

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661		DATE(S) OF INSPECTION 3/9/2026-3/17/2026* FEI NUMBER 3011286996	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Nabila Ikhelef-Gribi, Site Operational Head Pearl River			
FIRM NAME Protein Sciences Corporation		STREET ADDRESS 401 N Middletown Rd	
CITY, STATE, ZIP CODE, COUNTRY Pearl River, NY 10965-1298		TYPE ESTABLISHMENT INSPECTED Licensed Biological Drug Substance 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 Inadequate controls for inventory of critical starting materials in (b) (4) used in the manufacture of Flublok Monovalent Drug Substance, which is used to manufacture Flublok recombinant influenza vaccine. Specifically, During the FDA inspection conducted on March 10, 2026, your firm's system for storage and identification of master cell banks (MCBs), working cell banks (WCBs), master virus banks (MVBs), and working virus banks (WVBs) used in the manufacture of Flublok drug substance was found to be inadequate. Cell and virus banks are considered critical starting material for Flublok Monovalent Drug Substance and are stored in (b) (4) - Your firm's validated materials inventory tracking system (b) (4) lists master and working cell and virus bank locations as a generic identifier (b) (4) (b) (4) which is not unique to a (b) (4) records do not differentiate between (b) (4) (b) (4) During inspectional (b) (4) reconciliation of your cell and virus bank inventory on March 11, 2026, discrepancies were observed between your (b) (4) inventory and physical inventory. Examples of discrepancies the (b) (4) system failed to accurately account for the physical inventory are listed in the following table:			
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		Richard L Bartlett Investigator Signed By: Richard L. Bartlett -6 Date Signed: 03-17-2026 13:24:04 X	
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Material Name	Material Lot Number	(b) (4) (b) (4) Spreadsheet Quantity	(b) (4) System Quantity
Express SF+ Working Cell Bank	(b) (4)		
Express SF900 Master Cell Bank			
Express SF+ Master / Working Cell Bank			
Express SF+ Master Cell Bank			
SF 9 (b) (4) Working Cell Bank			

**The movement of one vial from Lot (b) (4) to production on February 14, 2026, for use in Flublok drug substance batch (b) (4) was not documented in (b) (4) contrary to the traceability requirements in your procedure QU-(b) (4)-0000136.*

- During inspectional inventory of (b) (4) conducted on March 10, 2026, (b) (4) unlabeled (b) (4) were observed within a (b) (4) labeled for storage of Express SF+ Working Cell Bank from Material Lot# (b) (4). Approximately (b) (4) labels were observed as peeling off their

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respective (b) (4) potentially compromising the ability to identify (b) (4) contents. - Master cell banks and working cell banks are stored (b) (4) differentiated only by (b) (4) location. Similarly, master virus banks and working virus banks for baculovirus are stored (b) (4) Additionally, your firm's (b) (4) (virus bank storage), (b) (4) (cell bank storage), and (b) (4) (backup) are (b) (4) each with capacity to house (b) (4) Your firm does not physically identify individual (b) (4) identity is determined by the (b) (4) (b) (4) posing a risk to mix-up of (b) (4) identification. Your firm's primary method of identifying location of master or working cell or virus bank (b) (4) via an uncontrolled spreadsheet refers to (b) (4) identifiers (b) (4) through (b) (4) for vial location. Written procedure titled "Management of Seed Lots and Cell Banks", QU-(b) (4)-0000136, Version 2.0, Approved April 4, 2023 Section 3.10 <i>Storage, Steps</i> (b) (4) and (b) (4) state: (Step (b) (4)): Vials of different seed lots and cell banks must be segregated to prevent mix-up. (Step (b) (4)): Seed lots and cell banks must be physically segregated to prevent mix up and documented by area management. No risk assessment was performed to justify that your firm's current level of segregation and determination of (b) (4) identity is adequate to prevent mix-up. - A (b) (4) labeled for "non-GMP" research and development use was observed stored (b) (4) alongside qualified MCB and WCB materials. No assessment was done to assess the risk of mix-up.			
OBSERVATION 2 Computerized systems used for the collection and analysis of quality data have not been validated. Specifically,			
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The Excel spreadsheet used for environmental monitoring data collection, trending, and analysis has not been validated. Your firm has not demonstrated that this system is accurate, reliable, and capable of ensuring the integrity of the data generated and maintained within your environmental monitoring program. OBSERVATION 3 Flow of materials and equipment is not designed to prevent contamination. Specifically, Room (b) (4) is a Grade (b) (4) with (b) (4) for movement of (b) (4) - (b) (4) the warehouse receiving area - (b) (4) to the (b) (4) warehouse (b) (4) storage area - (b) (4) (Room (b) (4)) - (b) (4) the manufacturing (b) (4) (Grade (b) (4)) for (b) (4) of (b) (4) Your firm's environmental monitoring data for Room (b) (4) shows consistent mold recoveries (% of all (b) (4) mold recoveries) with rates of 16.19% in 2023, 22.09% in 2024, and 28.10% in 2025. Although the frequency of sporidical cleaning was increased, no corrective actions have been implemented to address the fundamental deficiency in material flow and segregation. OBSERVATION 4 Written procedures designed to prevent microbiological contamination of drug substance are not established or are not followed.			
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Specifically,

On 03/15/2026, two operators were observed ungloved over a designated "clean zone" in Room (b) (4), a Grade (b) (4). The clean zone contained (b) (4) and (b) (4) (b) (4) that were then introduced into the BSC for (b) (4) Flublok Lot (b) (4) of (b) (4) drug substance. One operator was wearing a flat-band ring at the time his hand was exposed.

Environmental Monitoring of the BSC is less stringent during sampling than routine EM. During (b) (4) (b) (4) activities on 03/15/2026, EM monitoring of the BSC in Room (b) (4) was only conducted with (b) (4) settle plates during (b) (4) sample collection. (b) (4) routine monitoring of this BSC under dynamic conditions (normal or simulated) requires (b) (4) settle plates, (b) (4) plate samples, active air sampling, and non-viable particulate sampling.

Furthermore, personnel monitoring is not performed for BSC operators following sampling of the bulk drug substance (b) (4). On 03/15/2026, two operators donned sterile sleeves and gloves prior to sampling of drug substance Flublok Lot (b) (4) of (b) (4) a BSC. Following completion of sampling activities, no personnel monitoring was performed as your firm does not consider (b) (4) (b) (4) (which includes (b) (4)) as a critical step in the process.

OBSERVATION 5

Equipment and Facilities are not designed to prevent the potential for contamination.

Specifically,

On 03/09/2026, (b) (4) utilized for holding Flublok drug substance was observed with apparent corrosion, chipping paint, and condensation. (b) (4) was holding drug substance Lot (b) (4) of (b) (4) Lot (b) (4) of B/Austria, and Lot (b) (4) of B/Austria at the time of the

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observation. Condensate droplets were noted on the (b) (4) holding drug substance Lot (b) (4) of (b) (4) pooling condensate was also noted on the (b) (4) floor. OBSERVATION 6 The Quality Unit has failed to provide adequate oversight and ensure the implementation of effective corrective and preventive actions. Specifically, Your firm's own Product Quality Reviews (PQRs) for 2024 and 2025 identified that the root cause category of "Methods" accounted for approximately 41% and 40%, respectively, of critical/major/significant deviations in each review period. Despite this recurring trend being formally documented in two (b) (4) reviews, the Quality Unit has not initiated a Corrective and Preventive Action (CAPA) to systemically address this issue. During the 2025 review period, your firm initiated Significant deviations QE-137857 (Root Cause - Methods) which resulted in rejection of Flublok Drug Substance batch (b) (4) and QE-159034 (Root Cause – Methods) which resulted in rejection of Flublok Drug Substance batch (b) (4) During the 2024 review period, your firm initiated Major deviation PRLD24E0046 (Root Cause – Manpower/Attention Error with Methods identified as a contributing factor requiring corrective action) which resulted in rejection of Flublok Drug Substance batch (b) (4)		
*DATES OF INSPECTION 3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/15/2026(Sun), 3/16/2026(Mon), 3/17/2026(Tue)		
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X Matthew J Gretkierewicz
Investigator
Signed By: MATTHEW J. GRETKIEREWICZ-S
Date Signed: 03-17-2026 13:24:51

X Christian Lynch
Investigator
Signed By: Christian D. Lynch-S
Date Signed: 03-17-2026 13:25:32

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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."