DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

**OBSERVATION 1**

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

Specifically,

Drug products containing penicillin are produced in the same ISO Class 5 environment as non-penicillin beta-lactam drug products; only a cleaning utilizing Sterile (b)(4) is performed between batches.

There are (b)(4) ISO Class 5 hoods within the ISO Class 7 buffer room used by the firm to produce sterile drugs. There is no assurance that the cleaning process used within the hoods prevents cross-contamination between penicillin and non-penicillin beta-lactam drug products.

For example, on 11/09/18, I observed the production the following drug products in Hood# E28777: Ertapenem 500mg/100mL NS, Rx# (b)(6) followed by Vancomycin HCl 850mg, Rx# (b)(6) followed by Penicillin G Potassium, 3MU/D5W 50mL, Rx# (b)(6). Between the production of these drug products, only a cleaning utilizing (b)(4) is performed. There is no cleaning agent used between products to effectively breakdown penicillin activity or the beta-lactam ring.
OBSERVATION 2
You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

Actionable microbial contamination was discovered inside the ISO Class 5 aseptic processing environment; however no evaluation of product impact was made.

For example, on 11/30/2016, an environmental monitoring sample collected from ISO Class 5 work surface, Hood# 67437, during cleanroom certification resulted in an actionable excursion of \( (b) (4) \) colony forming units. There were no documented corrective actions performed. In addition, there were no evaluations conducted for products made on or before 11/30/16 to include: Cefepime 1gm/50mL NS, Rx# (b)(6) (b)(4), Rx# (b)(6); Vanco 1gm/250mL, Rx# (b)(6)

*DATES OF INSPECTION*