OBSERVATION 1

You produced beta-lactam drugs without providing adequate containment, cleaning of work surfaces, and cleaning of utensils to prevent cross-contamination.

Specifically,

Beta-lactam drugs are produced in non-designated areas sharing the same work surfaces and equipment that are also used to produce non-beta-lactam drugs, of which are not cleaned/sanitized with bleach and isopropyl alcohol (70%) to provide adequate inactivation of the drug. For example, the following prescriptions for beta-lactam drugs were produced on work surfaces and equipment that were cleaned/sanitized with (b) (4) and later used to produce non-beta-lactam drugs, which may be at risk of cross-contamination:

- Rx (b) (6) Amoxicillin capsules 150mg on 4/25/2018
- Rx (b) (6) Cyclophosphamide capsules 13mg on 7/19/2018
- Rx (b) (6) Cyclosporine liquid suspension 50mg/mL on 7/13/2018

Additionally, there are no controls or procedures in place for production of beta-lactam drugs to be contained within a separate air handling unit. The use of (b) (4) HEPA-filtered containment hoods for production of beta-lactam drugs is optional, as reported by the pharmacist-in-charge.
OBSERVATION 2

Cleaning methods are not established in a written procedure nor are appropriate cleaning agents specified.

Specifically,

a.) Drug product production equipment such as capsule filling trays and spatulas/mortars/pestles/spinners are not rinsed with purified water and/or sanitized with appropriate sanitizing agents after cleaning with hot water and dish soap.

b.) There are no defined/labeled areas for storage of “clean” and “unclean” drug production equipment/utensils and cloth cleaning towels. These items were observed on counter tops in the cleaning area by the 2-compartment sink without identification of “clean” or “unclean” status or any other unique identifier.

c.) There are no cleaning procedures defining what cleaning/sanitizing agents are acceptable and when/how to use them. For example, (b) (4) is used to clean/sanitize benchtops and analytical balances after use for each drug product produced (witnessed after production of budesonide capsules 1mg: Rx (b) (6) and metronidazole capsules 62.5mg: Rx (b) (6)); however, (b) (4) may also be used to clean/sanitize benchtops as well, as reported by the pharmacist-in-charge. Additionally, there are no specified cleaning/sanitizing agents (bleach and IPA 70%) or instructions for cleaning work surfaces and equipment after production of beta-lactam containing drug products.
OBSERVATION 3

Analytical balances, used for weighing drug materials/components, are not uniquely identified nor appropriately calibrated on a periodic basis, nor periodically weight checked with an appropriate certified weight set. Examples include, but not limited to:

- (b) (4) (Model [b] (4])
- (b) (4) (Model [b] (4])
- (b) (4) (Model [b] (4])
- (b) (4) (Model [b] (4])

No calibration or maintenance records for the aforementioned analytical balances, used for drug product production, were provided. During production of a prescription fill for budesonide capsules 1mg on 7/27/2018 (Rx [b] (6)) it was observed that a non-calibrated analytical balance was used.

OBSERVATION 4

Prescription production records are deficient in that they do not include the following:

- name of manufacturers, lot numbers, and expiry dates of all materials/components used.
- identification of any automated, mechanical, or electronic equipment that is used during drug processing; e.g. analytical balances.
- proof or second-check verification of weights/volumes recorded for each component used.

For example, the prescription production records for a prescription fill of a tramadol suspension 20mg/mL (Rx [b] (6)) on 7/09/2018 lack these aforementioned items.
OBSERVATION 5

Your pharmacy does not have an established training program for technicians nor do you maintain any training record documentation for on-the-job training that was provided to them. Dosage forms prepared by technicians range from aqueous solutions, oils/suspensions, capsules, chew treats, eye drops, to transdermals.

OBSERVATION 6

Appropriate protective apparel is not always worn by technicians to protect drug products from contamination during production. Specifically, several technicians were observed producing drug formulations without hair nets and/or designated gowning/apparel during the inspection. For example, during production of metronidazole capsules 62.5mg (Rx (b) (6) on 7/31/2018 a technician with long hair was observed without a hairnet.

OBSERVATION 7

Your pharmacy does not have established written procedures for handling and maintaining records for quality-related events, such as for complaints, ADE/MedWatch reporting, recalls, deviations, and investigations. For example, no records for a complaint investigation involving a prescription refill of phenobarbital capsules 6mg on 10/19/2017 (Rx (b) (6) for super potency were provided.

OBSERVATION 8

Your pharmacy does not have established written procedures or adequate controls in place for receipt and storage of materials/components used to produce drug products.
Specifically,

a.) Materials/components used to produce drugs are not all classified and/or identified upon receipt as either being non-hazardous, hazardous/highly potent, containing beta-lactams, or controlled substances.

b.) Storage of hazardous/highly potent materials, controlled substances, and beta-lactam containing materials are not always segregated or accounted for appropriately.

c.) Inventory records for materials/components used to produce drugs are not maintained for those currently on-hand.

d.) Pertinent information on incoming materials/components used to produce drugs, such as the name of manufacturers and whether they are an approved supplier, lot numbers, and if an accompanying CoA for bulk chemical materials/components is received, are not recorded and/or checked for as per a written procedure.

OBSERVATION 9

Criteria for Beyond Use Dates (BUDs) assigned to drug formulations produced by your pharmacy are not formally and appropriately established in a written procedure nor supported with cited literature references and/or stability studies. For example, no cited literature or other evidence was provided in support of a BUD of 60 days for a phenobarbital suspension 6mg/mL (Rx (b) (6)).