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 ORAPHARM2_RESPONSES@fda.hhs.gov	9/13/2022-9/30/2022* FEI NUMBER 3011286349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Shaun P. Riney, CEO/Managing Partner	
FIRM NAME Qualgen, LLC	STREET ADDRESS 14844 Bristol Park Blvd
CITY, STATE, ZIP CODE, COUNTRY Edmond, OK 73013-1891	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

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

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

Specifically,

a) Quality Assurance (QA) is (b) (4) Work Orders per SOP QG-1158 Generating Work Orders, revision 0 effective June 29, 2021.

In addition, the system for documenting Work Orders is deficient. For example, Work Orders do not always contain sufficient information regarding the activities/tasks actually performed. Proposed solutions are sometimes noted in the Work Order however, your firm does not always document if the proposed solution was performed and/or what other tasks were performed to complete the Work Order. For example, Work Order (b) (4) noted as opened and closed on June 17, 2022, states the "(b) (4) has a 1 X 1 inch area under paint that is corroded". In speaking to the QC employee who opened and closed the work order, the proposed solution was not performed and instead the blower was removed from the unit. This was not documented in the work order.

b) Your firm failed to assess your cleaning/disinfection procedure after residue from cleaning/disinfection agents was found to have accumulated on railings and other surfaces in the ISO 7/ISO 8 Cleanrooms. Work Orders (b) (4) created July 16, 2022 and (b) (4) created August 27, 2022 were initiated to remove the residue however, no evaluation was performed by QA to determine if the current cleaning/disinfection process is appropriate and/or adequate.

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	Patty P Kaewussdangkul, Investigator Margaret M Annes, Investigator	X Margaret M Annes Investigator Signed By: Margaret M. Annes -S Date Signed: 09-30-2022 09:39:13	9/30/2022

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c) CAPA 21-0005 was created due to a previous 483 observation regarding documentation of work orders and failure to complete opened work orders. CAPA 21-0005 does not contain documentation of the completion of the tasks identified including entering all open Work Orders from 2019-2021 that were "captured on the cleanroom inspection forms as well as ones that were documented in the work order logbooks from during this time". QA signed the CAPA as completed on December 21, 2021.

d) Your firm has no written procedures for the re-packaging of non-sterile (b) (4) caps used for vials of hormone pellets. The (b) (4) caps are re-packaged by your firm from bulk into (b) (4) for entry into the ISO 7/8 Cleanrooms in the unclassified area of the facility. In addition, Change Request (CR) #(b) (4) removed the requirement to (b) (4) caps in the (b) (4) in the ISO 8 Prep Room (b) (4) into the ISO 7 Cleanroom. The non-sterile caps are then opened/exposed in the ISO 7 Cleanroom where (b) (4), and (b) (4) of hormone pellets occurs. Your firm did not assess or perform a study to demonstrate that the (b) (4) caps do not pose an added risk to bioburden and/or cleanliness of the cleanroom. CR (b) (4) states the (b) (4) caps are "(b) (4)" however, there is no definition or documentation of what "(b) (4)" means.

e) The Final Report for Study (b) (4) used to support Change Request (CR) #(b) (4), was not signed by QA. (b) (4) is a (b) (4) to be used in lieu of cleanroom goggles. CR (b) (4) was signed by QA on June 9, 2022 however, the form does not indicate if the change was approved or rejected.

f) Your firm has no documentation of an assessment/evaluation of the (b) (4) used for (b) (4)) used in making hormone pellets, including whether it is appropriate of use in pharmaceutical manufacturing and if your current process for cleaning the tooling is appropriate.

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g) Your firm failed to fully implement Change Request (CR) (b) (4). The CR stated that sampling of the (b) (4) will be conducted during gowning qualification, however sampling of the (b) (4) was never conducted and not integrated in your gowning qualification forms.

OBSERVATION 2

Written procedures are not followed that describe the examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

Your firm is not conducting an AQL sampling and inspection of vials (hormone pellets) after (b) (4)

OBSERVATION 3

Drug products failing to meet established specifications are not rejected.

Specifically,

Your firm's SOP entitled, "Release or Rejection of Sterile Pellet Drug Products and Specifications" Document QG-1144, Effective 17 August 21 states that (b) (4) . However, On February 11, 2022 your firm's Quality Control Unit approved and released a lot of Testosterone/Cholesterol 200mg sterile pellets, Lot (b) (4) that failed thickness, a release specification. This lot was distributed to several states.

OBSERVATION 4

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Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,
Your firm does not follow your SOP entitled, "Handling of Complaints" QG-1069, Revision 5, Effective 17 Jun 22, regarding how to receive, document and conduct complaint investigations. There were consumer complaints that did not have a conclusion, were not properly documented, not adequately investigated, and/or have not been closed (b) (4) from initial complaint receipt. For example,

- Complaint CIN-22-012 dated April 7, 2022 stated that five patients from one clinic had infections after the implantation of your firm's Testosterone/Cholesterol pellets, Lot (b) (4) and (b) (4). Your firm's investigation did not document the conclusion/outcome in the customer inquiry/complaint record but was closed by QA on June 29, 2022.
- Complaint CIN-22-036 received July 15, 2022: Your firm received an email from the complainant asking to speak to someone about a potential problem with pellets from your firm. Your sales representative spoke with the clinic but did not initiate a customer inquiry/complaint record to state the nature and details of the complaint or products affected. An email sent to the complainant by your Director of Sales on July 18, 2022 mentions that the complaint was regarding two infections. No other follow up was conducted by your Quality Unit and this complaint was still open at time of inspection. The complaint file consisted of a few emails with the clinic.
- Complaint CIN-22-033 dated July 1, 2022 regarding "poor response from pellets" was still open at time of inspection and your firm has not conducted an investigation regarding this complaint. The lot numbers listed in this complaint are:
  - Testosterone/Cholesterol 200mg, Lot (b) (4).
  - Testosterone 200mg/Anastrozole 20mg, Lot (b) (4).

OBSERVATION 5

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

Specifically,
a) Your firm uses Testosterone API from (b) (4) different manufacturers to make hormone pellets. Your firm has no documented justification for not including in each (b) (4) dose audit/bioburden testing lots of Testosterone pellets made with Testosterone API from each manufacturer.

b) Your firm uses (b) (4) to communicate with your technicians located in the cleanrooms during the production of hormone pellets that are charged and stored in an unclassified area. On 9/14/2022, we observed a technician (b) (4) the (b) (4) with (b) (4) but fail to fully wipe down the headphones to ensure it was appropriately disinfected prior to entry from an unclassified area to the ISO8 anteroom. Furthermore, your firm has not determined if the (b) (4) used to disinfect the (b) (4) is suitable for use in disinfecting the (b) (4)

OBSERVATION 6
Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,
Your firm conducts potency testing ((b) (4)) of your hormone pellets containing estradiol or testosterone in house. The test methods require the use of (b) (4) as a reagent for the (b) (4) solution needed to perform the test however, your firm is not using pharmaceutical or laboratory grade (b) (4) instead your firm is using (b) (4) brand (b) (4) . There is no assurance that the (b) (4) brand (b) (4) is suitable for its intended use.

OBSERVATION 7

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Written procedures are lacking for the use of cleaning and sanitizing agents designed to prevent the contamination of equipment.

Specifically,
On 9/13/2022 and 9/14/2022, we observed the top of a container of (b) (4) wipes left open in the ISO8 anteroom after the technician was finished gowning. The container was closed as soon as we mentioned it to your firm. However, on 9/15/2022, the same container top was left open for at least (b) (4). Your firm uses the (b) (4) wipes to disinfect the (b) (4) located in the ISO8 anteroom and to disinfect the (b) (4) that technicians don over their sterile hood prior to entry into the ISO7 rooms used in the production of hormone pellets. Your firm does not document the lot number of the wipes on cleaning logs. Furthermore, your firm has not established a use by date of the (b) (4) wipes after opening of the container.

OBSERVATION 8
Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,
Your firm's batch production records for your hormone pellets are deficient in that:
a) Active Pharmaceutical Ingredients (API) such as Testosterone, Estradiol and/or Anastrozole are not properly weighed out during the (b) (4) instead a (b) (4) is used to measure out the API used in each (b) (4) batch.
b) Batch production records do not include complete labeling including specimens or copies of all labeling used for each batch of drug product produced. For example, your firm does not include an example/copy of the (b) (4) packaging labeling.
c) No documentation or justification of established production time limit deviations. For example, your firm has established a production limit of (b) (4) and (b) (4) for the production of Testosterone Pellets 200mg however, Lot # (b) (4) exceeded this timeframe and there was no explanation

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found on the batch production record.

OBSERVATION 9

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

Specifically,

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

a. The quantity or volume.

Examples of your drug product labels that do not contain this information:

Estradiol 6mg Pellet,
Estradiol 25mg Pellet,
Testosterone 25mg Pellet
Testosterone 200mg Pellet

***DATES OF INSPECTION**

9/13/2022(Tue), 9/14/2022(Wed), 9/15/2022(Thu), 9/16/2022(Fri), 9/19/2022(Mon), 9/20/2022(Tue), 9/22/2022(Thu), 9/23/2022(Fri), 9/27/2022(Tue), 9/29/2022(Thu), 9/30/2022(Fri)

X Patty P Kaewussdangkul
Investigator
Signed By: Patty P. Kaewussdangkul -S
Date Signed: 09-30-2022 09:39:51

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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."