

IHEEM

Authorising Engineer (Decontamination)

Competency Framework: Overview

Unit 1 – Management Skills

Management skills, presentations and chairing of sessions as part of the role, management requirements (CORE).

- Effective management, leadership and decision making
- Chairing and contributing to meetings, discussion and written communication methods
- Presentation methods for effective outcomes
- Statistics and statistical process control for Competency Framework
- Personnel matters and Health & Safety

Unit 2 – Equipment and Processes

Non-steam forms of sterilization; steam for sterilization (generation and distribution, equipment, processes); washer disinfectors; water standards for decontamination; environmental controls; purchasing and specifications; packaging methods, materials and processes.

- Non-steam forms of sterilization and the fundamentals of steam generation
- Theory of steam generation
- Steam plant designs and their water supplies
- Latest pressure regulations, steam distribution pipework systems and management
- Audit steam systems
- Management, analysis of results and principles of steam use
- Principles of steam in the sterilization procedures and processes
- Log and audit, product compatibility and safety notices, risk analysis
- Washer Disinfector principles, reporting and auditing, testing and validation
- Water standards for endoscope processing
- Methods for testing microbial levels
- Design of air management; supply and standards
- Environmental requirements and control
- Specifications and tendering
- Regulatory requirements and standards, design considerations, packaging materials and standards

Unit 3 – Roles and Responsibilities and Legal Aspects

GMP medicinal products and medical devices; quality systems and quality assurance requirements; tracking and traceability systems and methods; medical device regulations directives; auditing of systems and departments (including reporting); roles and responsibilities of personnel including AE(D) and AP(D); AE(D) role legal requirements,

- Validation requirements of equipment, development and preparation of the technical specifications of the equipment
- Purpose and principles of QMS, the medical devices directive and medical devices regulations

- Auditing process and lifecycle, development of the Technical File, understanding and applying or resolving areas of manufacturer's instructions for QA
- Organisational reporting structures as applied through national guidance, standards and legislation
- Legal requirements of contracts
- Understanding the needs of producing a reliable and compliant system, ensuring an understanding of the tracking system, meeting the needs of the MHRA
- MDR directives – understanding legislation, key elements, conformity, notified bodies
- Understand key personnel involvement, their roles and differences
- The role of the AE(D)

Unit 4 – Decontamination and Microbiology Fundamentals

Basic understanding of microbiology and the sterilization/disinfection process with F0 and A0 criteria; abnormal prions/problems in decontamination; disinfectants and detergents including fundamentals, endoscopy and processes; chemical indicators; biological indicators; environmental cleaning and disinfection.

- Understanding bioburdens, microbial contamination, microbiology and abnormal prions
- Understanding detergents, disinfectants, principles and advantages/disadvantages of lubricants
- Understanding principles, standards and testing of Chemical Indicators and Biological Indicators
- Understanding principles and operations of cleaning and disinfection

Unit 5 – Standards & Guidance

General standards overview

- Standardisation and the role of standards, the language and how they should be interpreted
- National, regional and international standards bodies

Unit 6 – Validation, Calibration, Periodic Testing and Maintenance

Understanding of test methods and validation processes including measurement and calibration; decontamination equipment testing, reporting and auditing of porous load, microbiology labs, pharmaceutical, bench top types.

- Calibration principles from a UKAS laboratory, principles and understanding of site checking and test equipment
- Validation program to meet local NHS requirements and standards, maintenance requirements
- Auditing of validation and test reports
- Maintenance of decontamination equipment and training of personnel