



Question 9: I am responsible for adding an isolator for sterility testing into the microbiology lab. I know very little about this new technology. Where do I start?

Answer: You asked a very good, but a very open ended question which I'd like to start answering. Then maybe we can get together by telephone or in person to start working our way through the project. I'm so glad that we can start talking about the project in the planning phase. This will end-up saving a considerable amount of time and money as the project progresses.

Here are the basic steps. Start by working on the first two and we can help you formalize them and build a scope for the project, leading to the rest.

1. Define your requirements.
 - a. How many sterility tests are you going to run per day/week/month? (can be based on current and/or projected numbers)
 - b. What types of products and/or containers will be tested? How many of each?
 - c. How will you test each item? Which will be direct inoculation and which will use membrane filtration?
 - d. Are there any special needs (rapid turnaround of a specific product/sample, multiple products, toxic compounds, etc...)
2. Define your constraints.
 - a. When do you need to be up and running samples?
 - b. Has a facility/room already been selected? If so, what is its size, shape and HVAC characteristics (we can help you make modifications, if necessary)
 - c. Is there an existing sterility testing lab operation that needs to be transferred or is this a new or separate project?
3. Write a User Requirements Spec.
 - a. This can be a formal or informal document organizing the above info from #1 and #2 into a bid package for isolator manufacturers.
4. Select an isolator system / vendor
 - a. You can choose from a wide variety of flex and rigid wall isolators and standard or custom designs.
 - b. You may opt to test without an isolator, using a hood.
5. Select a validation/consulting firm or develop an in-house validation team.
6. Write a validation master plan and/or strategy document
 - a. Here you want to document key facility and isolator design decisions and layout your validation strategy.
7. Order equipment.
 - a. Lead time is typically 14-24 weeks, depending upon the complexity and the customization.
8. Factory Acceptance Testing (also gets operators and validation involved and ready)
9. Finalize facility preparation.
 - a. Physical facility items (construction/etc..., if necessary)
 - b. SOP development and approval
10. Installation / Site Acceptance Test
11. Validation (IQ/OQ/PQ)
 - a. Facility commissioning
 - b. Equipment testing
 - c. Sanitization process qualification
 - d. False Negative Testing / Simulated Sterility Test
12. Operator Final Training
 - a. Using isolators and other equipment
 - b. New procedures for testing, environmental monitoring, etc...
13. START STERILITY TESTING
 - a. As a firm, Advanced Barrier Concepts, Inc. provides all of the above services, with the exception of construction work and fabrication of isolators. The preceding items are in a general order of execution, but are not all sequential. There are many general design factors plus in-house requirements to consider. We hope that this provides some sort of a framework for formulating your thoughts into a plan. We also encourage you to take a tour of the ETIC site and read selected articles and presentations on various topics.