DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	8/19/2025-9/4/2025* FEI NUMBER 3011286349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen Anderson, Executive Vice President/Pharmacist In Charge

FIRM NAME	STREET ADDRESS
Qualgen, LLC	14844 Bristol Park Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Edmond, OK 73013-1891	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

There is insufficient physical or spatial separation from operations and other drug products to prevent mix-ups and cross-contamination.

Specifically,

Hazardous drugs were produced without appropriate containment, separation, and cleaning to prevent cross-contamination.

A) The (b) (4) ISO (b) (4) production rooms where testosterone and estradiol implantable pellets are manufactured are positive pressure to the shared ISO (b) (4) ante room where employees don and doff gowning and PPE. The shared ISO (b) (4) ante room is not cleaned between production of testosterone and estradiol drug products in the adjoining ISO (b) (4) production rooms.

B) Your firm does not have documentation to demonstrate that the (b) (4) and (b) (4) cleaning agents used during (b) (4) cleaning of the ISO (b) (4) production rooms and ISO (b) (4) ante and prep rooms are effective for deactivation of hazardous drug residues such as testosterone and estradiol. Additionally, your firm has not evaluated the effectiveness of your cleaning process to demonstrate that cleaning agents and procedures are effective to deactivate, decontaminate, and clean hazardous drug residues from your classified production areas.

C) The (b) (4) used by all production employees are not being cleaned in accordance with your firm's procedure titled, (b) (4) Cleaning and Storage, QG-1183,

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	Logan T Williams, Investigator Zachary L Stamm, Investigator X Zachary L Stamm Investigator Signed By: ZACHARY L. STAMM -S Date Signed: 09-04-2025 15:21:17	9/4/2025

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eff. 1/13/2025, that requires (b) (4) cleaning of the (b) (4) unit with (b) (4) to inactive hazardous drug residues. The (b) (4) units are used by employees in both testosterone and estradiol production and when not in use are stored in the ISO (b) ante room outside the ISO (b) production area directly next to where employees don and doff gowning.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

REPEAT OBSERVATION FROM INSPECTION CONDUCTED 2/6/2024 – 3/19/2024

Specifically,

A) Your procedure to document cleaning of (b) (4) Units is not fully followed. Your firm's procedure QG-1183, "(b) (4) Cleaning and Storage" effective 1/13/2025, states that pre-use and post-use cleaning of the (b) (4) units by production employees should be documented and verified in your firm's (b) (4) Cleaning Logs, ELB-2025-009, at the time of completion of each cleaning activity. Video recording of production operations conducted on 8/11/2025 show production employees conduct the pre-cleaning and post cleaning of the (b) (4) units but does not provide evidence to demonstrate that the (b) (4) cleaning was documented at the time of completion. Production employees verified the (b) (4) Cleaning Logs are not kept inside the classified rooms and therefore cannot be completed contemporaneously.

B. Your firm's procedure QG-1247, "Post-Production Vial Inspection for Pellets" effective 8/14/2025 states that vials will be inspected for approximately (b) (4) each.

-Testosterone 12.5mg pellet, lot K171, exp 5/19/2026 had (b) (4) vials inspected in

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approximately (b) (4). This process should take approximately (b) (4) (b) (4) without any breaks for (b) (4) to inspect per the procedure.

-Estradiol 25mg pellet, lot K209, exp 07/21/2026, had (b) (4) vials inspected in approximately (b) (4). This process should take approximately (b) (4) to inspect per the procedure.

-Testosterone 37.5mg pellet, lot K185, exp 06/16/2026, had (b) (4) vials inspected in approximately (b) (4). This process should take approximately (b) (4) to inspect per the procedure.

-Testosterone 25mg pellet, lot K189, exp 06/16/2026, had (b) (4) vials inspected in approximately (b) (4). This process should take approximately (b) (4) to inspect per the procedure.

In addition, your firm's visual inspection process routinely utilizes (b) (4) visual inspectors, however, only one visual inspector is signing off in the batch record for the work performed.

C.Calibration procedures are not fully followed, for example:

- Procedure QG-1275, "Operational SOP for Digital Calipers" effective 12/23/2024 states that calipers used in production of pellets are calibrated at a minimum of (b) (4) points at (b) (4). Your firm calibrated caliper assets (b) (4) and (b) (4) to the following calibration points, (b) (4). Asset (b) (4) and asset (b) (4) were used in the in-process testing for production of Testosterone 12.5mg, lot K171, to measure pellet thickness to a target specification between (b) (4) to (b) (4). These assets were calibrated 1/16/2025.

- Procedure QG-1198, "Operational SOP for (b) (4) Balance" effective 4/14/2025 states that (b) (4) scales will be calibrated in a bracketed range between (b) (4). Your

firm calibrated scale asset (b) (4) at the following points: (b) (4) . Asset (b) (4) was used in the production of Estradiol Granulation batch KGE807 to weigh approximately (b) (4) of Estradiol. Asset (b) (4) was calibrated on 4/30/2025.

D. Your firm's procedure QG-1069, "Handling of Complaints" rev 11, effective 12/04/2024 and rev 13, effective 7/11/2025, states that if Qualgen requires additional information in order to complete the complaint assessment process, a follow-up email regarding the complaint will be sent to the customer.

-Your firm opened complaint CIN-25-048 on 4/29/2025. This complaint has not been investigated nor has documented follow up occurred as required by your procedure. This complaint is for an Empty Vial and was reported to the firm as Testosterone 25mg, lot K207, however, the customer received lot K027.

-Your firm opened complaint CIN-25-074 on 7/22/2025. This complaint has not been investigated. The complaint intake documents "Customer claims that 7 patients have had problems with the pellets. 1 patient had theirs removed due to an infection." Your firm has not completed the complaint intake form nor documented follow up as required by your procedure to obtain specific information related to the problems being experienced. Seven lots are implicated in this complaint, your firm has not identified which lot is related to the infection.

E. Work instruction for potency testing of API are not fully followed. The current version of Work Instruction form QG-1251A, "Potency Testing of API", effective 5/14/2025, as well as the previous version effective 10/28/2021 states that testosterone reference standard calibration curve and QCs need to be made (b) (4) However, Since the beginning of 2024 your firm has been making reference standard calibration curves (b) (4) Reference standard calibration curves are used for the finished product UV-VIS

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potency testing of testosterone/cholesterol and testosterone/stearic acid pellets conducted in-house by Qualgen quality control employees per test method TM-0001 "Test /Method Analysis of Testosterone Pellets by UV/VIS Spectrophotometer", effective 7/13/2025.

F. Your firm's procedure for operation and use of the (b) (4) as part of Testosterone granulation is not fully followed. On 8/19/2025, we observed the use of non-pharmaceutical grade plastic (b) (4) baggies were observed being used as a make-shift hopper cover and for collection on the bottom of your (b) (4) used for particle size reduction in testosterone granulation operations, lot (b) (4) The Operational SOP for (b) (4) QG-1249, effective 1/27/2024, does not include directions to use (b) (4) baggies during the granulation process. The (b) (4) baggies used during granulation are non-sterile food grade and have not been evaluated and approved for use in production by the quality unit.

G. Your firm's procedure for receipt of materials and components is not fully followed. Your firm's procedure QG-1239, "Material Management and In-Process Controls", effective 8/14/2025, states all raw materials must be logged into the raw material receiving log, QG-1239D and all incoming materials must be logged into QG-1239B. After the materials are logged the Product Receiving form, QG-1239D (QG1239A for raw materials), must be completed for all incoming materials and components. On 3/27/25, (b) (4) x 22-ounce bottles of (b) (4) were delivered to Qualgen LLC, 511 Hundred Oaks Dr, Ste 160 and received by Qualgen logistics personnel. As of 8/19/2025, these cleaning materials was not logged in a receiving log or on a product receiving form.

OBSERVATION 3

The quality control unit lacks responsibility to reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically,

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Your firm failed to evaluate a HEPA filter in the ISO-(b) (4) Testosterone cleanroom that was certified with no airflow. This room was certified in May 2025 and the certification report shows the (b) (4) HEPA filter was not providing any airflow. This room is designed with (b) (4) HEPA filters. Your firm's quality and production management were not aware that this HEPA filter was receiving no airflow and could not provide a date when the HEPA filter air supply was cut off. This room has been routinely used for granulation and compression of Testosterone since the certification on 5/02/2025. Your firm's last certification with a working (b) (4) HEPA filter in the Testosterone suite was 10/30/2024.

In addition, your firm's procedure QG-1256, "HEPA Filter Certification", effective 12/23/2024 rev. 1a states that "Any indication of poor air control (e.g., non-unidirectional, turbulent) must be corrected before use."

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

REPEAT OBSERVATION FROM INSPECTION CONDUCTED 2/6/2024 – 3/19/2024

Specifically,

Your firm's revalidation of (b) (4) asset (b) (4) during sterilization of stoppers, (b) (4) (b) (4), performed on 5/1/2025, utilized in the container closure of vialed pellets did not meet the maximum load or time for the cycle used in production. Your firm's production oven cycle is (b) (4) or (b) (4) stoppers across (b) (4) rays and (b) (4) shelves. The validated cycle is (b) (4) or (b) (4) stoppers across (b) (4) trays and (b) (4) shelves. In addition, your firm does not have load patterns documented in any procedure, work instruction, or training material for new operators. The load pattern for stoppers is also not included in the revalidation protocol. Cycle parameters are also not verified by a second reviewer during production or batch review. The (b) (4) temperature and time are (b) (4) set by a single operator prior to each cycle run.

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OBSERVATION 5

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

Specifically,

A) Your firm's environmental monitoring alert and action limits are not scientifically justified. Your firm's procedure for environmental monitoring, QG-1218, "Environmental Monitoring", effective 07/03/2025, states that the personnel fingertip sample alert and action levels in ISO-(b)(are ≥2 CFU and ≥5 CFU, respectively. Your firm's Director of Quality stated that these limits were taken from USP <1116> and USP <797>, however, your firm has not evaluated the suitability of those levels within your operations. For example, your firm recovered mold during personnel fingertip sampling but did not investigate or identify the recovered organism to the species level based on the action level. Estradiol 18mg, lot K113, exp 4/14/2026 produced on 4/28/2025 had one mold CFU recovered from the glove of a production technician. Testosterone 37.5mg, lot K185, exp 6/16/2025 produced on 6/23/2025 had one mold CFU recovered from the glove of a production technician.

B) Your firm does not sample the table or the equipment utilized during milling of testosterone API for microbial growth. The (b) (4) table and (b) (4) is a high traffic area that is frequently touched during granulation and milling of Testosterone API. Your firm's QC Director stated that this area was missed when developing sample locations and agreed that it should be routinely sampled.

*DATES OF INSPECTION

8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri), 8/25/2025(Mon), 8/26/2025(Tue), 8/27/2025(Wed), 8/28/2025(Thu), 8/29/2025(Fri), 9/04/2025(Thu)

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EMPLOYEE(S) SIGNATURE

Logan T Williams, Investigator
Zachary L Stamm, Investigator

X Zachary L Stamm
Investigator
Signed By: ZACHARY L. STAMM
-S
Date Signed: 09-04-2025
15:01:17

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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."