Getting Ready for a Sterilization Assessment

Sterilization Assessment Planning Guidelines:

We have prepared this document to serve as a guideline to help customers prepare for an effective microbiology audit. During a standard microbiology audit, conducted by BSI, or its subcontractors, the following documents are reviewed for technical content and completeness:

- Controlled environment procedures and verification data including:
  - Gowning
  - Cleaning
  - Routine viable and non-viable monitoring
  - Disinfectant usage
  - Disaster recovery planning
  - Other facilities data as required:
    - Water system validation, HEPA and HVAC, compressed air systems
    - Pest control procedures/logs
- Routine sterilization procedures
- Sterilization validation protocols (and any technical agreements/contracts)
- Sterilization validation data including:
  - Bioburden, Bioburden Recovery
  - Sterility, Bacteriostasis/Fungistasis
  - Applicable load configurations/dosing maps/supporting data as required
- Packaging equipment qualification and routine packaging procedures
- Training records as required for activities listed above
- Sterile load release records

Other documentation, such as calibration records, are identified on-site during a tour of your facility. This is a partial list for your reference and other documents may be identified during the audit based on need or current findings.

In addition to ISO 13485, other standards our Microbiology Team assesses against include:

- Sterilization: ISO 11135, ISO 11137, ISO 17664, ISO 17665, ISO 14937
- Controlled Environments: ISO 14644, ISO 14698
- Sterile Device Packaging: ISO 11607, ASTM D4169, ISTA, ASTM F88, ASTM F1140

If customers have any questions, we encourage them to directly contact their assigned Microbiology Assessor.

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