DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	5/27/2026-6/10/2026* FEI NUMBER 3008546445

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John P. Maravich, General Manager - Bedford, NH Campus

FIRM NAME	STREET ADDRESS
Lyophilization Services of New England, Inc. dba PCI Pharma Services	23 Commerce Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bedford, NH 03110-6835	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, written and followed.

Specifically,

I. Your firm failed to enact adequate production process controls for manufacturing of commercial sterile drug product. For example:

a. Your firm failed to provide documented evidence to demonstrate the use of (b)(4) goggles in the Grade A and B cleanroom spaces and its potential impact in the environment from skin flora and subsequent microbial contamination risk to sterile drug products. On 06/02/2026 we observed multiple operators in room (b) (4) ((b)(4)) performing the setup for the (b)(4)) for sterile drug product (b)(4) Lot # (b)(4) and wearing (b)(4) Goggles ID# 70071542560 which includes (b)(4) of the goggles.

b. A change to stop applying a sporicidal as part of the disinfection regimen for (b)(4) (b)(4) in the aseptic manufacturing area at the (b)(4) was implemented 2/5/25 without a risk assessment to evaluate the microbiological impact of the change. As part of CAPA-2024-1332, the firm stopped

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	Daniel L Zheng, Investigator Armen H Youssoufian, Investigator Ogechi C Nna, Investigator Talia A Faison, FDA Center Employee Wayne E Seifert, FDA Center Employee	X Daniel L Zheng Investigator Signed By: DANIEL L ZHENG -S Date Signed: 06-10-2026 16:49:34	6/10/2026

applying the sporicidal agent (b)(4) onto the (b)(4) during installation and cleaning. The firm continues to use (b)(4), a non-sporicidal agent, to sanitize the (b)(4) during these steps. However, the firm does not apply any sporicidal agent to the (b)(4) Since 2/5/25, approximately (b)(4) lots of the (b)(4) drug product have been manufactured on this (b)(4) line, of which approximately (b)(4) lots have been released.

c. On June 02, 2026 at approximately 7:34AM, in room (b) (4) at the (b)(4), an operator was observed leaning into the (b)(4) during pre-production setup. During this intervention, the operator's gown made contact with interior surfaces of the (b)(4) Although the operator performed a partial surface disinfection following the intervention, not all (b)(4) interior surfaces contacted by the operator's gown were wiped down prior to the resumption of setup activities.

d. During setup of the (b)(4) assembly for (b)(4) of sterile drug product (b)(4) lot (b)(4) in ISO-5/6 Room (b) (4) Building (b)(4) on 6/2/2026, operators were observed forming the aseptic connections between Assembly (b)(4) and Assembly (b)(4) as well as between Assembly (b)(4) and the (b)(4) on the line of demarcation between ISO-5 and ISO-6. Your firm's procedures require these connections to be made within unidirectional Grade A first air from HEPA units within the Grade A area, and your firm was unable to provide evidence that Grade A first air could be maintained on the line of demarcation.

e. Your firm failed to perform environmental monitoring to evaluate the risk to ISO-5 environments during critical process interventions. Specifically, during filling of drug product (b)(4) your firm's

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process involves opening a (b)(4) door in ISO-5/6 Room (b)(4) to load (b)(4) into the filling line hopper, exposing the Grade A (b)(4) interior to the surrounding room. Your firm does not perform environmental monitoring in the vicinity of this intervention to evaluate potential exposure of (b)(4) to contaminants and has provided no scientific justification for the absence of environmental monitoring at this location.

f. Your firm failed to perform personnel monitoring in accordance with firm procedures and good manufacturing practices. For example, during setup activities for filling of sterile drug product (b)(4) lot (b)(4) in ISO-5/6 Room 107, Building (b)(4) on 6/2/2026, (b)(4) production operators were observed rolling only half of each finger for (b)(4). Your firm's procedures for personnel monitoring, including SOP-07509 Environmental Monitoring of the 29H Aseptic Area During Processing, require operators to complete a (b)(4) for personnel monitoring.

~~Additionally, at the conclusion of (b)(4) setup activities for (b)(4) on 6/2/2026, a QC microbiologist was observed sanitizing their (b)(4) with (b)(4) and allowing the agent to dry before immediately performing (b)(4) for personnel monitoring. Your firm's procedures for personnel monitoring, including SOP-07509, prohibit (b) (4) before personnel monitoring, which may mask contamination and compromise the reliability of personnel monitoring data.~~

g. Your firm's dynamic airflow pattern analysis studies (smoke studies) conducted for the 25 Commerce Drive Facility conducted on 7 February 2025 (VAL-0025011) and 1 May 2025 (VAL-0026208) are inadequate. Your firm lacks smoke studies to demonstrate unidirectional

first pass airflow over exposed vials during dynamic operating conditions for the sterile filling line.

II. Additionally, failure to adhere to or establish process controls, an equipment design that ensures the (b)(4) drug product manufactured at (b)(4) by (b)(4) fill line has the identity, strength, quality, and purity it purports or is represented to possess. Specifically:

a. On 27 May 2026, observed was the (b)(4) fill line under (b)(4) decontamination, with (b)(4) extended into the (b)(4) by (b)(4). At two locations, (b)(4) from alternate sides of the (b)(4) were in contact with each other, potentially inhibiting the (b)(4) sanitization process. At another location, an (b)(4) was touching the (b)(4) side wall. According to SOP-07627, "Operation of the Fill (b)(4) Revision 7, Effective date 14 April 2026, Section 7.6.9 states to ensure the (b)(4) surface is not in contact with any load item or component within the (b)(4) You failed to follow the procedure.

b. Observed during (b)(4) fill line (b)(4) decontamination were unwrapped sterile forceps in tool holders inside the (b)(4) Multiple forceps were positioned with tips in contact with the tool holder mounting bar which is not a sterile surface. SOP-07637, "Aseptic Technique for Filling (b)(4) Revision 3, Effective date 14 June 2024, Section 7.4.12 states to position sterilized parts, such as forceps, to ensure maximum air flow and to ensure that first air is present. You failed to follow the procedure.

c. On 28 May 2026, observed was the filling process for (b)(4) drug product Batch (b)(4) At the time of fill line stoppage, the (b)(4) fill needles used in the filling process

were observed with prominent drug product droplet formation at the fill needle tips, a sterility assurance concern.

d. The fill needle holder and (b)(4) system transfer arm located directly above open and filled vials are sanitized surfaces, not sterile.

e. The (b)(4) drug product fluid pathway located in Grade C space next to the fill line (b)(4) includes (b)(4) sterilizing (b)(4), a (b)(4) drug product bag and (b)(4) drug product (b)(4), with the (b)(4) assembly including many connections and clean connects. During the (b)(4) sterile (b)(4) process, there is no instruction for visual verification and documentation for absence of leaks.

f. Observed during the (b)(4) drug product filling process for Batch (b)(4) multiple QC operators performed (b)(4) interventions at various (b)(4), environmental monitoring settling plate exchange. Aseptic technique during interventions were inconsistent or absent per the following:

i. No visual check of the external surfaces of (b)(4) at time of (b)(4) insertion. SOP-07637, Section 7.3.3 states to visually inspect the (b)(4) for installation and proper seating prior to use. Additionally, SOP-07642, "Fill-Line Set-up and Aseptic Interventions for (b)(4)", Revision 4, Effective date 10 September 2025, Section 7.2.3 states to visually inspect the (b)(4) used for holes or tears prior to use. You failed to follow the procedures.

ii. No visual checks of the front and back surfaces of (b)(4) for obvious defects

upon entry. SOP-07637, Section 7.3.5 states to visually inspect the (b)(4) for holes or tears prior to any manipulations within the (b)(4) You failed to follow the procedure.

iii. No visual checks of the front and back surfaces of (b)(4) after completing interventions. SOP-07637, Section 7.3.6 states to visually inspect the (b)(4) for holes or tears after any use that could have potentially damaged the (b)(4) You failed to follow the procedure.

iv. Reaching straight into (b)(4) over critical surfaces and blocking first air when entering. SOP-07642, Section 7.2.2 states aseptic technique should be followed when using the (b)(4) minimizing the entry of the (b)(4) into first air. You failed to follow the procedure.

v. Rapidly entering and exiting (b)(4) to (b)(4) when accessing items inside the (b)(4) during interventions. SOP-07637, Section 7.3.4 states to insert (b)(4) into the (b)(4) to reduce impact to the (b)(4) internal pressure avoiding disturbance of first air. Additionally, SOP-07642, Section 7.2.5 states when (b)(4) (b)(4) operators [sic] movements should be (b)(4) to ensure that the (b) (4) pressure is not disturbed. You failed to follow the procedures.

g. Observed during the (b)(4) drug product environmental monitoring settling plate exchange for Batch (b)(4) a sterile forceps was used and returned to the tool holder with the tip facing down and the handle over the sterile tip blocking first air. SOP-07637, Section 7.4.12

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states to position sterilized parts, such as forceps, to ensure maximum air flow and to ensure that first air is present. You failed to follow the procedure.

h. On 1 June 2026, observed was the simulated (b)(4) fill line setup process for the (b)(4) system that included mounting the (b)(4) sterilized (b)(4) to the (b)(4) transfer arm by (b)(4) open door intervention. Mounting included tightening the (b)(4) with a sanitized wrench, with the use of the sanitized wrench failing to maintain the quality of those surfaces intended to remain sterile. Furthermore, assembly of the (b)(4) system included the operator's upper torso and head within the (b)(4) with exposed face skin. Post (b)(4) system installation, you failed to sanitize the (b)(4) doors prior to closure back into Grade A air supply from Grade C space.

i. The (b)(4) fill line (b)(4) asset J0007 includes a fixed recipe for CIP, with the CIP process validated based on (b) (4) TOC swab testing. Although the cleaning process is validated, the recipe does not control to a final rinse conductivity value that would provide a robust cleaning process to account for variability in the batch manufacturing process.

j. According to Document: POL-05158, (b)(4) and (b)(4) Rev 02, Effective date 14 November 2023, Section 7.1 General Requirements, Subsection 7.1.1 specifies (b)(4) and/or (b)(4) intervals is based on visual inspection of each system for discoloration during preventative maintenance activities as performed at a minimum every (b)(4) years. You fail to follow the procedure with routine preventative maintenance failing to visually inspect stainless steel surfaces for absence of (b)(4)

k. On 28 May 2026, observed were (b)(4) sterilized rotary pumps assembled to the (b)(4)

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fill line where blue surgical wrap was secured by (b)(4) to the drug product fluid pathway ports, with the application of (b)(4) at the critical pump interface ports potentially presenting a (b)(4) penetration, sterilization challenge.

1. The smoke study for the (b)(4) dispense process does not represent the manufacturing process procedurally for appropriate use of (b)(4) A hanging forceps obstructed the use of an (b)(4) (b)(4) and hanging packaged media plates were located above the (b)(4) hopper. The (b)(4) hatch mechanism and (b)(4) chute and hopper design fails to allow for the dispensing of (b)(4) in a manner that maintains those surfaces and component intended to remain sterile, which includes first air broken by sanitized (b)(4) You fail to have a smoke study for the (b)(4) open door (b)(4) system installation.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your firm's investigations into personnel monitoring (PM) action level excursions at (b)(4) failed to assess aseptic gowning practices such as the use of (b)(4) goggles as a potential root cause. Data for the facility shows action level recoveries of skin flora at the chest and/or forehead of 1 CFU/mL or more in your Grade A cleanroom spaces for approximately 90 instances from December 2024 to March 2026. Despite these action level recoveries at the chest and/or forehead in your Grade A cleanroom space, your firm reported the root causes as inconclusive and isolated incidents with no investigation into the breach in aseptic gowning. CAPA-2025-0563 was initiated on 05/05/2025 to address the increased PM recoveries at the Bedford, NH facility, however, the CAPA remains open

with no documented investigation into the probable aseptic breach in gowning, nor implementation of corrective actions to address the recoveries.

OBSERVATION 3

Your firm failed to establish adequate 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, procedures in support of (b)(4) drug product manufacture at (b)(4) are deficient or not available. For example:

a. On 28 May 2026, observed during the (b)(4) drug product Batch (b)(4) filling process was a forceps used to remove debris from a vial (b)(4), with an (b)(4) used in the process extending over open vials, breaking first air. SOP-07637, *"Aseptic Procedure for* (b)(4) *Aseptic Technique for Filling* (b)(4) v3.0, Effective date 14 June 2024, Section 7.4.7 indicates personnel should avoid reaching over any open or partially (b)(4) vials during aseptic production operations as much as possible, to avoid interruption of first air. The procedure fails to restrict reaching over open or partially (b)(4) vials by sanitized (b)(4) (b)(4).

b. You indicate that the (b)(4) fill line (b)(4) system is (b)(4) rinsed with (b)(4) in preparation for (b)(4) sterilization. There is no procedure or training performed for the equipment rinse process. You further fail to have a procedure for the validated (b)(4) rinse of the filling pumps nor is there visual confirmation and documentation that the pumps are clean.

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c. SOP-07617, *"Routine Environmental Monitoring of Non-Aseptic Area at* (b)(4) *"*, Revision 2, Effective date 06 November 2024 specifies for Grade C space surrounding the (b)(4) fill line (room (b) (4)), Section 7.2.3: Rooms associated with non-aseptic areas will be routinely monitored as found, Note: (b)(4) per SOP-07618. You fail to conduct environmental monitoring within Grade D and C space during manufacture, under dynamic conditions in assurance the manufacturing space is in a state of control.

d. On 27 May 2026, (b)(4) personnel were gowning in Room 120-C. In a prior gowning (b) (4) personnel were gowning as one individual was ungowning. PQ-J0001-001, *Environmental Monitoring Performance Qualification (EMPQ) of Clean Rooms at the LSNE* (b)(4), issue date 28 August 2023 identifies a limit of (b)(4) personnel to be present in gowning (b) (4) 120-C at any given time. SOP 07593, *"Gowning Procedure and Personnel Flows"*, Revision 6, Effective date 20 February 2026 fails to prevent the potential for contamination in personnel gowning (b) (4) 120-C by not restricting access based on the EMPQ. You failed to implement procedural controls and area signage for established room maximum occupancy limits. You further failed to implement restrictions to prevent simultaneous gowning and degowning activities.

e. SOP-07593, *"Gowning Procedures and Personnel Flows"*, Revision 6, Effective date 20 February 2026, Section 7.1.12.3 indicates to wash hands in provided sink and soap for a minimum of (b)(4), ensuring that all exposed skin on the hands is washed, followed by dry hands prior to entry into the cleanroom. The washing of hands for entry into GMP space is not

conducted according to a specific process consistent with good industry practice nor is there an illustration of the hand washing process at the washing station.

OBSERVATION 4

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, utilities in support of (b)(4) drug product are not monitored in assurance the qualified validated state is maintained. Equipment and facilities used in the manufacture of (b)(4) drug product at (b)(4) are not adequately maintained. For example:

a. The (b)(4) water system used as (b)(4) water for the multiple effect still and clean (b)(4) generator fails to have water environmental monitoring testing conducted at any frequency to a specification.

b. The (b)(4) distribution system used in back fill of the (b)(4) and a point of use drop at the (b)(4) fill line fails to have environmental monitoring testing conducted at any frequency to a specification.

c. Observed in Grade C space surrounding the (b)(4) fill line were two wheeled carts, with the cart caster assemblies in a deteriorated state, rusty. Other carts in manufacturing space were observed with a similar attribute but to a lesser extent.

d. Observed in personnel (b)(4) 165-C was a (b) (4) mounted to the wall in a deteriorated state, broken with cracks in multiple locations.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
John P. Maravich, General Manager - Bedford, NH Campus	
FIRM NAME Lyophilization Services of New England, Inc. dba PCI Pharma Services	STREET ADDRESS 23 Commerce Dr
CITY, STATE, ZIP CODE, COUNTRY Bedford, NH 03110-6835	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, your firm is unable to use some (b)(4) (b)(4) without breaking first air to open vials. For example, (b)(4) on the (b)(4) (b)(4) which your firm uses for routine interventions during the filling process for sterile drug product (b)(4) , cannot be introduced into the (b)(4) environment without breaking first air to open vials, post-wash and (b)(4) , on the vial (b)(4) and vial (b)(4) Your firm's procedures for aseptic technique prohibit operators from breaking first air.

OBSERVATION 6

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically, on 6/1/2026, a divot approximately two to four inches long was observed approximately one foot off the ground on the corner of a wall pillar in ISO-5 Room 149A Sterile Staging, Building 25 Commerce, immediately next to the exit door of the (b)(4) oven. Similarly, on 6/2/2026, a floor divot approximately one inch in diameter was observed in ISO-6 Room 108, Building (b)(4) , approximately five feet from the closed (b)(4) exposing what appeared to be concrete subsurface under the cleanroom floor lining.

***DATES OF INSPECTION**

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Daniel L Zheng, Investigator Armen H Youssoufian, Investigator Ogechi C Nna, Investigator Talia A Faison, FDA Center Employee Wayne E Seifert, FDA Center Employee	X Daniel L Zheng Investigator Signed By: DANIEL L ZHENG -S Date Signed: 06-10-2026 16:49:34	6/10/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri), 6/01/2026(Mon), 6/02/2026(Tue), 6/03/2026(Wed), 6/04/2026(Thu), 6/10/2026(Wed)

X Armen H Youssoufian
Investigator
Signed By: ARMEN H. YOUSSOUFIAN -S
Date Signed: 06-10-2026 16:49:55

X Ogechi C Nna
Investigator
Signed By: 2004008930
Date Signed: 06-10-2026 16:50:34

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	Daniel L Zheng, Investigator Armen H Youssoufian, Investigator Ogechi C Nna, Investigator Talia A Faison, FDA Center Employee Wayne E Seifert, FDA Center Employee	X Daniel L Zheng Investigator Signed By: DANIEL L. ZHENG -S Date Signed: 06-10-2026 16:49:34
		6/10/2026

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."