DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	3/17/2026-4/21/2026* FEI NUMBER 1000119582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael S. Sawaya, General Counsel and VP of QA/RA

FIRM NAME	STREET ADDRESS
Altaire Pharmaceuticals, Inc.	311 W Ln
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Aquebogue, NY 11931	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 OBSERVED:

OBSERVATION 1

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

Specifically,

A) Your firm made significant changes to the aseptic manufacturing area in 2024, including demolition of the buffer zone that was located in front of the ISO 5 Cleanrooms (b)(4) and (b)(4) and construction of ISO 5 (b)(4) (b)(4) and (b)(4) for personnel and material entry into Cleanrooms (b)(4) and (b)(4) respectively. The following media fills performed by your firm for the post renovation requalification of the Cleanrooms are inadequate as described below:

i) In addition to the aforementioned construction activities, several modifications were made to the (b)(4) Filler located in Cleanroom (b)(4) including repositioning of the filler. Media fill protocol # PRT1446 Rev. 08, used for the post renovation requalification of the Cleanroom (b)(4) did not specify the number of media fills required for the requalification. Your firm decided to use the routine (b)(4) media fill performed in (b)(4) (Lot # (b)(4), Report # V1739) for the post renovation requalification of Cleanroom (b)(4) This media fill failed due to identification of five (5) contaminated media fill units with microbial growth (mold & bacteria). Despite this media fill failure, instead of performing multiple consecutive successful media fills, your firm decided to use the (b)(4) media fills performed in (b)(4) (Lot # (b)(4), Report # V1742) and (b)(4) (Lot # (b)(4),

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Report # V1778) for the post renovation requalification of Cleanroom (b)(4) Your firm lacks sufficient data to support the qualification of Cleanroom (b)(4) The following sterile drug products were manufactured during (b)(4) (in between media fills Lot #s (b)(4) and (b)(4) in Cleanroom (b)(4) and commercially distributed by your firm in July - December 2025:

- (b)(4) Lot # (b)(4) Expiry Date: (b)(4)
- (b)(4)), Lot # (b)(4) Expiry Date: (b)(4)
- (b)(4), Lot # (b)(4), Expiry Date: (b)(4)
- (b)(4) Lot # (b)(4), Expiry Date: (b)(4)
- (b)(4) Lot # (b)(4), Expiry Date: (b)(4)

ii) In addition to the aforementioned construction activities, several modifications to the (b)(4) Filler located in Cleanroom (b)(4) were made, including repositioning of the filler. Media fill protocol # (b)(4) Rev. 07, used for the post renovation requalification of the Cleanroom (b)(4) did not specify the number of media fills required for the requalification. Your firm decided to use the (b)(4) media fill performed in (b)(4) (Lot # (b)(4), Report # V1740) for the post renovation requalification of Cleanroom (b)(4) This media fill failed due to identification two (2) contaminated media fill units with microbial growth (mold). Despite this media fill failure, instead of performing multiple consecutive successful media fills, your firm performed only a single media fill (Lot # (b)(4) Report # V1741) in 2024, and decided to use the (b)(4) media fills performed in (b)(4) (Lot # (b)(4), Report # V1769) and (b)(4) (Lot # (b)(4) Report # V1784) for the post renovation requalification of Cleanroom (b)(4) Your firm lacks sufficient data to support the qualification of Cleanroom (b)(4) The following sterile drug products were manufactured in April 2025 (in between media fills Lot #s (b)(4) and (b)(4) in

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Cleanroom (b)(4) and commercially distributed by your firm in July 2025:

(b)(4) Lot # (b)(4), Expiry Date: (b)(4)

(b)(4), Lot # (b)(4), Expiry Date: (b)(4)

iii) In addition to the aforementioned construction activities, several modifications to the (b)(4) Filler located in Cleanroom (b)(4) were made, including repositioning of the filler. Media fill protocol # PRT1441 Rev. 09, used for the post renovation requalification of the Cleanroom (b)(4) did not specify the number of media fills required for the requalification. Instead of performing multiple consecutive successful media fills, your firm decided to use the routine (b)(4) media fill performed in (b)(4) Lot # (b)(4), Report # V1735 & V1735 Addendum) for the post renovation requalification of Cleanroom (b)(4) While this media fill was deemed acceptable, the next (b)(4) media fill (Lot # (b)(4) Report # V1770) performed by your firm in May 2025 failed due to identification one (1) contaminated media fill unit with microbial growth. Your firm lacks sufficient data to support the qualification of Cleanroom (b)(4) At least (b)(4) batches of sterile (b)(4)) were manufactured between September 2024 and May 2025 in Cleanroom (b)(4) and commercially distributed by your firm.

B) Your firm's SOP # S-49-10, entitled, "Standard Operating Procedure for Sterile Media Filling" does not require revalidation when (b)(4) contaminated media fill units were observed during a media fill study. Instead, it states in sections 7.14.02.01 and 7.14.02.02, (b)(4)

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contaminated units shall result in an investigation, including consideration of a re-validation." The following are some examples, wherein your firm failed to perform revalidation after obtaining (b)(4) contaminated unit:

Media fill Lot # (b)(4) for Cleanroom (b)(4) resulted in five (5) contaminated units out of (b)(4) incubated units.

Media fill Lot # (b)(4) for Cleanroom (b)(4) resulted in two (2) contaminated units out of (b)(4) incubated units.

Media fill Lot # (b)(4) for Cleanroom (b)(4) resulted in eleven (11) contaminated units out of (b)(4) incubated units.

C) Your firm's routine (b)(4) media fill study for Cleanroom (b)(4) (Lot # (b)(4), Protocol # PRT1475 Rev. 07, Report # V1769) is incomplete. During the Day 2 ((b)(4)) active aseptic media fill operations simulating the PM shift, the air handling system in the cleanroom was unexpectedly shut down for 20 minutes due to an unannounced fire alarm test performed by a third-party contractor. Your firm aborted the media fill at 1:24 PM and rejected (b)(4) filled media fill units. Your firm lacked adequate controls, communication protocols, and coordination procedures to ensure that maintenance activities by third-party contractors would not interfere with critical aseptic processing operations. Multiple required protocol activities were not completed for this media fill, such as Day 2 PM shift operator interventions, mechanic interventions, microbiology interventions including end of the run sampling, and personnel monitoring. Your firm passed the media fill study based on a risk assessment that relied on

historical performance data rather than completion of all required protocol activities.

D) According to Investigation Number 23-003 initiated after the failed media fill study (Lot # (b)(4), Protocol # PRT1475 Rev. 06 & Report # V1699), your firm observed the turbid media fill units during the post incubation inspection on (b)(4), and this investigation report was approved on 6/13/2023. However, at least (b)(4) batches of (b)(4) (Lot #s (b)(4), and (b)(4) that were manufactured in the Cleanroom (b)(4) after this aforementioned failed media fill study were not quarantined, instead they were commercially distributed by your firm on (b)(4), prior to the completion and QA approval of the media fill failure investigation report (Investigation #23-003).

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A) Your firm's risk assessment # STU0904, entitled, "ERGONOMIC RISK ASSESSMENT ROOM (b)(4) (b)(4) FILLER", in pages 11-13, describes the following modifications to the (b)(4) Filler: 1) Repositioning the entire filling line toward the South wall, 2) Removal of (b)(4) equipment (b)(4) (b)(4), and (b)(4)), 3) Repositioning (b)(4) and (b)(4) (Northwest), and 4) (b)(4) conveyor length by approximately (b)(4) inches. However, no equipment qualification (IQ, OQ & PQ) was performed by your firm for the (b)(4) Filler after the aforementioned modifications, and prior to starting commercial manufacturing. Your firm

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manufactured at least (b)(4) batches of (b)(4) mL in Cleanroom (b)(4) using the (b)(4) Filler after its modification.

B) Your firm's risk assessment # STU0927, entitled, "Study Report for the Ergonomic Risk Assessment Room (b)(4) in page 7, describes the following modifications performed by your firm to the (b)(4) Filler: 1) the (b)(4) length was reduced from (b)(4) ", and 2) the (b)(4) from the (b)(4) to the (b)(4) that supplies the (b)(4) was (b)(4) by approximately (b)(4) 3) the (b)(4) was (b)(4) by (b)(4) and the (b)(4) by (b)(4) inches, and 4) (b)(4) Filler was repositioned (b)(4) However, no equipment qualification (IQ, OQ & PQ) was performed by your firm for the (b)(4) Filler after the aforementioned modifications, and prior to starting commercial manufacturing. Your firm manufactured (b)(4) of each of the following drug products in Cleanroom (b)(4) using the (b)(4) Filler after its modification: (b)(4) mL (Lot # (b)(4)), (b)(4) mL (Lot # (b)(4) (Lot # (b)(4) mL, (b)(4) Lot # (b)(4)), and (b)(4) , Lot # (b)(4) mL.

C) Your firm's risk assessment # STU0914, entitled, "Study Report for the Ergonomic Risk Assessment Room (b)(4) Filler" in page 7, describes the following modifications performed by your firm to the (b)(4) Filler: 1) the length of the (b)(4) on the (b)(4) of the (b)(4) Filler was (b)(4) from (b)(4) ", and 2) re-positioning the (b)(4) Filler (b)(4) . However, no equipment qualification (IQ, OQ & PQ) was performed by your firm for the (b)(4) Filler after the aforementioned modifications, and prior to commercial manufacturing. Your firm manufactured (b)(4) (b) (4) of each of the following drug products in Cleanroom (b)(4) using the (b)(4) Filler after its modification: (b)(4) Lot # (b)(4)), and

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(b)(4) (Lot # (b)(4)).

D) Your firm's original process validation study (Protocol # PRT1618 Rev. 01 & Report # V0103) for (b)(4)) was conducted in 2005 for the (b)(4) size. According to your Associate Director of Quality, your firm stopped manufacturing (b)(4) in 2019. Your firm then began manufacturing (b)(4) batch of (b)(4) in 2023. However, the 2023 process validation study (Protocol # (b)(4) & Report # V1682) for the (b)(4)Kg batch size only entailed the manufacturing (b)(4) (b) (4) of (b)(4), without a scientifically sound written justification demonstrating that (b)(4) (b) (4) is adequate to show that the scaled-up manufacturing process consistently and reproducibly delivers quality drug product.

E) Your firm's original process validation study (Protocol # (b)(4) Rev. 01 & Report # V0104) for (b)(4)) was conducted in 2005 for the (b)(4) batch size. According to your Associate Director of Quality, your firm stopped manufacturing (b)(4) in 2019. Your firm then began manufacturing a scaled up (b)(4) batch of (b)(4) in 2023. However, the 2023 process validation study (Protocol # (b)(4) & Report # V1689) for the (b)(4) batch size only entailed the manufacturing (b)(4) (b) (4) of (b)(4) without a scientifically sound written justification demonstrating that (b)(4) (b)(4) (b) (4) is adequate to show that the scaled-up manufacturing process consistently and reproducibly delivers quality drug product.

F) Your firm's original process validation study (Protocol # PRT1617 Rev. 01 & Report # V0128) for (b)(4)) was conducted in 2010 for the (b)(4) batch size. According to your Associate Director of Quality, your firm stopped manufacturing (b)(4) in 2019. Your firm then began manufacturing a scaled up (b)(4) size of (b)(4) in 2023. However, the 2023 process validation study (Protocol # PRT1617 & Report # V1683) for the (b)(4)

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(b)(4) size only entailed manufacturing (b)(4) (b) (4) of (b)(4) without a scientifically sound written justification demonstrating that (b)(4) (b) (4) is adequate to show that the scaled-up manufacturing process consistently and reproducibly delivers quality drug product.

G) Your firm's original process validation study (Protocol # PRT0645 & Report # V0755) for (b)(4) was conducted in 2010 for the (b) (b)(4) size. According to your Associate Director of Quality, your firm stopped manufacturing (b)(4) in 2019. Your firm then began manufacturing a scaled up (b)((b)(4) size of (b)(4) in 2023. However, the 2023 process validation study (Protocol # PRT1624 & Report # V1688) for the (b)(4) size was only entailed manufacturing (b) (b)(4) (b) (4) of (b)(4) without a scientifically sound written justification demonstrating that (b)(4) (b) (4) is adequate to show that the scaled-up manufacturing process consistently and reproducibly delivers quality drug product.

H) Your firm's original process validation study protocol (PRT0805) for (b)(4), in section 3.01 states, "This protocol is applicable to the manufacture of the (b)(4) (b)(4) trial batches of the (b)(4)) USP…". However, your firm manufactured only a single batch (Lot # (b)(4)) in 2011 and generated an interim process validation report (V0891) and this study was not completed. According to your Associate Director of Quality, your firm stopped manufacturing (b)(4) in 2018. Your firm resumed manufacturing (b)(4) in 2025. However, the 2025 process validation study (Protocol # PRT1723 & Report # V1794) was conducted only entailed manufacturing a single batch (Lot # (b)(4)) of (b)(4) Your firm does not have a scientifically sound written justification demonstrating that a single batch manufactured in 2011 and a single batch manufactured in 2025 is adequate to show that the manufacturing process consistently and reproducibly delivers quality drug product. In addition, your firm approved the process validation report on 4/1/2026, subsequent to the request made for process validation documents during the inspection, and the subject batch (Lot # (b)(4)) was commercially distributed on 12/16/2025, prior to approval of this

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report.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A) Your firm's investigation (Investigation Number 22-003) for the Cleanroom (b)(4) media fill failure (Lot # (b)(4) Protocol # PRT1446 Rev. 04 & Report # V1686) is inadequate, because your firm concluded in page-6 of the investigation report that "the most probable root cause is improper gowning or aseptic technique by personnel in Room (b)(4) A single tip or bottle that had not been sterilized properly is a possible root cause", without adequate supporting evidence. During the investigation, no specific gowning deficiency was identified, and the Certificate of Conformance for components showed compliance with sterilization parameters.

B) Your firm's SOP # QM-52-02, entitled, "Aseptic Gowning and Technique Qualification and Area Certified Personnel", in page-10 states the following requirement to implement any remedial action for personnel monitoring excursions: "The (b)(4) Significant excursions exceeding the Action Limit (Level) and above (b)(4) (for example, the sum of (b)(4) and (b)(4) cfu in a (b)(4) period." However, your firm has no scientifically sound written justification to conclude that no action is necessary unless cleanroom personnel have (b)(4) excursions exceeding (b)(4) CFU each in a (b)(4) period. Consequently, your firm failed to generate CAPA and implement preventive actions to minimize the likelihood of recurrence for the following personnel monitoring excursion investigations (EER):

EER #	Operator / Mechanic/	Recovery	Action Limit	ISO 5 Location	Root cause/ Probable Root	Product/Batch #

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	Sanitist				Cause	
02-003-24	(b)(6), (b) (Sanitist)	18 CFU	(b)(4) CFU	Room (b)(4)	Lapse in aseptic technique	N/A
04-006-24	(b)(6), (b) (Mechanic)	7 CFU	CFU	Room (b)(4)	Lapse in aseptic technique	(b)(4)
07-001-23	(b)(6), (b) (Operator)	19 CFU	CFU	Room (b)(4)	Lapse in aseptic technique	
12-003-23	(b)(6), (b) (Mechanic)	24 6	CFU CFU	Room (b)(4)	Lapse in aseptic technique	
02-006-24	(b)(6), (b) (Mechanic)	13	CFU	Room (b)(4)	Lapse in aseptic technique	

C) Your firm failed to generate CAPA and implement preventive actions to minimize the likelihood of recurrence for the following OOS investigations (CLI) as described below:

OOS #	Product	Lot #	Test & Result	Specifications	Root Cause
CLI-25-005	(b)(4)		In process assay at (b)(4) In process assay at (b)(4)	NLT (b)(4) and NMT (b)(4)	Sample did not fully dissolve in solution
CLI-25-002			(b)(4) Assay: (b)(4)	NLT (b)(4) and NMT	(b)(4) error

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				(b)(4)	
CLI-24-005	(b)(4)		(b)(4) CRT Stability Assay: (b)(4)	NLT (b)(4) and NMT (b)(4)	Mixing error
CLI-24-003			(b)(4) CRT Stability Assay: (b)(4)	NLT (b)(4) and NMT (b)(4)	(b)(4) error
CLI-23-006			(b)(4) ACC Stability Assay: (b)(4)	NLT (b)(4) and NMT (b)(4)	Mixing error

D) Your firm's investigation (Investigation Number 22-003) into the media fill failure for Cleanroom (b)(4) (Lot # (b)(4) Report # V1686) states that your firm's microbiology laboratory concluded that the recovered microorganism is a gram positive (+) rod. However, the recovered organism was later identified by a third party to be *Sphingomonas yunnanensis*, a gram negative (-) rod. The potential root cause of this error was identified as underuse of decolorizing solution, an overabundance of the bacterial sample, or possible contamination of the sample by the analyst. However, your firm failed to generate CAPA and implement preventive actions to minimize the likelihood of recurrence.

E) Your firm has a history of growth promotion test failures for the in-house produced media ((b)(4)) used for various media fills conducted in Cleanroom (b)(4) as shown in page 10 of the growth promotion failure investigation report (MLI # 04-001-25). In addition to (b)(4) CFU of microorganisms, your firm also (b)(4) and (b)(4) of certain microorganisms in the growth promotion studies. Your firm's accepted the following media fills in spite of the growth promotion test failures as described below:

Media fill study (Lot # (b)(4) , Report # V1769):

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Preincubation growth promotion test for media showed no growth for *Bacillus amyloliquefaciens* in (b)(4) CFU and (b)(4) CFU inoculum samples, and growth was observed only for (b)(4) CFU inoculum sample.

Post-incubation growth promotion test for media showed no growth for *Bacillus amyloliquefaciens* in all three ((b)(4) CFU, (b)(4) CFU, and (b)(4) CFU) inoculum samples.

Media fill study (Lot # (b)(4) Report # V1741)

Preincubation growth promotion test for media showed no growth for *Bacillus amyloliquefaciens* in (b)(4) CFU and (b)(4) CFU inoculum samples, and growth was observed only for (b)(4) CFU inoculum sample.

Post-incubation growth promotion test for media showed no growth for *Bacillus amyloliquefaciens* in (b)(4) CFU and (b)(4) CFU inoculum samples, and growth was observed only for (b)(4) CFU inoculum sample.

Post-incubation growth promotion test for media showed no growth for *Bacillus spizizenii* (used as alternative for Bacillus subtilis) in Tray (b)(4) sample but showed growth in Tray (b)(4) sample.

Post-incubation growth promotion test for media showed no growth for *Micrococcus luteus* in Tray (b)(4) sample but showed growth in Tray (b)(4) sample.

F) Your firm's routine (b)(4) media fill study (Lot # (b)(4), Protocol # PRT1475 Rev. 06 & Report # V1699) conducted for Cleanroom (b)(4) in March 2023 failed due to identification of (b)(4)

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contaminated media fill units with microbial growth. Instead of genetically identifying all (b)(4) isolates, your firm (b)(4) selected and genetically identified only four isolates.

G) Your firm's investigation (Investigation Number 23-003) on page-23 describes that a (b)(4) media fill unit from Tray (b)(4) was discarded prior to Senior QA review as it was determined that the tube seal was not intact. However, visual examination of similar non-conforming units observed in Tray #s (b)(4) and (b)(4) by senior QA determined that the lack of integrity of the seal could not definitively be established by visual examination. No corrective action was implemented to prevent similar premature disposal of investigation samples.

H) The 2025 environmental and personnel monitoring trending reports show that the recovery rates for the Cleanroom personnel and the controlled areas exceeded your firm's limits based on USP <1116> as described below:

- Personnel monitoring results for gowning locations (Head, chest, and waist) were 1.17%, 1.47% and 2.05% for (b)(4), and (b)(4) 2025 respectively. The USP <1116> limit is < 1%.

- Viable surface sample recoveries for the floors of ISO 5 filling suites and (b) (4) after sanitization were 1.09%, 5.33%, and 1.33% for (b)(4) and (b)(4) 2025 respectively. The USP <1116> limit is < 1%.

- Viable surface sample recoveries for ISO 6 supporting areas were 4.13%, and 10.43% for (b)(4) and (b)(4) 2025 respectively. The USP <1116> limit is < 3%.

- Viable surface sample recoveries for ISO 7 areas were 5.36%, 6.56%, 19.05%, and 6.56% for (b)(4) and (b)(4) 2025 respectively. The USP <1116> limit is < 5%.

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	3/17/2026-4/21/2026* FEI NUMBER 1000119582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael S. Sawaya, General Counsel and VP of QA/RA	
FIRM NAME Altaire Pharmaceuticals, Inc.	STREET ADDRESS 311 W Ln
CITY, STATE, ZIP CODE, COUNTRY Aquebogue, NY 11931	TYPE ESTABLISHMENT INSPECTED Manufacturer

☐Passive air sample recoveries for ISO 7 areas were 23.08%, 15.38%, and 25.00%, for (b) (4) and (b) (4) 2025 respectively. The USP <1116> limit is < 5%.

☐Active air sample recoveries for ISO 8 areas were 56.04%, 70.33%, 76.92%, and 47.73% for (b) (4) (b) (4) and (b) (4) 2025 respectively. The USP <1116> limit is < 10%.

In spite of exceeding the USP <1116> limits for several (b) (4) in 2025, your firm has not performed any investigation to identify root causes and institute adequate preventive actions.

OBSERVATION 4

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

Specifically,

A) Your firm does not perform post filling viable surface sampling of the filling needles of the filling machines, as your firm's procedure, QM-54-12, entitled, "Environmental Monitoring Program for Nonviable and Viable Particles in Aseptic Core and Filling Rooms" does not require sampling of the filling needles. The following are examples of filling machines used by your firm:

i) (b)(4) Filler located in Cleanroom (b)(4) used for filling of (b)(4) [redacted], and (b)(4).

ii) (b)(4) Filler located in Cleanroom (b)(4) used for the filling of (b)(4) [redacted]

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iii) (b)(4) Filler located in Cleanroom (b)(4) used for filling of (b)(4), and (b)(4).

B) Your firm's procedure QM-51-14, entitled, "Bioburden Monitoring of Cleanroom Personnel Garment", in page 15 states the action level for personnel monitoring of gown sites (other than glove and forearm) for aseptic operation operator, aseptic sanitization operator, and aseptic mechanic, working in the aseptic area as (b)(4) CFU/Plate (max (b)(4) CFU/gown). However, your firm has no scientifically sound written justification for the aforementioned action level limits.

C) Your firm's investigation (INV#24-001) into the Room (b)(4) media fill failure (Lot (b)(4) Report # V1739) in page 16 states that the action limit for Aseptic Mechanic (b) (4), (b) (6), left glove fingertips and right glove fingertips as (b)(4) CFU. However, your firm has no scientifically sound written justification for the aforementioned action level limits. Aseptic Mechanic (b) (4), (b) performs aseptic assembly of filling equipment in ISO 5 Cleanrooms. Page 16 of this investigation report also mentions that the following personnel monitoring recoveries for Aseptic Mechanic (b) (4), (b) (6) were not investigated because they were within the limits:

- 2 CFU recovered from right glove fingertips on 10/08/2024
- 1 CFU recovered from left glove fingertips on 10/09/2024

D) Your firm's procedure QM-54-12, entitled, "Environmental Monitoring Program for Nonviable and Viable Particles in Aseptic Core and Filling Rooms", in page 17 states the action level for surface sampling of Class 1000 (ISO 6) Wall/Equipment as (b)(4) CFU/Plate. However, your firm has

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no scientifically sound written justification for the aforementioned action level limit.

E) Goggles donned by operators for aseptic operations within Grade A areas are not suitably designed to prevent shedding particulates and other contaminants to the environment under working conditions. Cleanroom operators wear goggles that have direct vent openings, including 5 holes on the top measuring approximately (2) 9/16 inch, (2) 3/8 inch, and (1) 1/8 inch.

F) On (b)(4), during the manufacturing of submission batch of (b)(4) mL, Lot # (b)(4) in Cleanroom (b)(4) using (b)(4) Filler, Operator (b)(6), (b) loaded the (b)(4) without removing the (b)(4) bag. In addition, during an intervention her hand moved over the open (b)(4) blocking the first air.

G) Your firm's airflow visualization studies (smoke studies, Protocol # PRT1702) are deficient as follows:

No smoke studies were performed to evaluate the filling line setup by the mechanic.

ii) Smoke study (Protocol # 1711 & Report # STU0918) did not include evaluation of setup of aseptic connection between the drug product holding tank and the tube feeding the drug product to the filler in Cleanroom (b)(4)

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

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Specifically,

A) The disinfectant efficacy studies (Protocol # PRT1577Rev.01, Report #s STU0882 & STU0903) conducted by your firm are deficient, because not all cleanroom surfaces are included in these studies for evaluation. For example, (b)(4) worn by operators and the (b)(4) were not evaluated in these studies

B) The equipment cleaning validation study (Protocol # (b)(4) conducted by your firm for (b)(4) as Base) is deficient in that, your firm performed cleaning execution using a single batch (Lot # (b)(4)) for this study and generated interim equipment cleaning validation report (V0918). This interim report in Section 5.02 states that (b)(4) batches will be subjected to cleaning validation, and a final cleaning validation report will be generated. However, your firm never performed the (b)(4) batch manufacture, equipment cleaning and swabbing cycles for this equipment cleaning validation and this study was not completed.

OBSERVATION 6

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A) Your firm's procedure, QC-58-06, in Section 7.06.01 states "Timely review of notebooks and all applicable supporting raw data is a best practice in the handling of laboratory data. Laboratories should attempt to ensure data is reviewed within (b)(4) working days from the completion of the analysis". However, I observed that your firm failed to follow this procedure as described below:

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i) As of 3/19/2026, electronic data generated using UV Instrument (LE-0173) since 6/4/2025 has not been reviewed by your firm.

ii) As of 3/19/2026, electronic data generated using IR Instrument (LE-0159) since 11/4/2025 has not been reviewed by your firm.

iii) Your firm uses UV instrument for assay and color tests, and the laboratory test report for the following drug products were approved by QA without completing electronic data review for the in-process and finished product tests:

- (b)(4) Lot # (b)(4)
- (b)(4)), Lot # (b)(4)
- (b)(4), Lot # (b)(4)

B) Your firm's procedure, QC-58-06, in Section 7.01.02 states, "Data Reviewers cannot review data they generated." However, Analyst (b)(6), (b) performed testing of (b)(4) Lot # (b)(4), and he also signed off as data reviewer for the data he generated.

C) Your firm's procedure, QC-58-06, in Section 7.07 states that QA (b)(4) oversight of data review/audit process includes spot checking of two separate reported results by verifying electronic audit trails. However, this QA spot check audit trail review was not performed since May of 2022.

D) The following OOS investigation (CLI) forms have timestamp discrepancies as described

below:

i) CLI-24-003 investigation form has a timestamp date of 24 FEB 6; however, this form was signed by various personnel on 1/31/2024, 2/2/2024, and 2/5/2024.

ii) CLI-25-002 investigation form Attachments II and III have timestamp date of 25 MAR 6; however, this form was signed by various personnel on 3/4/2025.

iii) CLI-23-006 investigation form has a timestamp date of 23 NOV 9; however, this form was signed by various personnel on 10/27/2023 and 11/7/2023.

OBSERVATION 7

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

Specifically,

A) Your firm's procedure, QC-58-06, in Section 7.06.01 states "Timely review of notebooks and all applicable supporting raw data is a best practice in the handling of laboratory data. Laboratories should attempt to ensure data is reviewed within (b)(4) working days from the completion of the analysis". However, I observed that your firm failed to follow this procedure as described below:

i) As of 3/19/2026, electronic data generated using UV Instrument (LE-0173) since 6/4/2025 has not been reviewed by your firm.

ii) As of 3/19/2026, electronic data generated using IR Instrument (LE-0159) since 11/4/2025 has not been reviewed by your firm.

iii) Your firm uses UV instrument for assay and color tests, and the laboratory test report for the following drug products were approved by QA without completing electronic data review for the in-process and finished product tests:

- (b)(4)), Lot #(b)(4)
- (b)(4)), Lot #(b)(4)
- (b)(4), Lot #(b)(4)

B) Your firm's procedure, QC-58-06, in Section 7.01.02 states, "Data Reviewers cannot review data they generated." However, Analyst(b)(6), (b) performed testing of (b)(4), Lot #(b)(4), and he also signed off as data reviewer for the data he generated.

C) Your firm's procedure, QC-58-06, in Section 7.07 states that QA (b)(4) oversight of data review/audit process includes spot checking of two separate reported results by verifying electronic audit trails. However, this QA spot check audit trail review was not performed since May of 2022.

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i) CLI-24-003 investigation form has a timestamp date of 24 FEB 6; however, this form was signed by various personnel on 1/31/2024, 2/2/2024, and 2/5/2024.

ii) CLI-25-002 investigation form Attachments II and III have timestamp date of 25 MAR 6; however, this form was signed by various personnel on 3/4/2025.

iii) CLI-23-006 investigation form has a timestamp date of 23 NOV 9; however, this form was signed by various personnel on 10/27/2023 and 11/7/2023.

OBSERVATION 8

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

Specifically,

A) According to your aseptic mechanic (b) (6), (b) (7) your firm reduced the (b)(4) and the (b)(4) during the modification of the (b)(4) Filler in Cleanroom (b)(4) However, your firm's risk assessment # STU0927, entitled, "Study Report for the Ergonomic Risk Assessment Room (b)(4) failed include these changes. Your firm included these changes in the updated risk assessment (STU0927 Rev. 01) only after it was raised during the inspection.

B) Sterile components were stored for about (b)(4) years without documented maximum hold times supporting this extended storage period. This resulted in the failure of the media fill lot # (b)(4) (Investigation # 24-001) due to probable contamination of the aseptic filling components. The following are the components used in the aforementioned failed media fill study:

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- Sterile (b)(4) that were received on (b)(4), and used on 10/17/2024 (about (b)(4) months later)
- Sterile (b)(4) that were received on (b)(4) used on 10/17/2024 (about (b)(4) months later)
- Sterile (b)(4) that were received (b)(4), used on 10/17/2024 (about (b)(4) months later)

Your investigation (24-001), on page 3, identified that "The tape adhesive appeared to have degraded during long term storage." However, your firm did not establish hold times (use by date) for sterilized components to ensure their suitability for use after long term storage.

C) Your firm's procedure, QA-60-09, entitled, "Quality Assurance Trending of Environmental Monitoring Reports" in section 5.13.01, states, "The completed (b)(4) Trending Report (Attachment "J") will be distributed no later than the end of the (b) (4) of the subsequent calendar year". However, your firm has not completed environmental monitoring annual trending reports for 2023, and 2024. The 2025 report was completed by your firm on 4/10/2026 after a request was made for environmental monitoring trending reports during this inspection.

D) Your firm has not completed the (b)(4) requalification required by the protocols (b)(4) Rev. 05 and PRT1061 for the following equipment:

i) As of 4/17/2026, (b)(4) requalification for (b)(4) (Equipment

ID: CR-003) is not completed for 2023, 2024, and 2025. Your firm uses this equipment to sterilize product transfer hoses, carboys, filling line parts, etc.

ii) As of 4/17/2026, the 2025 (b)(4) requalification for (b)(4) (Equipment ID: CR-004) is not completed. Your firm uses this equipment for the sterilization of (b)(4) amber glass bottles used for the manufacturing of (b)(4).

E) Your firm's procedure QA-29-11, entitled, "Annual Product Review (APR) Reports" in sections 7.12 and 7.13 states, "All Annual Product Review Reports are to be completed by March 31st and forwarded to Regulatory Affairs. Regulatory Affairs will complete a final review of all APRs by April 10th." However, the following APRs were not completed on time:

2022 (b)(4)) APR was approved on 11/16/2023

2023 (b)(4)) APR was approved on 1/2/2026

2024 (b)(4)) APR is not completed yet

2022 (b)(4) APR was approved on 10/26/2023

2023 (b)(4) APR was approved on 8/19/2024

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2022 (b)(4) APR was approved on 10/20/2023

2023 (b)(4) APR was approved on 7/10/2024

***DATES OF INSPECTION**

3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/26/2026(Thu), 3/27/2026(Fri), 3/30/2026(Mon), 3/31/2026(Tue), 4/01/2026(Wed), 4/06/2026(Mon), 4/10/2026(Fri), 4/13/2026(Mon), 4/16/2026(Thu), 4/17/2026(Fri), 4/21/2026(Tue)

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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."