

Microbiology Assessment Planning Guide



Preparing for a BSI microbiology audit

A sterile medical device is a device that must be free from live bacteria or other microorganisms and their spores. Our Microbiology team is able to support you as a manufacturer by providing expert feedback on controlled environments and the sterility of your medical device. We have developed this guide to provide information on what to expect during a BSI microbiology audit and to support you in preparing for your audit.

During a standard microbiology audit conducted by BSI, the following documents are reviewed for technical content and completeness:

Controlled environment procedures and verification data, including:

- Air quality, including routine viable and non-viable monitoring
- Cleaning, disinfectant usage
- Gowning
- Disaster recovery planning
- Other facilities data as required (for example, pest control logs/procedures, water system validation)

Routine sterilization procedures

Sterile load release records

Sterilization validation protocols, including any technical agreements and contracts

Sterilization validation data, including:

- Applicable load configurations/dosing maps and supporting data, as required
- Bioburden and bioburden recovery
- End-user sterilization instructions (if applicable)
- Sterility, including bacteriostasis/fungistasis
- EO residual testing

Packaging equipment qualification and routine packaging procedures, including:

- Validation of sterile barrier

Training records as required for activities listed above

This is not a complete documentation list; other documents, such as calibration records, are either assessed on-site during a tour of your facility, or may be identified during the audit based on need or current findings.

In addition to ISO 13485, reference to harmonized standards include:

- Controlled Environments: ISO 14644, ISO 14698
- Sterile Device Packaging: ISO 11607 series
- Sterilization: ISO 11135, ISO 11137, ISO 17664, ISO 17665, ISO 14937, ISO 13408, ISO 10993

We encourage you to contact your microbiology assessor with any queries or visit our website:
bsigroup.com/microbiology-es/