DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	8/10/2026-8/19/2026* FEI NUMBER 3025336457

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Joseph W. Bagan, CEO	
FIRM NAME STAQ Pharma of Ohio, LLC	STREET ADDRESS 255 Phillipi Rd
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43228-1307	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm's visual inspection qualification procedure for sterile injectable drug products compounded and packaged in syringes is inadequate to ensure that visual inspectors are appropriately qualified to detect defects.

A. The visual inspection qualification process does not require operators to distinguish between critical and major defects and the acceptance criteria to pass qualification is (b) (4) of defective units identified, regardless of defect severity. For example, the current qualification (b) (4) for (b) (4) syringes contains (b) (4) defects, of which (b) (4) are critical defects and (b) (4) are major defects. During qualification, operators are not required to document the specific defect type identified, and qualification proctors determine only whether the rejected units contained an actual defect. Thus, operators may fail to identify up to (b) (4) critical defects and still be qualified for visual inspection.

B. A single visual inspection challenge (b) (4) is maintained for both training and qualification purposes. The challenge (b) (4) used to qualify visual inspectors for products compounded and packaged in (b) (4) syringes does not include known defect types listed in

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the batch production records, such as precipitation (cloudiness), particles adhered to the container, and particles adhered to the stopper. In addition, training records do not document whether visual inspection operators are trained on all known defect types prior to qualification.

C. Visual inspection data, such as rejected units by defect type, inspector, or shift, are not trended in a manner sufficient to detect systemic defect patterns or identify individual inspector performance issues at the OH location.

Since August 2025, approximately (b) (4) batches of compounded drug products have been released.

OBSERVATION 2

Batch production and control records do not include in-process results for each batch of drug product produced.

Specifically,

Actual light intensity values measured prior to starting visual inspection are not recorded in the production batch records; instead, the records document only whether the established light intensity acceptance criteria was met using a "Yes/No" check box. For example, for Succinylcholine Chloride 20 mg/mL, 10 mL in 10 mL syringe, Injection Batch 62116169A (batch size (b) (4) syringes, manufactured on (b) (4), BUD 10/30/2026), light intensity was measured during visual inspection, however, the batch record only documented whether the light intensity met the established acceptance criteria.

OBSERVATION 3

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

Media fills or aseptic process simulations performed do not closely simulate actual production conditions or represent all syringe configurations. In addition, operators were not qualified prior to the introduction of new gowning components to ensure that the gowning was donned appropriately.

A. Your firm's media fill program does not include worst-case conditions for all syringe sizes used in sterile compounding operations. No media fill has been performed for the (b) (4) syringe size ((b) (4)) since 2024. Approximately, (b) (4) batches in (b) (4) syringes have been compounded and released since October 2025. For example, Sodium Chloride 9 mg/mL, (b) (4) in (b) (4) syringes, Injection Batch 62169152A (batch size (b) (4) syringes, BUD 12/08/2026) was compounded on (b) (4) .

B. Your firm's media fill program does not adequately simulate actual aseptic production conditions. During media fills, operator fatigue, prolonged aseptic technique, and extended exposure time within the cleanroom environment are not being evaluated or challenged. Operators fill between (b) (4) units during a media fill, however operators may fill (b) (4) syringes during actual compounding. For example, during an operator qualification using 5 mL syringes (Batch 52001187A produced on (b) (4)), only (b) (4) syringes were filled by an operator. In contrast, during operations for the compounding of Dexmedetomidine HCl 4 mcg/mL, 5 mL in 5 mL syringe Batch 62123162A (batch size (b) (4) syringes, manufactured on (b) (4) , BUD 12/20/2026), the same operator filled (b) (4) syringes continuously.

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Columbus, OH 43228-1307	Outsourcing Facility

C. Your firm introduced sterile sleeve covers as a component of the sterile gowning process without ensuring that all operators were qualified to don this new gowning component prior to implementation.

***DATES OF INSPECTION**

8/10/2026(Mon), 8/11/2026(Tue), 8/12/2026(Wed), 8/13/2026(Thu), 8/14/2026(Fri), 8/17/2026(Mon), 8/18/2026(Tue), 8/19/2026(Wed)

X Anna M Spiros
Investigator
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Investigator
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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."