Observation #1

There is a failure to thoroughly investigate any unexplained discrepancy or failure of a batch, regardless of whether the batch has been distributed, or a failure to expand an investigation to assess other batches that may also be impacted.

Specifically,

A review of your firm's endotoxin failure, occurring on 10/25/2017 for Lot No. 36029; Tri-Amino (L-Arginine HCL/L-Citrulline/L-Ornithine) 100/100/100 mg/mL, revealed that the investigation was incomplete in that:
1) Your firm failed to document a root-cause for the endotoxin failure.
2) Your firm did not implement any corrective actions or preventative measures to assure that future endotoxin failures will not occur when manufacturing this product.
3) Your firm did not evaluate whether other associated lots were impacted.

Review of your firm's potency failure, occurring on 10/16/2017 for Lot No. 35979; HCG Lyophilized 3000 IU/vial, revealed that the investigation was incomplete in that:
1) Your firm failed to document a root-cause for the potency failure.
2) Your firm did not implement any corrective actions or preventative measures to assure that future potency failures will not occur when manufacturing this product.
3) Your firm did not evaluate whether other associated lots were impacted.

THIS IS A REPEAT OBSERVATION