OBSERVATION 1

There is a failure to thoroughly review 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, Vancomycin, lot #13350 (Date prepared: 10/13/2015, Expiration date: 11/12/2015) was determined to be Out of Specification (OOS) for endotoxin. The lot was not distributed.

Your investigation failed to include a determination of the root cause for the endotoxin failure.

In addition, the following three sterility OOS investigations and eleven potency OOS investigations have been open for more than thirty days, indicating the lack of an efficient and robust CAPA system:

Sterility OOS:
Nicardipine, Lot #13384, produced: 10/19/2015, BUD: 12/03/2015, investigation initiated 11/13/2015
Oxytocin, Lot #12772, produced: 08/10/2015, BUD: 08/10/2015, investigation initiated 08/26/2015
Morphine, Lot #13170, produced: 09/17/2015, BUD: 11/01/2015, investigation initiated 09/28/2015

Potency OOS:
Norepinephrine, Lot #13484, produced: 11/03/2015, BUD: 12/18/2015, investigation initiated 11/18/2015
Oxytocin, Lot #13466, produced: 11/03/2015, BUD: 12/03/2015, investigation initiated 11/22/2015
Amiodarone, Lot #13488, produced: 11/04/2015, BUD: 12/19/2015, investigation initiated 11/24/20
Amiodarone, Lot #1513515, produced: 11/09/2015, BUD: 12/24/2015, investigation initiated 11/18/2015
Amiodarone, Lot #13553, produced: 11/13/2015, BUD: 12/28/2015, investigation initiated 11/18/2015
Norepinephrine, Lot# 13208, produced: 09/22/2015, BUD: 11/06/2015, investigation initiated 09/28/2015
Ondansetron, Lot #13642, produced: 12/01/2015, BUD: 01/15/2016, investigation initiated 12/08/2015
Lidocaine, Lot #13730, produced: 12/14/2015, BUD: 01/13/2016, investigation initiated 12/28/2015
Calcium Gluconate, Lot #13698, produced: 12/08/2015, BUD: 01/22/2016, investigation initiated 12/28/2015
Phenylephrine, Lot #13708, produced: 12/10/2015, BUD: 01/24/2016, investigation initiated 12/29/2015

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.
Specifically,
A. Your media fill process simulations are not performed under the most stressful or challenging conditions. For example, protocol #b(4) entitled, "b(4) Operator Media Fill Qualification" dated 11/16/15 describes, in part, that (b) (4) However, your firm has produced lots of Oxytocin (b) (4) (i.e. (b) (4), Quantity: (b) (4)).

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
Specifically,
SOP #103-06.02 entitled, "Surface Sampling Procedure" (Effective date: 5/22/14) documents, in part, that surface sampling will be performed (b)(4). Review of monitoring records revealed that sampling was routinely performed (b)(4) and not (b)(4). Environmental monitoring is not done during production.
OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically, your SOP Document No.: SUG-SOP-SA-0001, entitled, “Sterile Compounding Area Cleaning and Disinfecting”, dated 12/15/2015, states that (b)(4) cleaning shall be performed with a sporocidal disinfectant, (b)(4) or equivalent; however, the cleaning records for (b)(4) do not document that cleaning was performed. For example:

(b)(4) No documentation that a sporocidal cleaning agent was used

(b)(4) No documentation that a sporocidal cleaning agent was used

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The cleaning records for (b)(4) including the (b)(4), do not indicate the sporocidal was used (b)(4)

OBSERVATION 5

Procedures for the preparation of master production and control records are not described in a written procedure.

Specifically, SOP #104-05.02 entitled, "Variance Investigation Policy" (Effective date: 7/15/15) does not include time limitations for the closure of investigations. Currently, your firm has at least 14 open investigations which were opened over 30 days ago.
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."