspection two additional instruments (UV-VIS and (b) (4)) within the QC laboratory were determined to have critical DI gaps. Your firm did not perform a comprehensive review of your data management systems and processes to identify potential weakness and ensure compliance to data integrity regulations.

G. You lack control over your media fill unit visual inspection qualification (b) (4) and process.

OBSERVATION 6

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, your firm relied on certificate of analyses (COA) for incoming shipments of high-risk components (b) (4) and (b) (4) from your suppliers. You have not tested each lot and container of (b) (4) and (b) (4) upon receipt to detect and quantitate diethylene glycol (DEG) and ethylene glycol (EG). (b) (4) and (b) (4) are used in the manufacture of drug products including (b) (4) , and (b) (4) In the last 3 years your firm has manufactured over (b) (4) lots of drug products containing (b) (4) and (b) (4) for distribution. The products have any an expiration date of 1 to 4 years.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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SHANNON L. MAISANO -S
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Date: 2025.07.14 18:15:59 -04'00'

Martin M. Kimani -S
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Robert J. Ham -S
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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 judgment, 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."