DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1. Environmental monitoring of surfaces for microbial contamination is not performed after the completion of sterile operations in the ISO 5 area. Your firm only performs such monitoring on a (b)(4) basis.

2. Technician's gloves are not monitored for microbial contamination after the completion of sterile operations. Glove finger tips are monitored on (b)(4) basis.

3. Environmental monitoring for non-viable particulates and viable air counts is not performed during routine sterile operations. Such monitoring is performed (b)(4) basis.

4. Pressure gauges in the ISO 7 clean room and the ISO 8 Ante Room are not continuously monitored for air pressure differential. Instead personnel perform a (b)(4) of the pressure reading and make a record on the Pressure Gauge Log.

OBSERVATION 2
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

1. Disinfectant cleaner is not sterilized prior to use in cleaning and disinfect the ISO 5 hood.

2. Non-sterile lint free wipes are used by the firm to clean and disinfect the ISO 5 hood.

**OBSERVATION 3**

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

Gowns/coveralls, facemasks, goggles and bouffant hair nets worn by operators working inside ISO 5 zones are not sterile.

**DATES OF INSPECTION**

6/01/2016(Wed), 6/06/2016(Mon)