Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Quality Risk Management and Incident Learning in Pharmacy Technical Services

Unit Reference Number: K/652/4159

Level: Four (4)

Credit Value: 6

Minimum Guided Learning Hours: 36

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand sources of quality and safety risk in service systems	1.1 Analyse how system, process and human factors can create risk in pharmacy technical services
	1.2 Evaluate the likely consequences of a defined quality or safety hazard
2. Be able to assess risks to service quality	2.1 Apply an appropriate risk assessment method to a defined pharmacy process
	2.2 Recommend proportionate risk controls and escalation based on the assessment
	2.3 Record a risk assessment and proposed controls through an approved quality route
3. Be able to report quality incidents and near misses	3.1 Analyse an incident, near miss and unsafe condition using relevant organisational definitions
	3.2 Record and refer quality information about an incident or near miss within own role and organisational requirements
	3.3 Contribute relevant factual quality information to a defined incident review
4. Be able to use incident learning to support quality controls	4.1 Analyse contributory factors and learning from a defined incident or near miss
	4.2 Evaluate how proposed actions could reduce the chance or impact of recurrence

The intellectual property rights remain with Open Awards.

	4.3 Communicate quality-system learning from an incident or near miss through an appropriate route

Indicative Content	
LO1	AC 1.1 must include analysis of how process, system and human factors interact to create risk in a defined service. Factors could include handovers, workload, interruptions, equipment, materials and information flow. AC 1.2 must include evaluation of who or what could be affected, the likely severity and the limits of available information for a defined hazard. It could include exposure, existing controls and possible product impact.
LO2	AC 2.1 must include application of an appropriate method to identify a hazard, consider likelihood and impact, account for existing controls and record a justified risk judgement. It could use the organisation's risk matrix. AC 2.2 must include proportionate proposed controls, their expected effect on residual risk and the need for escalation where thresholds or authority limits are reached. It could compare prevention, detection and mitigation options. AC 2.3 must include recording of the risk assessment, rationale, proposed controls, ownership and review or escalation status through an approved route. It could use a risk register or equivalent controlled record.
LO3	AC 3.1 must include use of relevant organisational definitions to distinguish an incident, near miss and unsafe condition in a defined case. It could include an event with possible product or patient impact. AC 3.2 must include timely, factual recording and referral of relevant quality information, protection of evidence and observance of confidentiality and role limits. It could include a chronology and links to source records. AC 3.3 must include provision of relevant factual information to a defined incident review, identifying gaps and separating fact from interpretation. It could include records, a chronology or evidence about process controls.
LO4	AC 4.1 must include analysis of supported contributory factors and the quality-system learning from an incident or near miss, without equating cause with blame. It could draw on human-factors or systems approaches. AC 4.2 must include evaluation of how proposed actions might prevent recurrence, improve detection or reduce impact, including possible limitations. It could include a measure for checking whether an action works. AC 4.3 must include communication of a specific quality-system lesson through an appropriate route, with regard to audience, confidentiality and follow-up. It could include an approved briefing or improvement record.

Assessment Requirements
Risk assessment concerns quality systems and process controls, including their potential effect on patient safety. Reporting must follow local routes; the unit does not assess clinical incident management, patient assessment or medicine-related treatment decisions. Use anonymised incidents or realistic cases where access is restricted.

The intellectual property rights remain with Open Awards.

Factual contribution to incident review and shared learning does not require the learner to conduct a clinical investigation.

The intellectual property rights remain with Open Awards.