Guide to USP 797 Environmental Sampling

When is envrionmental sampling required?

- As part of the commissioning and certification of new facilities and equipment
- Following any servicing of facilities and equipment
- Every 6 months as part of re-certification
- In response to identified problems with end products or staff techniques

When is corrective action warranted?

- Whenever CFU counts exceed the action level for the corresponding ISO class
- Whenever "Highly pathogenic microorganisms (e.g. gram-negative rods, coagulase positive staphylococcus, molds and yeasts)" are recovered regardless of CFU count

Current Action Limits

Sample Type	Action Level
Surface - ISO Class 5	>3 CFUs/plate
Surface - ISO Class 7	>5 CFUs/plate
Surface - ISO Class 8	>100 CFUs/plate
Air - ISO Class 5	>1 CFUs/1000L
Air - ISO Class 7	>10 CFUs/1000L
Air - ISO Class 8	>100 CFUs/1000L
Fingertip (Post garb/Post mediafill)	>3 CFUs/tech

How to use your lab results:

Unfortunately there are many potential sources for contamination in a clean room. USP <797> lays out common sources of contamination and emphasizes that human operators working in controlled areas are the most common source of contamination. Below are guidelines to assist in eleminating sources of contamination and reducing CFU counts to below appropriate action levels. It is critical to trend environmental sampling data to catch problems early. If there is an increase in CFUs recovered between sampling dates, even if the CFU counts do not exceed action limits, it is advisable to investigate the increase in CFU count.

- Review Pharmacy technicians internal SOPs in regards to personnel garbing and aseptic technique
- Properly disinfect and clean any object entering the controlled areas
- Only the essential supplies for a day's operation should be brought into the controlled areas. Cardboard and manufacturer's packing should never be brought into the ante room
- Carts should be easy to clean and must be cleaned each time before entering a controlled area
- If a sink is located in the ante room, it should be disinfected frequently and surface sampled for viable organisms
- Cleaning schedules should at least meet the minimum requirements outlined in USP <797>
- Cleaning agents should be used per the manufacturer's recommendations and should leave no residue
- Cleaning cloths, mops, wipes, etc. should be low-lint
- Take necessary actions to ensure unidirectional flow of air from the PEC through the buffer areas into the ante room (cleanest to dirtiest)
- Ensure that the minimum air changes per hour are met or exceeded. 30 ACPH in ISO class 7 areas
- Avoid storing objects in the controlled area. Any items that slow air flow or provide a surface for particles to land and accumulate increase the risk of contamination.

When is additional testing required?

Areas that did not fall within the action limits or recovered highly pathogenic organisms should be resampled once corrective action has been taken. Resampling is required for re-certification if the original samples recovered unacceptably high CFU counts or highly pathogenic organisms. Additional sampling beyond that required for certification is recommended.