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	8/24/2026-9/8/2026* FEI NUMBER 3015144909

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark Spiecker, President

FIRM NAME	STREET ADDRESS
STAQ Pharma, Inc.	14135 E 42nd Ave Ste 50
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Denver, CO 80239-5214	Producer of Sterile Drug Products

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

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

Specifically, your firm does not maintain your facility adequately to prevent water intrusion into the mezzanine space directly above ISO-7 spaces utilized to produce injectable drug products purported to be sterile. On August 27, 2026, I observed standing water on top of non-impervious (b) (4) flooring within the mezzanine immediately above ISO-7 Production Room (b) (4) (Room (b) (4), which contains an ISO-5 (b) (4) Laminar Airflow Workstation, (b) (4) Series. Subsequent inspection revealed notable staining on the back side of five (5) cleanroom tiles. This condition was present during the production of Fentanyl Hydrochloride 160 mcg/mL 50 mL Syringes, Lot 26166677A.

OBSERVATION 2

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

Specifically, on September 1, 2026, Sterile Filling Technician (b) (6), (b) (7) (C) was observed in ISO-7 Production Room (b) (4) (Room (b) (4) producing Fentanyl 10 mcg/mL 100mL IV Bags, Lot 26102671A, at an ISO-5 (b) (4) Laminar Air Flow Workstation. While exchanging an environmental monitoring (EM) active air sample plate, (b) (6), (b) (7)(C) was observed extending her arms fully into the hood, up to her shoulders. The EM active air sample plate is positioned on a

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	John P Mistler, Investigator X John P Mistler Investigator Signed By: JOHN P. MISTLER -S Date Signed: 09-08-2026 12:50:41	9/8/2026

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stand located above the (b) (4) IV Bag Filling and Closing Machine, greater than 12 inches from the deck of the hood, posing a risk of microbiological contamination. Additionally, the firm's personnel monitoring program includes (b) (4) sampling; however, at an action level of (b) (4) Colony Forming Units (CFUs), posing a risk of environmental assurance and potentially missing sources of microbial contamination.

OBSERVATION 3

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, (b) (4) located in ISO-7 Production Room (b) (4) (Room (b) (4) and ISO-7 Production Room (b) (4) (Room (b) (4) exhibited visible discoloration, appearing brownish to blackish in color, on (b) (4) In Room (b) (4), (b) (4) is utilized to hold a (b) (4) bin for in-process product to be placed in prior to exiting the room. In Room (b) (4) environmental monitoring equipment used during the production of drug products is placed (b) (4) of (b) (4). Cleaning of (b) (4) of (b) (4) occurs (b) (4) however, your firm has not assessed the discolorations for potential risk to cleanroom environment and product.

*DATES OF INSPECTION

8/24/2026(Mon), 8/25/2026(Tue), 8/26/2026(Wed), 8/27/2026(Thu), 8/31/2026(Mon), 9/01/2026(Tue), 9/02/2026(Wed), 9/03/2026(Thu), 9/04/2026(Fri), 9/08/2026(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."