

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100	DATE(S) OF INSPECTION 8/25/2020-9/3/2020*
	FEI NUMBER 3015144909

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph W. Bagan, CEO

FIRM NAME STAQ Pharma, Inc.	STREET ADDRESS 14135 E 42nd Ave Ste 50
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CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80239-5214	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility
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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**

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

For example:

a) An investigation (DEV 20-020, July 2020) concerning the leaking of finished and filled syringes in Ketamine HCL 10 mg/ml, 5 ml in a 5 ml syringe lot (b) (4) discovered during visual inspection of filled drug product, did not fully pursue root cause to determine adequacy of container and closure system integrity for marketed sterile drug products and specifically why filled syringes were found leaking. Per the investigation, "The most probable root cause for product leaking beyond the plunger stoppers in (b) (4) syringes for lot (b) (4) is materials [the syringe]." ..." [STAQ] Method and machinery are possible contributing factors..."

b) Visual inspection results of filled syringes were found to contain extraneous unidentified visible materials (particles) during 100% visual inspection processes, but no investigation was opened to identify the foreign materials, determine root cause as to how visible substances are found in a drug that is (b) (4) and containerized/filled in a HEPA filtered (ISO 5) environment, and prevent recurrence. For example, the following lots were found with some syringes containing foreign substances:

i) Ketamine HCL 10 mg/ml lot (b) (4) 5 ml fill in a 5 ml syringe found 7 syringes containing particles in June 2020.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michael A Charles, Investigator	Michael A Charles Investigator Signed By: Michael A. Charles -6 Date Signed: 09-03-2020 07:35:0 X _____	DATE ISSUED 9/3/2020

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- ii) Hydromorphone HCL 0.2 mg/ml lot (b) (4) 2 ml fill in a 3 ml syringe found 1 syringe containing a particle in June 2020.
- iii) Morphine Sulfate 1 mg/ml lot (b) (4) 2 ml fill in a 3 ml syringe found 1 syringe containing a particle in July 2020.
- iv) Hydromorphone HCL 0.2 mg/ml lot (b) (4) 50 ml fill in a 50 ml syringe found 1 syringe containing a particle in August 2020.

OBSERVATION 2

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

For example:

- a) The Smoke Study performed in Production Room D is not adequate to show production areas have unidirectional airflow, as the Study shows detection of some instances where there is turbulence.
- I) The Smoke Study in the ISO 5 hood in Room D shows that air (smoke) rises towards the ceiling in areas adjacent to the ISO 5 Hood instead of cascading towards the floor where uptakes are located, indicating turbulence instead of unidirectional airflow. Turbulence is also indicated in areas where ISO 5 air meets ISO 7 air.
- II) The ISO 7 area, where the ISO 5 hood is located, was not fully included in the Smoke Study to demonstrate air flow adequacy and impact on the ISO 5 environment. The hood generates (b) (4) directed (ISO 5) air and is open to the ISO 7 environment which produces vertically (downward) flowing air.

The Smoke Study video shows the following from the hood in Production Room D:

- i) At 00:37-00:40 there is turbulence

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- ii) At 00:50-00:54 there is turbulence
- iii) At 01:33-01:47 there is air rising upwards
- iv) At 02:03-02:07 there is turbulence

b) Transfer of items from ISO 7 to ISO 5 are transferred directly, not fully in an aseptic manor. For example, the formulation bag, syringes and caps are transferred directly without an aseptic step at the point of transfer from ISO 7 to ISO 5.

c) Your media fills were not performed under the most challenging or stressful conditions. For example:

-Media Fill (Process Simulation) does not include processing media (b) (4) (a process step prior to (b) (4)).

OBSERVATION 3

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

For example:

- a) Media plates used for detecting microbes (in ISO 5 hood areas during filling) with active air sampling do not contain neutralizing agents to ensure detection and growth of microbes in the presence of disinfecting agents utilized in the filling room.
- b) There is no environmental monitoring of aseptic setup in ISO 5 hood areas, i.e., no viable (air and personnel) and no particle monitoring.

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OBSERVATION 4

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

Specifically, classified area disinfecting procedures (SOP 201 Classified Area Cleaning) do not ensure contact times are accomplished, there is no contact time established for (b) (4) and there is nothing in the procedure determining how much area can be wiped with a single mop surface or hand wipe surface. For example, it was observed on 8/27/2020, as a regular practice, that the Operator used the same hand wipe surface to disinfect multiple production surfaces within the same ISO area.

OBSERVATION 5

The labels of your outsourcing facility's drug products are deficient.

The templated labels received of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(A) and 503B(a)(10)(B) . Specifically, the dosage form of the product, such as "Injection" for the IV formulations, was missing. Some examples include:

1. Fentanyl Citrate 100 mcg/2ml
2. Fentanyl Citrate 250 mcg/5ml
3. Fentanyl Citrate 1000 mcg/20ml
4. Hydromorphone HCL 0.4mg/2ml
5. Hydromorphone HCL 2mg/10ml
6. Ketamine HCL 50mg/5ml
7. Ketamine HCL 30mg/3ml

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- 8. Midazolam 2mg/2ml
- 9. Midazolam 25mg/25ml
- 10. Morphine Sulfate 2mg/2ml
- 11. Morphine Sulfate 5mg/5ml

***DATES OF INSPECTION**

8/25/2020(Tue), 8/26/2020(Wed), 8/27/2020(Thu), 8/28/2020(Fri), 9/03/2020(Thu)

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