Microbiology Assessments

Updated February 2016

Reducing the risks in sterile product certification

BSI has a unique approach to sterile product certification – that sterilization and microbiology is a specialized process and therefore requires a specific set of skills. **RISK** is the key. We believe the risk to the patient is too great **NOT** to use specialists in microbiology. All our Microbiology assessments are carried out by fully qualified Microbiologists.

Why have Microbiology audits?

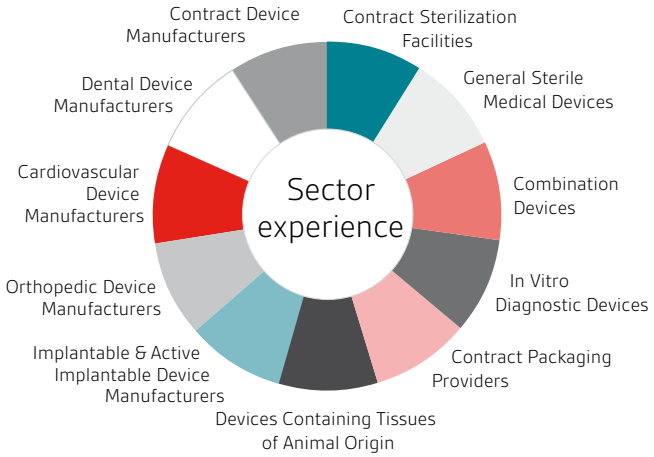
- To verify that you have effective controls in place to assure the sterility of your product
- To verify that you have effective controls in place to assure a low product bioburden
- To assess the suitability and effectiveness of instructions for end user sterilization and reprocessing
- To assess the suitability and effectiveness of disinfectants
- To assess the effectiveness of sterilizers

BSI is trusted by the top two largest global sterilization service providers to complete their Quality and Sterilization Audits, and is the Notified Body of choice for over 90% of contract sterilization registrations worldwide.

Worldwide expertise

The BSI Microbiology Team currently encompasses over 10 technical experts, with over 110 years experience between them.

The BSI Microbiology team has a global reach, with Auditors throughout Europe, USA and Asia.



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...making excellence a habit.™

Microbiology audit procedure

A typical microbiology assessment from BSI would include the following steps:

- Plant tour – we'd like to follow the flow of product and raw materials from receipt to release, looking for any potential contamination control issues
- We will gown and enter the controlled environments and typically look at the following:
  - Gowning practices
  - Cleaning practices and cleaning agents
  - Room condition
  - Product processing from a contamination perspective
  - Review of monitoring
  - Condition of HEPA filtration
  - Water systems (as appropriate)
  - Compressed air (as appropriate)
  - Training
  - Review of:
    - Packaging process/shelf life
    - Sterilization validation activities
    - Sterilization processing activities
    - Sterile product release records

Why BSI?

- Benefit from over 110 years of microbiological experience
- Independent experts to verify the output of your internal experts and subcontractors
- State of the art knowledge of current and emerging best practice and avoidance of issues that could be catastrophic
- Peace of mind knowing that the you have been successfully reviewed by leading experts who have implemented and audited thousands of effective sterilization processes
- Confidence that your process has been thoroughly reviewed by the experts who participate in the work that defines the standards
- BSI believes that our approach to microbiology and sterilization adds value to certification and helps to ensure our customers are successful and patients are protected.

Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about BSI Microbiology audits, please **call or email us for an initial conversation**

Your partner in worldwide compliance: Call BSI today on 1300 730 134 or visit bsigroup.com/en-au – to start your partnership

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