OBSERVATION #1

The ISO 5 classified areas were not certified under dynamic conditions. Specifically, unidirectional air flow was not verified under operational conditions.

I reviewed the smoke study dated 11/7/18 and observed significant air turbulence inside the ISO 5 area. The failure to maintain unidirectional airflow was not investigated by your firm.

OBSERVATION #2

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst case activities and conditions that prove a challenge to aseptic operations.

Specifically, review of your media fill dated 9/28/18 revealed that a total of \( b(4) \) vials were sterile filled. However, during actual production, your firm routinely fills at least \( b(4) \) vials per batch.

For example, on 2/18/19, your firm produced Polidocanol 5% for Injection, lot #5P021819 which consisted of \( b(4) \) or approximately \( b(4) \) vials.

OBSERVATION #3

Your firm uses the following disinfectants in the ISO 5 area, \( b(4) \) Cleaner and \( b(4) \). The contact time of \( b(4) \) minutes has not been substantiated.