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# Qualification Unit

This unit forms part of a regulated qualification.

**Unit Title:** Cleanroom Science and Controlled Environments

**Unit Reference Number:** Y/652/4180

**Level:** Five (5)

**Credit Value:** 7

**Minimum Guided Learning Hours:** 50

| Learning Outcome (The Learner will): | Assessment Criterion (The Learner can): |
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| 1. Understand the scientific principles underpinning cleanroom performance and contamination control | 1.1 Critically evaluate the relative contribution of personnel, equipment, materials and utilities to particulate contamination within controlled environments |
| | 1.2 Analyse mechanisms by which microorganisms are introduced, transferred and dispersed within cleanroom environments |
| | 1.3 Evaluate the impact of airflow design, airflow visualisation studies and first-air principles on contamination control |
| | 1.4 Assess the relationship between environmental controls, contamination control strategies and sterility assurance objectives |
| 2. Understand cleanroom classification systems and environmental control technologies | 2.1 Critically compare EU GMP cleanroom classifications with ISO 14644 classification requirements |
| | 2.2 Evaluate HVAC design principles used to maintain environmental control within aseptic facilities |
| | 2.3 Assess the effectiveness of filtration technologies in controlling particulate and microbiological contamination |
| | 2.4 Justify environmental control parameters based on process, product and patient risk |

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| 3. | Be able to evaluate the impact of personnel, material and process flows on contamination risk within controlled environments | 3.1 | Assess contamination risks associated with personnel movement and interventions within cleanrooms |
| | | 3.2 | Critically evaluate gowning systems and qualification programmes used to minimise contamination risks |
| | | 3.3 | Analyse material transfer systems and associated contamination control measures |
| | | 3.4 | Develop recommendations to optimise personnel and material flow within controlled environments |
| 4. | Assess environmental monitoring and qualification data to determine the state of environmental control | 4.1 | Evaluate cleanroom qualification methodologies used to demonstrate environmental control |
| | | 4.2 | Analyse viable and non-viable environmental monitoring data to determine compliance status |
| | | 4.3 | Assess environmental trends to identify emerging contamination risks |
| | | 4.4 | Justify actions arising from adverse environmental monitoring results and qualification failures |
| 5. | Develop strategies for maintaining and improving cleanroom performance within a pharmaceutical quality system | 5.1 | Evaluate contamination control measures used to maintain a state of environmental control |
| | | 5.2 | Assess the effectiveness of cleaning and disinfection programmes within cleanroom environments |
| | | 5.3 | Develop improvement plans based on environmental performance data and quality metrics |
| | | 5.4 | Justify continuous improvement initiatives designed to enhance environmental control and regulatory compliance |

| Indicative Content | |
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| LO1 | 1.1 must include: Sources of particulate contamination associated with personnel, equipment, materials and utilities; particle generation, movement and deposition; relative significance of different contamination sources, e.g., skin shedding, equipment wear, packaging materials and utility-system contamination. |

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| | 1.2 must include: Sources of microbiological contamination; mechanisms of microbial introduction, transfer and dispersion; airborne and contact contamination pathways; influence of personnel, equipment, materials and environmental conditions.<br><br>1.3 must include: Airflow dynamics; unidirectional and non-unidirectional airflow; first-air principles; protection of critical areas; interpretation of airflow visualisation studies; factors affecting airflow effectiveness, e.g., equipment positioning, personnel movement and interventions.<br><br>1.4 must include: Environmental control principles; contamination control strategies (CCS); interaction between engineering, procedural and behavioural controls; relationship between contamination prevention, product protection, patient safety and sterility assurance. |
| LO2 | 2.1 must include: EU GMP Grades A–D; ISO 14644 classification requirements; particle concentration limits; classification at rest and in operation; differences between classification frameworks and their application to controlled environments.<br><br>2.2 must include: HVAC design principles; air handling units; air supply and extraction; airflow direction; pressure cascades; temperature and humidity control; environmental zoning; recovery and maintenance of environmental conditions.<br><br>2.3 must include: HEPA filtration principles; filtration effectiveness; factors affecting filter performance; integrity testing and maintenance requirements Could include: ULPA filtration or other filtration technologies relevant to the environment being evaluated.<br><br>2.4 must include: Risk-based selection and justification of environmental control parameters; consideration of product characteristics, process requirements, contamination risks and patient safety, e.g., pressure differentials, temperature, humidity, air cleanliness and recovery times. |
| LO3 | 3.1 must include: Personnel movement; intervention-related contamination risks; cleanroom behaviours; human factors; behavioural controls; impact of personnel activity on contamination prevention.<br><br>3.2 must include: Cleanroom gowning principles; garment selection and suitability; gowning procedures; garment integrity; personnel qualification; ongoing competency assessment and requalification; effectiveness of gowning controls.<br><br>3.3 must include: Material flow principles; material transfer systems; airlocks and transfer hatches; segregation; contamination risks associated with material movement; appropriate transfer and decontamination controls.<br><br>3.4 could include: Recommendations relating to personnel and material flow, e.g., revised workflows, improved environmental zoning, restricted access, transfer arrangements, intervention reduction, segregation or procedural controls. Recommendations should be justified against identified contamination risks. |
| LO4 | 4.1 must include: Cleanroom qualification lifecycle; Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), where applicable; qualification testing and acceptance criteria; requalification requirements; evaluation of evidence demonstrating environmental control, |

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| | e.g., airflow measurements, filter integrity, particle classification, pressure differentials and recovery studies.<br><br>4.2 must include: Viable and non-viable environmental monitoring; interpretation of results against specified limits; identification of excursions and adverse findings; implications for the state of environmental control<br>Could include: Data from settle plates, contact plates, active air sampling, personnel monitoring and particle counting.<br><br>4.3 must include: Environmental monitoring trends; alert and action levels; identification of changes in environmental performance; assessment of emerging contamination risks, e.g., repeated low-level contamination, increasing microbial counts, recurring excursions or changes in organism profiles.<br><br>4.4 must include: Evaluation of adverse monitoring and qualification findings; potential impact on product and process quality; investigation and escalation requirements; selection and justification of proportionate corrective and preventive responses. |
| LO5 | 5.1 must include: Effectiveness of engineering, environmental, procedural and behavioural contamination controls; integration within the CCS; identification of control weaknesses; maintenance of a state of environmental control.<br><br>5.2 must include: Cleaning and disinfection principles; selection and suitability of cleaning and disinfecting agents; cleaning methods and frequencies; contact times; sporicidal controls; effectiveness monitoring; relevant cleaning validation requirements.<br><br>5.3 must include: Interpretation of environmental performance data and quality metrics; identification and prioritisation of improvement needs; development of improvement objectives, actions, responsibilities, timescales and effectiveness measures. 5.3 could include: Environmental KPIs, monitoring trends, deviations, audit findings and contamination investigations as sources of improvement evidence.<br><br>5.4 must include: Justification of continuous improvement initiatives using environmental performance, quality and risk evidence; anticipated impact on contamination control, patient safety and regulatory compliance; effectiveness monitoring and sustainability of improvements |

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## Assessment Requirements

Assessment must demonstrate application of specialist knowledge to pharmaceutical manufacturing, aseptic services or pharmacy technical services environments.

Evidence must demonstrate Level 5 analytical and evaluative capability, including the ability to interpret technical information, assess complex contamination risks, make justified judgements and develop appropriate improvement recommendations.

Learners are not required to have responsibility for cleanroom qualification, facility management or regulatory approval. Assessment may draw on activities undertaken within their existing professional roles or on realistic technical scenarios where direct access to particular equipment, facilities or processes is unavailable.

Evidence may include:

- Technical reports and evaluations of cleanroom design or contamination control.
- Workplace-based projects or improvement proposals.
- Analysis of environmental monitoring and qualification data.
- Reviews of gowning, material transfer or cleaning and disinfection controls.
- Case studies involving contamination events or environmental control failures.
- Professional discussions and presentations, supported by appropriate technical evidence.
- Relevant portfolio evidence from workplace activities.

LO1 and LO2: Learners should evaluate relevant scientific principles and technologies in the context of their application. An explanation of cleanroom classifications or HVAC systems alone is not sufficient evidence where the AC requires critical comparison, evaluation or justification.

LO3: Assessment should include consideration of an existing or proposed personnel/material flow arrangement. Learners should identify potential contamination risks and develop justified improvements. The recommendations do not need to be implemented.

LO4: Assessment must include interpretation of environmental monitoring and/or qualification evidence. Learners should be provided with sufficient data to identify trends, adverse findings and appropriate responses. Descriptive accounts of monitoring procedures alone is not sufficient.

LO5: Learners must develop an improvement plan and justify proposed actions using relevant quality or environmental performance evidence. The plan should be proportionate to the identified problem and include a means of evaluating effectiveness. Implementation is not required.

Where an integrated project or case study is used, evidence may support multiple assessment criteria provided achievement of each criterion can be clearly identified.

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