

This presentation will address the step by step approach to investigating and reporting investigation results for microbial contamination encountered in controlled room monitoring, during the manufacturing process or in the end product.

- Discussion on critical systems where microbial contamination may affect product quality
- Confirming the validity of contamination
- Identifying the risks and liabilities
- Administrative Controls for Investigating Microbial Contaminations
- Systems to investigate when microbial contamination occurs
 - Establishing an investigation plan
 - Identifying areas to investigate
 - Data review
 - Interviews
 - Summarizing findings
- Determine the Assignable Cause: Systems to inspect for tracking the contamination to the source
- Developing a Corrective Action Plan Recommendations
- Points to Consider while compiling the Investigation Report