Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Applied Experimental Design and Statistics for Technical Services

Unit Reference Number: L/652/4187

Level: Five (5)

Credit Value: 7

Minimum Guided Learning Hours: 45

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand principles and approaches to experimental design within pharmaceutical technical services	1.1 Evaluate the principles of experimental design and their application to technical investigations
	1.2 Compare experimental design approaches and evaluate their suitability for different technical investigations
	1.3 Evaluate the factors influencing the validity, reliability and reproducibility of experimental results
	1.4 Assess ethical, safety and regulatory considerations relevant to experimental work within pharmaceutical environments
2. Be able to design experiments and apply statistical methods to technical and quality data	2.1 Develop an experimental plan to investigate a specified technical or quality problem
	2.2 Apply descriptive and inferential statistical methods to analyse technical or quality datasets
	2.3 Apply statistical process control methods to evaluate process stability and performance
	2.4 Present and communicate statistical findings to support technical decision-making
3. Be able to evaluate experimental and process data to support evidence-based decisions	3.1 Interpret experimental results to identify significant findings and relationships between variables

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	3.2	Analyse sources of variation, error and uncertainty within experimental and process data
	3.3	Evaluate the quality and integrity of experimental and process data
	3.4	Evaluate experimental and statistical evidence to identify opportunities for process optimisation
	3.5	Develop justified recommendations for process improvement based on experimental and statistical findings
4. Be able to apply statistical evidence to quality risk management and continuous improvement	4.1	Apply statistical methods to identify and assess quality risks within a technical process
	4.2	Evaluate statistical evidence to support investigation and corrective and preventive action decisions
	4.3	Develop recommendations for integrating statistical analysis into routine quality monitoring and continuous improvement

Indicative Content	
LO1	1.1 must include experimental objectives and hypotheses; independent and dependent variables; controls; replication; randomisation; sources of bias; principles of reproducibility and reliability. 1.2 must include the principles, applications, advantages and limitations of different experimental approaches; selection of experimental designs according to objectives, process characteristics and available resources. Other examples include factorial designs, Design of Experiments (DoE), randomised designs and observational studies. 1.3 must include control of experimental variables; measurement reliability; sources of bias and error; replication; appropriate sample selection; documentation and traceability; factors affecting the reproducibility of findings. 1.4 must include relevant health and safety requirements; risk assessment; ethical considerations; product quality and patient-safety implications; data integrity; appropriate authorisation and control of experimental activities in regulated environments.
LO2	2.1 must include identification of the investigation objective or hypothesis; selection and justification of an experimental approach; identification of variables and controls; sampling and replication arrangements; data collection methods; consideration of relevant safety, quality and documentation requirements. 2.2 must include calculation and interpretation of descriptive statistics, including mean, median, standard deviation and variance; application of appropriate

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	inferential statistical methods, including confidence intervals and hypothesis testing; justification of the selected methods. 2.3 must include selection and interpretation of appropriate control charts; identification of common-cause and special-cause variation; evaluation of process stability; use of statistical evidence to identify potential process concerns. Other examples include process capability indices and relevant statistical process control techniques. 2.4 must include appropriate presentation of data and statistical results; selection of suitable tables, charts and visualisations; explanation of findings and their significance; adaptation of technical information for relevant audiences; accurate communication of limitations and uncertainty.
LO3	3.1 must include interpretation of experimental and statistical results; identification of significant effects, relationships or trends; assessment of the strength and relevance of findings against the investigation objectives. 3.2 must include identification and evaluation of random and systematic errors; measurement uncertainty; process variability; potential confounding factors; implications for the reliability and interpretation of results. 3.3 must include completeness, accuracy, consistency and traceability of data; identification of missing, anomalous or unreliable information; relevant data-integrity principles; implications of data-quality limitations for interpretation and decision-making. 3.4 must include assessment of experimental findings and process performance; identification of factors influencing efficiency, consistency or product quality; consideration of process constraints, statistical evidence and relevant quality requirements. 3.5 must include evidence-based improvement recommendations; consideration of statistical significance and practical relevance; potential effects on process control, product quality and regulatory compliance; limitations of the available evidence; appropriate measures for evaluating improvement effectiveness.
LO4	4.1 must include selection and application of appropriate statistical approaches to identify adverse trends, variability and emerging quality risks; interpretation of findings in relation to product quality, process performance and risk controls. Other examples include trend analysis, control charts, capability analysis and risk-based evaluation of process data. 4.2 must include analysis of data relating to deviations or quality concerns; evaluation of evidence supporting potential causes; use of statistical findings to inform corrective and preventive actions; consideration of the reliability and limitations of the evidence. 4.3 must include appropriate applications of statistical monitoring and review; selection of relevant measures and reporting arrangements; use of statistical evidence to support continuous improvement, QRM and quality-system decisions; consideration of implementation and ongoing evaluation requirements.

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Assessment Requirements

Assessment must demonstrate the application of specialist knowledge and skills in experimental design, statistical analysis and data interpretation within pharmaceutical manufacturing, aseptic services or pharmacy technical services environments.

Learners must demonstrate Level 5 analytical and evaluative capability, including the ability to design appropriate experiments, select and apply statistical methods, evaluate the reliability of data, interpret findings and develop justified recommendations.

LO2, LO3 and LO4 require evidence of applied skills. Learners must develop an experimental plan, undertake appropriate statistical analyses, interpret technical and quality data, and use findings to support evidence-based decisions.

Assessment may use authentic workplace investigations and datasets or realistic technical scenarios supported by sufficient experimental or process data.

Learners are not required to implement experimental changes to live pharmaceutical processes, undertake unauthorised testing or hold responsibility for approving changes to validated systems.

The qualification does not confer occupational competence or professional authorisation in its own right.

Evidence may include:

- Experimental design proposals and investigation plans
- Evaluations comparing experimental methodologies
- Statistical calculations and analyses
- Completed control charts and statistical process control evaluations
- Process capability assessments
- Experimental and process-data interpretations
- Technical reports presenting statistical findings
- Data-quality and integrity evaluations
- Quality risk assessments supported by statistical evidence
- Investigation or CAPA recommendations
- Process optimisation proposals
- Professional discussions supported by technical evidence

LO1 – Experimental design principles

Learners should evaluate different experimental approaches within realistic pharmaceutical technical services contexts.

Assessment should require consideration of experimental validity, reproducibility, bias, safety and regulatory controls.

Learners should demonstrate why a particular design is appropriate for a stated investigation rather than simply describing different types of experimental design.

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LO2 – Experimental design and statistical analysis

Learners must develop an experimental plan for a specified technical or quality problem.

The plan should establish the investigation objectives, experimental approach, variables, controls, data collection requirements and relevant risk considerations.

Learners must also apply statistical methods to suitable technical or quality datasets.

Assessment should include descriptive statistics, an appropriate application of inferential statistics and statistical process control.

Learners may use spreadsheet software or suitable statistical analysis tools. The assessment should focus on correct method selection, application, interpretation and evaluation rather than requiring extensive manual calculation.

LO3 – Data interpretation and evidence-based decisions

Learners must interpret experimental or process results and evaluate their significance.

Assessment should include consideration of variability, error, uncertainty and data quality.

The evidence should enable learners to distinguish between statistically significant findings and findings that have practical or operational importance.

Recommendations for process optimisation must be supported by relevant analytical evidence, with appropriate recognition of limitations and risks.

LO4 – Quality risk management and continuous improvement

Learners must apply statistical thinking to a realistic quality or process concern.

Assessment should require analysis of relevant data to identify risks, evaluate evidence supporting potential causes and develop justified recommendations.

Learners are not required to implement CAPA or operate an entire quality risk management process. The focus is the use of statistical evidence to inform risk assessment, investigation and improvement decisions.

Where an integrated technical investigation is used, the same dataset may generate evidence across multiple criteria, provided the different analytical and evaluative requirements are clearly demonstrated.

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