Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Environmental Monitoring and Contamination Control

Unit Reference Number: D/652/4182

Level: Five (5)

Credit Value: 6

Minimum Guided Learning Hours: 45

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand environmental monitoring systems, methods and regulatory requirements	1.1 Evaluate the purpose, scope and regulatory requirements of environmental monitoring within pharmaceutical environments
	1.2 Compare environmental monitoring methods and justify their application to different controlled environments
	1.3 Evaluate environmental monitoring sampling plans, frequencies and alert and action levels
	1.4 Evaluate the contribution of environmental monitoring to contamination control and quality risk management
2. Be able to analyse environmental monitoring data and evaluate contamination risks	2.1 Apply appropriate trending and statistical techniques to environmental monitoring datasets
	2.2 Identify and analyse abnormal trends, excursions and out-of-trend environmental monitoring results
	2.3 Evaluate the significance of environmental monitoring findings in relation to process risk and sterility assurance
	2.4 Develop evidence-based conclusions and recommendations from environmental monitoring data
3. Be able to investigate contamination events using structured methodologies	3.1 Evaluate environmental monitoring findings to determine the need for investigation

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	3.2	Apply structured investigation methodologies to identify potential causes of contamination events
	3.3	Analyse investigation evidence to assess the impact of contamination events on product quality and process control
	3.4	Produce an evidence-based contamination investigation report with justified conclusions
4. Be able to develop and evaluate corrective and preventive actions for contamination control	4.1	Develop corrective and preventive actions to address identified contamination risks and investigation findings
	4.2	Establish and apply measures to evaluate the effectiveness of contamination-related CAPA
	4.3	Develop recommendations to integrate CAPA outcomes into contamination control and continuous improvement

Indicative Content	
LO1	1.1 must include: Purpose of environmental monitoring in sterile and non-sterile pharmaceutical environments; relevant regulatory expectations; relationship between monitoring, contamination control, product quality and sterility assurance; role of monitoring within the contamination control strategy (CCS). 1.2 must include: Viable and non-viable monitoring; surface and personnel monitoring; suitability, limitations and application of monitoring methods to environmental conditions and contamination risks. Other examples include: Settle plates, contact plates, active air sampling, particle counters, gown monitoring and glove prints. 1.3 must include: Risk-based selection of monitoring locations, sampling frequencies and methods; principles for setting and reviewing alert and action levels; influence of cleanroom classification, process risk and historical monitoring performance. 1.4 must include: Integration of environmental monitoring with CCS and QRM; interpretation of monitoring evidence to evaluate the state of environmental control; contribution to identifying emerging risks and supporting quality decisions.
LO2	2.1 must include: Selection and application of appropriate trending techniques; analysis of environmental monitoring data over time; presentation and interpretation of results. Other examples include: Run charts, control charts, moving averages, frequency analysis and basic statistical process control. 2.2 must include: Identification of adverse trends, alert/action level excursions

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	and out-of-trend results; differentiation between expected variation and potentially significant changes; consideration of operational and environmental influences. Other examples include: Seasonal variation, repeated low-level contamination, personnel behaviours and changes in environmental conditions. 2.3 must include: Assessment of monitoring results against environmental conditions, process requirements, product risks and contamination control measures; significance of trends or excursions for environmental control and sterility assurance. 2.4 must include: Risk-based interpretation of findings; justification of recommended monitoring, investigation or control actions; communication of conclusions to relevant technical and quality stakeholders. Other examples include: Environmental monitoring reports, dashboards, trend summaries and presentations.
LO3	3.1 must include: Investigation triggers; classification and significance of environmental monitoring events; consideration of excursions, adverse trends and atypical microbiological findings; investigation and escalation requirements. 3.2 must include: Selection and application of root-cause analysis methods; assessment of contamination pathways; evaluation of potential contributory factors and root causes. Other examples could include: 5 Whys, Ishikawa diagrams, FMEA and other appropriate investigation tools. 3.3 must include: Evaluation of environmental monitoring, microbiological, equipment, process and personnel evidence; distinction between contributory factors and likely root causes; implications for product quality, sterility assurance and batch disposition. 3.4 must include: Clear investigation scope; relevant evidence; investigation methodology; evaluation of findings; conclusions and recommendations; compliance with applicable documentation and data-integrity requirements.
LO4	4.1 must include: CAPA lifecycle; distinction between corrective and preventive actions; relationship between identified causes and proposed actions; prioritisation based on risk; responsibilities and timescales. 4.2 must include: Measurable effectiveness criteria; follow-up monitoring; evaluation of post-implementation evidence; identification of recurrence or continuing risks. Other examples could include: Environmental monitoring trends, contamination rates, repeat deviations, quality metrics and compliance indicators. 4.3 must include: Integration of investigation findings and CAPA outcomes into CCS, QRM and quality management systems; communication of learning; recommendations for sustained improvement and prevention of recurrence.

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Assessment Requirements

Evidence may include:

- Environmental monitoring programme evaluations
- Analysis and interpretation of viable and non-viable environmental monitoring datasets
- Environmental trend reports, charts and dashboards
- Contamination investigation reports
- Root-cause analysis records
- Quality risk assessments
- CAPA plans and effectiveness evaluations
- Workplace projects or quality improvement proposals
- Case study evaluations and professional discussions supported by technical evidence

LO1: Learners should demonstrate understanding through comparison and evaluation of environmental monitoring methods, programme design and regulatory expectations. The assessment should include sufficient context to allow justified decisions concerning the suitability of monitoring arrangements.

LO2: Learners must analyse environmental monitoring data rather than simply describe monitoring techniques or reproduce existing reports. Data should be sufficiently detailed to enable identification of trends, excursions or changing environmental conditions and support risk-based conclusions.

LO3: Assessment should require the learner to investigate a realistic contamination event using a structured methodology. The evidence should enable consideration of multiple possible causes and justified conclusions. Where the available evidence does not establish a definitive root cause, learners should recognise and explain the uncertainty.

LO4: Learners should develop CAPA linked to identified contamination risks or investigation findings. Assessment must include measurable effectiveness criteria. Where actions have not been implemented, learners may evaluate suitable post-implementation evidence supplied through a case study or simulation.

Integrated assessment may be used where a single environmental monitoring investigation and improvement project provides evidence across multiple learning outcomes, provided each criterion is clearly evidenced.

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