DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Main Place 1201 Main St., Suite 7200 Dallas, TX 75202 214-253-5200 Industry Information: www.fda.gov/oc/industry	04/29/2021-06/15/2021
	FEI NUMBER 30112866349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Shaun P. Riney, CEO and Managing Partner

FIRM NAME	STREET ADDRESS
Qualgen LLC	14844 Bristol Park Blvd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Edmond, OK 73013	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 (I) (WE) OBSERVED:

OBSERVATION 1

Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closure, in-process materials, packaging materials, labeling, and drug products. The responsibilities and procedures applicable to the quality control unit are not in writing or fully followed.

Specifically,

a) On March 1, 2021, your firm began distribution of lot #(b) (4) of Testosterone Cypionate Injection 200mg/mL, labeled as a multi dose vial, before the results of the antimicrobial effectiveness test were received. The expiration date placed on the product was 17MAR21. On March 2, 2021, your contract testing lab notified your firm of a potential failure of the antimicrobial effectiveness test for the product. Your firm continued to distribute the lot until March 12, 2021. On March 16, 2021, your contract testing lab sent an email confirming failure of the antimicrobial effectiveness testing.

Your firm does not have a written procedure for the development, approval and release of new drug products for commercialization to ensure that all appropriate activities such as required testing, have been completed before release for distribution.

b) Your Quality Control Unit does not always document review and approval of changes prior to implementation. SOP QG-1129 cGMP Change Control, revision 3 effective September 2, 2020, states that "cGMP systems, processes, methods, materials, equipment, facilities, utilities, or documents may not be changed without a formal change control process done according to this procedure".

Examples of changes made without a change control include the following.

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	Margaret M. Annes	Margaret M. Annes, CSO Preston B. Hoover, CSO	06/15/2021

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I. At some point in January 2021, your firm implemented parametric release of sterile drug products (hormone pellets) without a change control. Requirements for validation, including protocols, (b) (4) dose audit requirements, procedures and other process controls and parameters were not defined and laid out in a change control.

II. In April 2021, your firm made a change to the visual inspection program for sterile hormone pellets that was not implemented via a change control. You changed the requirement for visual inspection of pellets post vialing from 100% inspection to an (b) (4) . Your firm did not evaluate whether the changes will meet the requirement to perform 100% visual inspection of sterile injectable/implantable drug products.

This is a repeat observation from the 08/2018-09/13/2018 inspection.

c) Your firm has no written procedures for how work orders, repairs and non-routine maintenance of facilities and equipment are to be documented, evaluated by Production and/or Quality as needed, and verified that activities have been completed.

For example,

I. Your firm does not have complete documentation related to repairs and maintenance that have been performed on all equipment, including the (b) (4) used for sterilizing stoppers, tweezers, and caps used for pellets. Failures of (b) (4) runs are noted in the logbook for the (b) (4) however, your firm does not always maintain documentation of the failures, including the printout from the (b) (4) indicating the failure or the batch records for the items that were being (b) (4)

Your firm does not always note what the failure was in the logbook for the (b) (4) or when a repair is performed. Failures that have been noted include low temperature and low water. Some repairs that have been reported include replacement of the water pump and exhaust assembly.

Your firm has not performed investigations of these failures or an evaluation to ensure the failures did not affect

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other items that had been sterilized.

II. Cleanroom Inspection Forms for inspections conducted in December 2020 and January, February, and March of 2021 reference issues that have not been corrected and Work Orders (WO) that were opened as far back as 2019 that have not been completed.

OBSERVATION 2

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

Specifically,

a) Your firm has no written procedures for conducting the (b) (4) test on (b) (4) used to make Testosterone Cypionate Injection 200mg/mL, including lot #(b) (4) that was compounded, (b) (4) , and vialed on January 16, 2021.

b) The process of removing cleanroom goggles due to fogging and the steps that should be taken by the technicians to deal with this issue are not defined in a written procedure.

c) On April 30, 2021, I saw a technician (b) (6) leave the ISO 7 (b) (4) Cleanroom, remove (b) (6) goggles in the ISO 8 Ante Room, dry goggles in the air coming from the door to the ISO 7 (b) (4) Room, place the goggles back on (b) (6) face, re-enter the ISO 7 (b) (4) Cleanroom without changing or spraying (b) (6) gloves, and then proceed to place a stainless steel cup used for pellets under the ISO 5 hood. The same technician left the ISO 7 (b) (4) Cleanroom several more times to clear (b) (6) goggles that were fogging up. At one point when placing the goggles back on (b) (6) face (b) (6) touched (b) (6) face with (b) (6) gloves. (b) (6) returned to the ISO 7 (b) (4) Cleanroom without changing gloves. Lot #(b) (4) of Testosterone 25mg pellets was made on that date.

On May 6, 2021, I saw the same technician leave the ISO 7 (b) (4) Cleanroom several times to remove (b) (6) goggles due to fogging. Several times I watched (b) (6) place (b) (6) goggles back on (b) (6) head without wiping them with a sterile (b) (4) wipe and then return to the ISO 7 (b) (4) cleanroom. Lot # (b) (4) of

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Estradiol Granulation was being made this day.

d) On May 6, 2021, I saw a technician (b) (6)) working in the ISO 5 BSC making Estradiol Granulation. (b) (6) came out of the BSC, removed (b) (6) sterile gloves, used the non-sterile gloves underneath to pull on both of the sleeves of (b) (6) gown, replaced (b) (6) sterile gloves and then went back to work in the ISO 5 BSC. Lot # (b) (4) of Estradiol Granulation was being made this day.

e) Cleanroom operators were observed placing utensils, such as a metal spatula, directly onto the surface (deck) of the ISO 5 biological safety cabinet during granulation of Estradiol lot # (b) (4) on May 6, 2021.

f) On May 10, 2021, I watched a technician gowning (b) (6). The technician grabbed the outer cuffs of the gown with non-sterile gloves. Lot #(b) (4) of Estradiol 12.5mg and lot #(b) (4) of Testosterone 87.5mg were made this day.

OBSERVATION 3

There are no written methods of cleaning or methods of processing to remove pyrogenic properties.

Specifically, your firm does not have a procedure for the sterilization/depyrogenation of glass beakers and cylinders and other utensils such as the (b) (4) used in the compounding of Testosterone Cypionate Injection. Your firm has no documentation to show that the glass beakers and cylinders and (b) (4) used in the production of lot #(b) (4) of Testosterone Cypionate Injection 200mg/mL on January 16, 2021 had been sterilized/depyrogenated before use.

OBSERVATION 4

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

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a) On April 30, 2021, I saw ready to use glass beakers and other equipment used to make the Testosterone Cypionate Injection drug product stored uncovered in the (b) (4) ISO 7 Cleanroom.

b) (b) (4) and (b) (4) used to make hormone pellets were found to have scratches, rust and/or discoloration. Examples include:

- (b) (4) (b) (4) for Testosterone 50mg
- (b) (4) (b) (4), Lower (b) (4) (b) (4) and Upper (b) (4) (b) (4) for Estradiol
- (b) (4) (b) (4), Upper (b) (4) (b) (4) and Lower (b) (4) (b) (4) for Testosterone 100mg
- (b) (4) (b) (4), Upper (b) (4) (b) (4) and Lower (b) (4)(b) (4) for Testosterone 100mg

There is no written procedure for (b) (4) the (b) (4) or (b) (4) and no documentation when specific (b) (4) or (b) (4) are(b) (4)

c) Your firm has no written procedures for how work orders, repairs and non-routine maintenance of facilities and equipment are to be documented, evaluated by Production and/or Quality as needed, and verified that activities have been completed.

For example, your firm does not have complete documentation related to repairs and maintenance that have been performed on all equipment, including the (b) (4) used for sterilizing stoppers, tweezers, and caps used for pellets. Failures of (b) (4) runs are noted in the logbook for the (b) (4) however, your firm does not always maintain documentation of the failures, including the printout from the (b) (4) indicating the failure or the batch records for the items that were being (b) (4)

Your firm does not always note what the failure was in the logbook for the (b) (4) or when a repair is performed. Failures that have been noted include low temperature and low water. Your firm provided several invoices for repairs that have been made to the (b) (4) in 2019 and 2020 that do not always list the (b) (4) being serviced and/or the repair activity being performed. Some repairs that have been reported include replacement of the water pump and exhaust assembly.

d) Work Order (WO) #06-10-20-02 (date created is not documented but the issue was observed April 30, 2020 that

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led to the creation of the WO) – states that "yellow painted brackets in (b) (4) chipping". This Work Order is still open and the issue has not been corrected. The(b) (4) are used to make hormone pellets.

e) Your firm does not monitor the temperature for the refrigerator where the reference standard for testosterone is stored.

OBSERVATION 5

Changes to written procedures are not reviewed and approved by the quality control unit.

Specifically, your firm does not always document review and approval of changes prior to implementation. SOP QG-1129 cGMP Change Control, revision 3 effective September 2, 2020, states that "cGMP systems, processes, methods, materials, equipment, facilities, utilities, or documents may not be changed without a formal change control process done according to this procedure".

Examples of changes made without a change control include the following.

III. At some point in January 2021, your firm implemented parametric release of sterile drug products (hormone pellets) without a change control. Requirements for validation, including protocols, (b) (4) dose audit requirements, procedures and other process controls and parameters were not defined and laid out in a change control.

IV. In April 2021, your firm made a change to the visual inspection program for sterile hormone pellets that was not implemented via a change control. You changed the requirement for visual inspection of pellets post vialing from 100% inspection to an (b) (4). Your firm did not evaluate whether the changes will meet the requirement to perform 100% visual inspection of sterile injectable/implantable drug products.

OBSERVATION 6

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

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Specifically,

a) The technicians working in the cleanrooms have goggles that are fogging up making it difficult to see. The operators will go from the ISO 7 cleanrooms to the ISO 8 Ante Room, remove their goggles and hold them up to the door to the ISO 7 (b) (4) Room ((b) (4) so that the air coming from the door can be used to de-fog the goggles. The technicians will then place these goggles back on their face and enter the ISO cleanrooms again. Sometimes the technicians will wipe the goggles with a sterile (b) (4) wipe before replacing them on their head and other times they did not. The process of removing goggles due to fogging and the steps that should be taken are not defined in a written procedure.

b) On April 30, 2021, I saw a technician working in the ISO 8 Prep Room preparing stoppers for sterilization, with hair coming out of (b) (6) hairnet.

OBSERVATION 7

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

Specifically,

a) Your firm has not evaluated whether not drying the testosterone reference standard as noted in the directions on the certificate from USP, has any effect on the assay testing performed on testosterone hormone pellets.

b) Your firm has no documentation for the validation of the endotoxin method used for the testing of the Testosterone Cypionate Injection 200mg/mL.

OBSERVATION 8

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

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Specifically, on various days including May 4, 2021, we observed the technicians working in the ISO 7 cleanrooms and ISO 8 Prep Room placing their gowning supplies on the single bench in the ISO 8 Ante Room with their bare hands without spraying the bench before placing them down or spraying/wiping the outer packages after touching them with ungloved hands before opening them for gowning. Lot #(b) (4) of Estradiol 18mg was made on May 4, 2021.

OBSERVATION 9

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design or suitably located to facilitate operations for its cleaning and maintenance.

Specifically,

a) There are (b) (4) hoods in the (b) (4) ISO 7 Cleanroom. (b) (4) Biological Safety Cabinet (BSC) (b) (4) Laminar Flow Hood (LFH). (b) (4) BSC was moved to it's current position to accommodate the (b) (4) LFH used for the compounding of Testosterone Cypionate Injection. The outlet needed to plug in equipment such as the non-viable particle counter and (b) (4) used for Estradiol granulation, is now behind (b) (4) BSC. The gowned operators are not able to plug in the equipment without rubbing their gown against the wall of the cleanroom and/or the side of (b) (4) BSC. We observed the operator plugging in the NVP counter on various dates including May 4, 2021.

SOP QG-1096 Aseptic Processing, revision 5 effective July 21, 2020, states under section 8.1.2 that "(b) (4) . (b) (4) ". PPE is defined as "Personal Protective Equipment which is worn to protect the aseptic environment from normal human flora".

b) On May 4, 2021, I saw the technicians working in the ISO 7 Cleanrooms and ISO 8 Ante Room and Prep Room, wheel the non-viable particle counter on a chair from the ISO 8 areas to the ISO 7 cleanroom areas without wiping down the entire chair. The chair was wheeled over the clean/dirty demarcation line in the ISO 8 Ante Room where gowning occurs to move it into each of the ISO 7 Cleanrooms ((b) (4) and (b) (4)). Your

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QC on the Floor employee stated that they were not to be moving the non-viable particle counter from room to room on a chair but instead should hand carry to each room and wipe down before using.

c) Stickers could be seen on the cleanroom chairs used in the ISO 7 (b) (4) Room (b) (4) ISO 7 (b) (4) Room (b) (4) and Prep Room. The stickers could be seen peeling away from the metal backsides of the chairs, including the chair that was used to wheel the non-viable particle counter between ISO 8 and ISO 7 areas.

OBSERVATION 10

Drug product 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 conducted a hold time study to justify the use of sterilized stoppers for vialing of hormone pellets beyond the date of sterilization. Examples of stoppers being used days after sterilization while being stored in an ISO 8 Prep Room include the following:
a) Lot #(b) (4) of Testosterone 87.5mg pellets – the rubber stoppers used were sterilized on 11/23/2020 and 12/04/2020 and used in the final product vialing on 12/09/2020.
b) Lot #(b) (4) of Testosterone 50mg pellets – the rubber stoppers used were sterilized on 12/04/2020 and used in the final product vialing on 12/12/2020.
c) Lot #(b) (4) of Testosterone 25mg pellets – the rubber stoppers used were sterilized on 11/25/2020 and used in the final product vialing on 12/14/2020.
d) Lot #(b) (4) of Estradiol 18mg pellets – the rubber stoppers used were sterilized on 12/09/2020 and used in the vialing of final product on 12/14/2020.
e) Lot #(b) (4) of Testosterone 200mg pellets – the rubber stoppers used were sterilized on 04/15/2021 and 04/19/2021, and used in the final product vialing on 04/28/2021.

OBSERVATION 11

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

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Specifically, SOP QG-1002 Cleanroom Inspection, revision 1 effective October 3, 2018, states that the purpose for routine (b) (4) inspections of the cleanrooms is "(b) (4) ". Cleanroom Inspection Forms for inspections conducted in December 2020 and January, February, and March of 2021 reference issues that have not been corrected and Work Orders (WO) that were opened as far back as 2019 that have not been completed. These include the following:

a) WO #10-23-19-01 created on 10/23/2019 – order to re-caulk/re-seal base and top boards and some ceiling tiles in the cleanrooms
b) WO #11-12-19-02 created on 11/12/2019 – ceiling above the BSC in the (b) (4) room needs to be replaced
c) WO #06-10-20-02 (date created is not documented but the issue was observed April 30, 2020 that led to the creation of the WO) – "yellow painted brackets in (b) (4) chipping"

OBSERVATION 12

Routine calibration of automatic, mechanical, and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, balances used for in-process weight checks, finished product release, and finished product release testing are not calibrated bracketing the range of use. The first test point after zero is (b) (4) or (b) (4). The maximum weight of any pellet is (b) (4).

OBSERVATION 13

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

Specifically, the current versions of the batch record for granulation of testosterone to be used in all testosterone

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pellets, does not reflect the current process. The batch records state that you are using an (b) (4) instead of the (b) (4) that was put into production in December 2020. The operators are making (b) (4) changes to the batch record to reflect the use of the (b) (4) however, the batch records lack certain information regarding the operations of the (b) (4) such as the speed the equipment is to be set at for granulation that was contained in previous versions of the batch record.

OBSERVATION 14

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 list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

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

a. Testosterone 200mg/ Anastrazole 20mg Pellets

Per section 503B(a)(10)(B)(i), this information should be included in/on the container if there is no space on the label for such information.

OBSERVATION 15

The containers of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

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

b. Testosterone 200mg/ Anastrazole 20mg Pellets

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6/15/202

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 judgement, 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."