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Microbiology Audit

Planning Guidelines

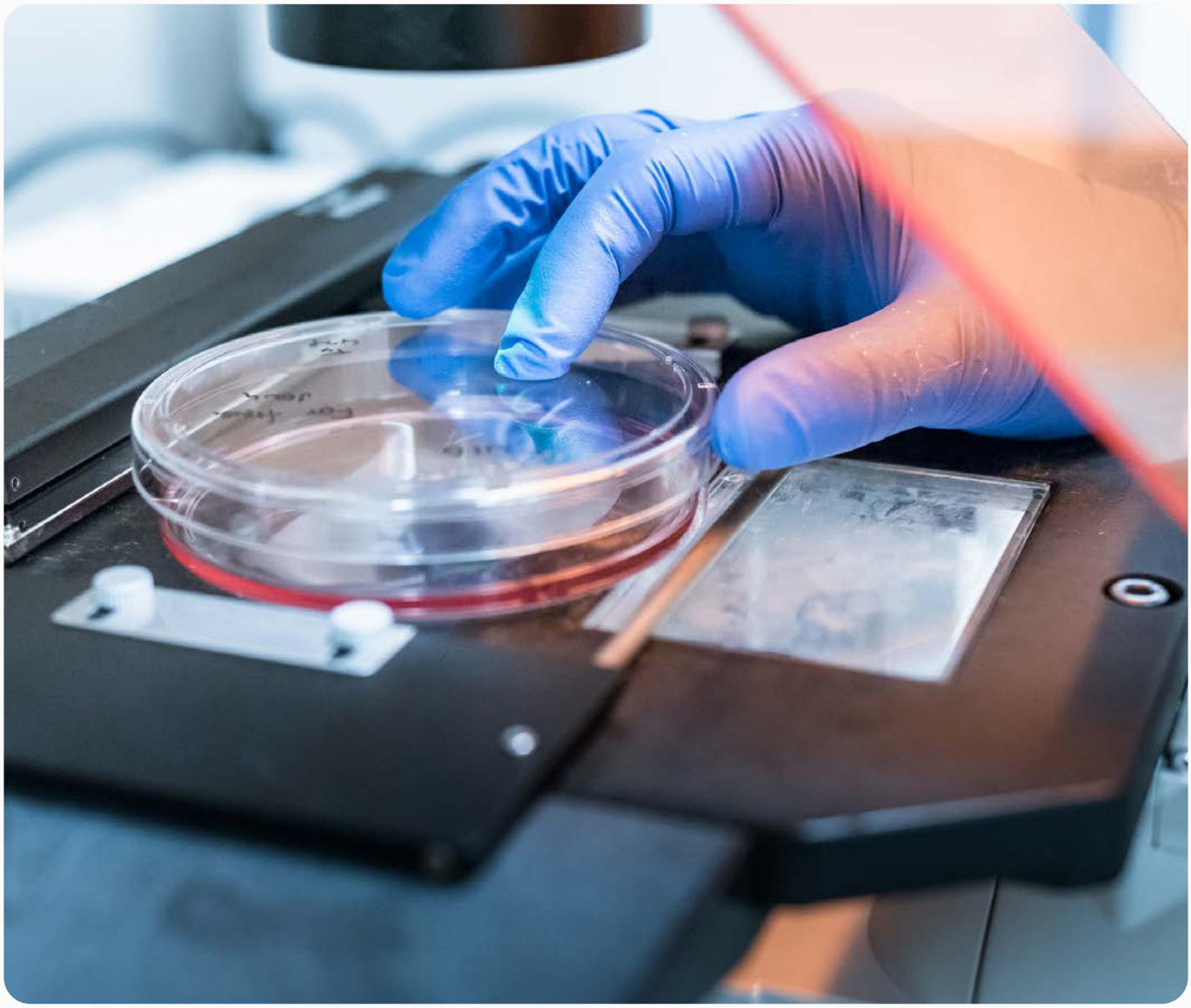
Introduction

Purpose

The purpose of this document is to provide guidance to prepare for Microbiology Audits. The Microbiology Audit is conducted to confirm the consistency of product bioburden and work environments, sterile barrier validation, sterile barrier shelf life, sterilization validation, release of sterile product and control of any subcontracted processes critical to product sterility. The information provided is intended as guidance only and is not to be considered a complete list of areas reviewed during a Microbiology Audit.

Scope

The scope of this guidance is the Microbiology Audit in the overall audit program aligning with the Stage 2 and recertification audits for all certification schemes including EC/EU certificates under applicable Directives and Regulations (MDD 93/42/EEC, AIMD 90/385/EEC, IVDD 98/79/EC, MDR EU/2017/745 and IVDR EU/2017/746), UKCA certificates under UK Medical Devices Regulations 2002, MDSAP/ISO 13485 certificates, and accredited ISO 13485 certificates.



Microbiology Audit Planning

The following is intended as a tool to prepare for a BSI microbiology audit, by outlining the minimum documents and records that may be reviewed during a standard microbiology audit conducted by BSI. It is also applicable to manufacturers who subcontract part or all of the manufacturing, packaging or sterilization processes.

Environmental control

ISO 14644 series, ISO 14698 series, EN 17141

- Cleanroom/controlled environment area qualification.
- Routine viable (microbiological) and non-viable (particulate) monitoring.
- Quality Agreements with subcontract manufacturers (if applicable).
- Risk evaluation and management related to contamination sources and routes.
- Gowning procedures and training logs.
- Cleaning procedures, logs and disinfectant usage.
- Power failure/breach/disaster recovery planning.
- Other facilities infrastructure data as required:
  - Water system validation, HEPA and HVAC, compressed air systems.
  - Pest control procedures/logs.

Sterilization validation – General requirements for all modalities

ISO 11737 series, ISO 11138 series, ISO 11135, ISO 11137 series, ISO 13408 series, ISO 14160, ISO 14937, ISO 17665, ISO 20857, ISO 22441, ISO 25424

- Validation Protocol(s) and Report(s).
- Summaries regarding commissioning of the sterilization equipment.
- Biological indicator data (as applicable)
  - Population verification.
  - Comparative resistance studies.
  - Biological indicator sterility testing data.
  - Biological indicator Reduced Incubation Time studies.
- All processing/cycle data (set points met, data meets acceptance criteria) and test reports (fractional, half, full) (as applicable).
- Validation of bioburden testing recovery method and test report.
- Bioburden determination and test reports.
- Product sterility testing and bacteriostasis/fungistasis testing.
- Routine sterilization procedures.
- Annual review of sterilization program.
- Product/process/cycle adoption and comparison data (as applicable).
- Procedures and records for sterile release of products.
- Control and monitoring of Endotoxin, including validation of test method.
- Evidence of control and management of suppliers.
- Vigilance/recall reports for issues arising from microbiology, sterilization and packaging.

Sterilization validation

Radiation methods (Gamma, Electron Beam, X-Ray Irradiation)

- Dose mapping report/product PQ.
- Calculation or determination of verification dose and full dose.
- Routine Dose audit program.

Gaseous methods including Ethylene Oxide

- Sterilant residual analysis reports.

Thermal methods

- Fo calculations.
- F_h calculations.

End user sterilization products and instruments

- Instructions for use that detail the validated sterilization and cleaning parameters
  - Please be aware that “standard hospital practice” is insufficient.
  - Sterilization parameters must be applicable to EU member states for MDR certification.
- Evidence of risk management addressing potential failure modes relating to the device intended use.
- Considerations for the lifetime of device and/or the maximum number of reuses.
- End-user cleaning, disinfection, and sterilization instructions for use
  - Validation protocol and report for cleaning processes.
  - Validation protocol and report for disinfection processes (as applicable).
  - Validation protocol and report for sterilization processes.

Shelf-life validation

ISO 11607 series, ASTM D4169, ISTA series, ASTM F88, ASTM F1140, ASTM F1980

- Protocol(s) (with acceptance criteria for each test performed) using appropriate test references and Report(s) including packaging sealing process validation.
- Statement of the intended shelf-life.
- Definition of the sterilization status of the test samples (1X, 2X sterilized) and appropriate statistical sampling.
- Shelf-life Studies
  - A summary of the accelerated aging parameters (temperature and humidity) and how the aging times were calculated.
  - Documented validation protocol for real time aging studies, including interim results if available.
- Actual physical/microbiological test data reports supporting the expiration date, or post aging, claim (peel testing, burst testing, dye testing, etc).
- A summary of the ship testing/transit simulation testing conducted and applicable test reports.
- Packaging equipment qualification and routine packaging procedures.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Your partner in progress

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