DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	8/24/2015-9/17/2015* FEI NUMBER 3011286349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shaun P. Riney , General Manager

FIRM NAME	STREET ADDRESS
Qualgen LLC	14844 Bristol Park Blvd
CITY, STATE, ZIP CODE, COUNTRY Edmond, OK 73013	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

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

a) Your firm lacks meaningful data for environmental monitoring. Your firm is performing environmental sampling (viable air and surface samples) in the ISO 5 (b) (4) and ISO 7 cleanrooms (b) (4) and not during and/or at the end of production.

b) Your firm has not established alert and action limits for environmental monitoring of surfaces and air (viable) in the ISO 5 (b) (4) ISO 7 cleanrooms, the ISO 8 Prep Room and ISO 8 Ante Room (b) (4) Examples of environmental monitoring excursions for which your firm has no documentation of an investigation being performed and the isolate(s) were not identified include the following.

i. On 7/27/15 during viable air sampling, 4 CFU were found in the ISO 5 (b) (4) in the (b) (4) Lab (b) (4) Your firm made lot #A039 of estradiol pellets 20mg on 7/27/15 in the (b) (4) Lab (ISO 7 cleanroom where the ISO 5 (b) (4) is located). You placed these pellets into vials under the ISO 5 (b) (4) on 7/28/15.

ii. On 7/31/15, during surface sampling of the (b) (4) (b) (4) your firm documented a count of TNTC (too numerous to count). Your firm (b) (4) (b) (4) (b) (4) (b) (4) (b) (4)

iii. On 8/3/15, your surface sample taken on the (b) (4) had a count of TNTC (too numerous to count). Lot #A045 of Testosterone 87.5mg pellets was

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made on this date.

iv. On 8/5/15, your environmental monitoring sample for viable air taken in the (b) (4) (b) (4) (b) (4) in the (b) (4) (b) (4) had a count of TNTC (too numerous to count). Lot #A047 of Testosterone Pellets 25mg was made in the room on 8/4/15 and placed into vials on 8/4/15. Your documentation is not complete to show who vialed the product and if vialing operations continued on 8/5/15; however, your firm (b) (4) the pellets on 8/5/15.

v. On 8/14/15, your environmental monitoring surface sample taken in the ISO 5 (b) (4) (b) (4) in the (b) (4) Lab (b) (4) showed 1 CFU. Your firm made lot #A054 of Estradiol 25mg pellets on 8/13/15 and put the pellets into vials on 8/14/15 under the ISO 5 (b) (4) (b) (4)

c) Your firm failed to monitor personnel gloves at least daily during periods of production. Your Pharmacist stated that they are to be sampling their gloves (b) (4) however, the employees working in the ISO 7 cleanroom (b) (4) Lab 1) on 8/24/15 did not sample their gloves after the production of Lot #A061 of Testosterone 25mg pellets. Your firm does not have documentation of employees sampling their gloves (b) (4) that production occurs. In addition, your firm does not have a written procedure that defines how often employees are to be sampling their gloves.

d) Your firm has not established alert and action limits for personnel monitoring of employees involved in making the testosterone and estradiol pellets. Examples of personnel monitoring excursions for which your firm has no documentation of an investigation being performed and the isolate(s) were not identified include the following.

i. On 7/30/15, employees (b) (6) and (b) (6) both had 1 CFU on their glove. Lot #A046 of Testosterone 100mg pellets was made on this date.

ii. On 8/5/15, employee (b) (6) had 1 CFU on their glove. Lot #A047 of Testosterone Pellets 25mg was made in the room on 8/4/15 and placed into vials on 8/4/15. Your documentation is not complete to show who vialed the product and if vialing operations continued on 8/5/15; however, your firm (b) (4) the pellets on 8/5/15.

iii. On 8/14/15, employee (b) (6) had 1 CFU on their glove. Your firm made lot #A054 of Estradiol 25mg

pellets on 8/13/15 and (b) (4)(b) (4) (b) (4)

e) Your firm failed to respond to, and investigate instances of positive pressure loss. The (b) (4) ISO 7 cleanrooms, (b) (4) are equipped with pressure differential indicating magnehelic gauges. Logs documenting the monitoring of pressure differentials during operations show that from 6/23/15 to 7/6/15 the gauge showing the pressure differential between the ISO 8 Ante Room and the unclassified area was at zero. On 7/6/15, there is a hand written note on the log stating that someone "...called to have fixed". Employees (b) (4) (b) (4) used for production of estradiol and testosterone pellets and granulations. From (b) (4) your firm made the following products in the ISO 7 cleanrooms:

- Estradiol granulation lots: (b) (4)
- Estradiol pellet lots: (b) (4) pellets)
- Testosterone granulation lots: (b) (4)
- Testosterone pellet lots: (b) (4)

f) Your firm is not monitoring pressure differentials periodically during production and you do not document the time that the pressure differential is measured each day.

OBSERVATION 2
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

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Specifically,

a) Your firm has not validated the sterilization process for any of the drug products that you prepare. Your firm prepares testosterone and estradiol pellets of varying strengths from bulk non-sterile APIs and excipients, (b) (4)(b) (4) them. The (b) (4) currently being used is (b) (4) A final report dated 6/4/15 for the qualification of the (b) (4) used by your firm to (b) (4) the pellets and stoppers notes that there was(b) (4) growth in some (b) (4)(b) (4) (b) (4)

   i. Your firm has had 4 sterility failures in the last two months. These include:
   ii. Lot #A023 of Estradiol 18mg (organism identified as *Propionibacterium acnes*)
   iii. Lot #A025 of Testosterone 25mg (organism has not been identified yet)
   iv. Lot #A031 of Testosterone 87.5mg (organism identified as *Staphylococcus epidermis*)
   v. Lot #A036 of Testosterone 37.5mg (organism has not been identified yet)

b) Your firm does not have documentation of smoke studies having been performed under dynamic conditions in the ISO 5 (b) (4) located in the two ISO 7 cleanrooms(b) (4) Lab 1 and (b) (4) .

c) On 8/24/15, while (b) (4)from lot #A061 of Testosterone 25mg (b) (4), the operators were observed using their gloved hands to move around the vials in the tray and then (b) (4) The operators were seen touching the top opening of the vials. These vials had already been processed in the (b) (4)

d) After the pellets are (b) (4) by the operator using their gloved hand.

e) On 8/24/15, at the end of operations for the day, the (b) (4) that had been processed in the (b) (4) (b) (4)but (b) (4)the ISO 5 (b) (4) in the (b) (4) Lab (Lab 1). (b) (4) (b) (4) Lot #A061 of Testosterone 25mg pellets was made on 8/24-25/15.

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OBSERVATION 3

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, your firm has not validated the cleaning, sterilization and depyrogenation process for the stoppers and vials used by your firm to package testosterone and estradiol pellets.

Stoppers (b) (4) are (b) (4) (b) (4) (b) (4) (b) (4) and then (b) (4) (b) (4) (b) (4). Approximately (b) (4) stoppers are (b) (4) (b) (4) (b) (4) The (b) (4) (b) (4)

Your firm has also not validated the sterilization of stoppers multiple times. For example, lot #A065 of Estradiol 22mg pellets had some stoppers that were initially (b) (4) on 8/28/15. The stoppers were not used in production that day and were (b) (4)(b) (4) (b) (4) and (b) (4) on 8/31/15.

(b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4). The vials are then (b) (4) (b) (4) (b) (4) (b) (4)

OBSERVATION 4

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Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

a) The ISO 8 Prep Room floor has holes cut through it for piping for hot water and cold water, as well as a waste pipe for sink (b) (4) These holes have not been closed or sealed in a way to generate a smooth cleanable surface. The concrete floor under the flooring can be seen around all 3 pipes, where a circle had been cut for each pipe. The surface underneath the sink has not been sealed the way other floor obstructions/irregular objects in the clean room were sealed. Your firm's General Manager stated that the floor was put in after the sink was installed; however the contractor had a difficult time installing the floor around the sink's pipes. The ISO 8 Prep Room is used to (b) (4)
(b) (4)
(b) (4)

b) Specifically, plumbing for sink (b) (4) drainage, waste and venting system is not constructed in a way to prevent airborne contaminates from entering the cleanroom from the sewer. Under the sink in your firm's ISO 8 Prep Room, the falling waste drain is equipped with a (b) (4) air vent on top of the vent stack. The open air gaps on the vent show no signs of filtration of the sewer air entering the room; furthermore, vials and stoppers used in production, (b) (4)
(b) (4)(b) (4)

c) The ceiling of the ISO 7 cleanrooms, the ISO 8 Prep Room and ISO 8 Ante Room is constructed of (b) (4) Panels are equipped with a (b) (4)
(b) (4) There is a noticeable lip between the panel and support rail that allows for the collection of production dust and airborne particulates. Also, the seals do not totally enclose the circumference of each ceiling tile, allowing open access directly into the ISO 7 (b) (4) Room and the ISO 8 Prep Room from the adjoining unclassified areas above and about. A narrow open gap was observed running along the length of an entire panel on the north east side of the ISO 8 Prep Room. On the same tile, a 2 inch by ½ inch gap was observed where the (b) (4) filler was missing. This allows direct/unobstructed observation into the

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cleanroom from the warehouse. A significant amount of air from the ISO 8 Prep Room was noticed coming out of the holes and gaps on 8/27/15.

d) According to the General Manager, one corner of the clean room has too much pressure and the panel can physically fly off the top of the preparation room. To correct this issue, the firm has used additional (b) (4) sealant around the gasket and placed several jugs of sterile water on top of the panel to facilitate the formation of a new seal. Another jug of water for injection was observed, holding down one panel of the ceiling to the (b) (4) compounding room, (b) (4)

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

a) Your firm has had four (4) sterility failures in the past 2 months. Your investigation into the failures failed to include all potential items that may have contributed to the failure including the fact that the sterilization process has not been validated. A final report dated 6/4/15 for the qualification of the (b) (4) (b) (4) used by your firm to (b) (4) the pellets and stoppers notes that there was (b) (4) (b) (4) growth in some (b) (4) (b) (4)

b) **Lot #A017 of Estradiol 20mg pellets**: This lot was part of process validation for this product. One of the samples tested for potency came back as 84.1%,which is below the potency range listed on your Certificate of Analysis (CoA) from your contract testing lab (b) (4) The CoA is dated 7/23/15. Your firm has no documentation of an investigation being performed into this failure.

c) **Lot #A050 of Estradiol 18mg pellets**: The original Certificate of Analysis (CoA) from your contract testing lab showed an assay value of 115.7% of label claim. Your firm released this lot for sale after the receipt of the test results from the lab. Your firm does not document in the batch records when the lot was released but the test results were received 8/26/15. When asked about the release of a product that did not meet label specifications, no one at your firm was certain of the exact final product specifications for potency. In addition, no one noted the discrepancy in the CoA from the lab in that the incorrect expected potency was listed. The lab amended the CoA on 9/8/15 to reflect the corrected result of 96.4%.

OBSERVATION 6

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

Specifically, your firm has not defined and put into writing all specifications for the release of each lot of drug products prepared by your firm. Your firm has not determined a drug release rate or any other physical quality outside of potency that might affect the quality of the testosterone and estradiol pellets made by your firm. When asked during the inspection on 9/8/15, no one at your firm was certain of the exact final product specifications for potency.

OBSERVATION 7

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

Your firm has not validated the process for making the testosterone and estradiol pellets.

OBSERVATION 8

In-process specifications are not consistent with drug product final specifications and derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate .

Specifically, your firm fails to ensure batch uniformity in that sample sizes and specifications for in-process testing of pellet weights were not established using suitable statistical procedures and do not conform to or are consistent with final product specifications. Your firm (b) (4) pellets (b) (4) Batch sizes have ranged from (b) (4) pellets for lot A033 testosterone 25 mg to (b) (4) pellets produced in lot A040 testosterone 200 mg. If (b) (4) of the (b) (4) pellets fall between (b) (4) (b) (4) The (b) (4)

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(b) (4) (b) (4) (b) (4). (b) (4) (b) (4) Examples of lots where there is least 1 pellet was outside of the weight range include:

a. Lot number A047 of Testosterone 25mg pellets, had 7 of the (b) (4) pellets that were outside of the established weight range of (b) (4) Three were below the range and 4 were above the range.
b. Lot number A051 of Estradiol 15mg pellets, had 4 of the (b) (4) pellets that were above the established weight range of (b) (4)
c. Lot number A053 of Estradiol 12.5mg pellets had 4 of the (b) (4) pellets that were outside of the established weight range of (b) (4)

OBSERVATION 9
The written stability testing program is not followed.

Specifically, your General Manager stated that the (b) (4) (b) (4) Your firm has no documentation to show that the lots of testosterone and estradiol pellets that have been placed on stability were packaged using the same vials and stoppers currently being used by your firm. Your General Manager stated that the (b) (4) (b) (4) (b) (4) the pellets. In addition, the lots of pellets were (b) (4) for (b) (4) and do not always reflect your current (b) (4)

Lots placed on stability include:

- 04201501-042015W of Estradiol 25mg pellets – this lot was packaged (b) (4). Your firm does not use (b) (4) This lot of pellets was (b) (4) (b) (4)

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- 05131501-051315Y of Testosterone 200mg pellets – there is no documentation of how the stoppers were prepared and there is no (b) (4) to show (b) (4) hey were (b) (4) This lot of pellets was (b) (4) (b) (4)
- 05131501-051515Z of Testosterone 25mg pellets – there is no documentation for the preparation of the vials and stoppers used. This lot of pellets was (b) (4) (b) (4) (b) (4)
- 05281501-060115F of Estradiol 6mg pellets – 5 of the (b) (4) checked (b) (4) were above the established weight range of (b) (4) There is no documentation of the preparation of the stoppers used. This lot of pellets was (b) (4) (b) (4).

OBSERVATION 10

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

Specifically,

a) Your firm does not have a written procedure describing the responsibilities of the quality control unit.
b) Your firm does not document the actual review and release of a lot of drug product.
c) Your firm does not have standard operating procedures that are specific to your firm's operations and that have been reviewed, approved and implemented.

OBSERVATION 11

Employees engaged in the manufacture and processing and packing and holding of a drug product lack the education and training and experience required to perform their assigned functions.

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Specifically, your firm has no documentation to show that employees have been trained to perform their job functions. The only documentation your firm has for training is a (b) (4) training courses. None of the training is specific to your firm's current operations or procedures.

OBSERVATION 12

The master production and control records are deficient in that they do not include complete manufacturing and control and instructions and sampling and testing and procedures and specifications .

Specifically,

a) Your firm does not document in the batch records for the testosterone and estradiol pellets, the date that the pellets were put into vials and by whom.
b) Your firm does not include in the batch records for the testosterone and estradiol pellets the (b) (4) for (b) (4) the pellets and stoppers.
c) Your firm does not require that the batch record include the (b) (4) printout be attached and verified for each (b) (4) of stoppers, pellets and crimp caps. Additionally, the master batch record does not include the (b) (4) to be used in the (b) (4) for pellets and stoppers including (b) (4)

OBSERVATION 13

Distribution records do not contain the name and strength of the drug product and description of dosage form and name and address of consignee and date and quantity shipped and lot or control number of drug product .

Specifically,

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a) Your firm is not always documenting the correct product and lot number being distributed. For example, in Packing Slip (b) (4) dated 7/28/15, your firm notes that (b) (4) pellets from lot #A018 of Testosterone 25mg and (b) (4) pellets from lot #A002 of Estradiol 25mg pellets were distributed. Your Head of Quality Assurance stated that when doing the lot reconciliation during the inspection, she thinks that no pellets from lot A002 were included in the shipment and that there were really (b) (4) pellets from lot #A018 in the shipment.

b) Packing Slip (b) (4) indicates that the product was shipped to a customer in (b) (4), (b) (6) however, the (b) (4) indicates that the product was shipped to a customer in (b) (4), (b) (6)

OBSERVATION 14

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

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:

- The statements, "This is a compounded drug" and "Not for resale" [sections 503B(a)(10)(A)(i) and 503B(a)(10)(A)(iii)(IX)].
- The date that the drug was compounded [section 503B(a)(10)(A)(iii)(V)].
- Storage and handling instructions [section 503B(a)(10)(A)(iii)(VII)].

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

- **Estradiol 6 mg pellet**
- **Testosterone 25 mg pellet**

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***DATES OF INSPECTION**

8/24/2015(Mon),8/25/2015(Tue),8/26/2015(Wed),8/27/2015(Thu),8/28/2015(Fri),8/31/2015(Mon),9/01/2015(Tue),9/03/2015(Thu),9/04/2015(Fri),9/08/2015(Tue),9/11/2015(Fri),9/17/2015(Thu)

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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."