Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Leadership, Change Management and Continuous Improvement

Unit Reference Number: R/652/4205

Level: Five (5)

Credit Value: 6

Minimum Guided Learning Hours: 35

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand leadership approaches and behaviours that support organisational change	1.1 Evaluate leadership approaches and their suitability for managing change within pharmaceutical technical services
	1.2 Assess the influence of leadership behaviours on colleague engagement, change adoption and workplace culture
	1.3 Evaluate the contribution of change leadership to quality, safety, performance and continuous improvement
2. Be able to apply structured change management approaches within pharmaceutical technical services	2.1 Evaluate change management models and select an appropriate approach for a specified change initiative
	2.2 Analyse the potential impact of a proposed change on people, processes and systems
	2.3 Develop a change management plan incorporating stakeholder engagement and communication arrangements
	2.4 Assess risks and barriers to implementing a proposed change and develop appropriate responses
	2.5 Apply appropriate communication and engagement techniques to support a change initiative
3. Be able to apply continuous improvement approaches within pharmaceutical technical services	3.1 Analyse operational or quality performance evidence to identify and prioritise opportunities for improvement

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	3.2	Apply an appropriate continuous improvement methodology to develop an improvement initiative
	3.3	Contribute to the implementation of improvement actions within a technical services environment
	3.4	Evaluate the effectiveness of an improvement initiative and recommend further actions
4. Be able to support colleagues through change and maintain team effectiveness	4.1	Assess human factors and individual needs that may influence responses to change
	4.2	Apply coaching, communication or other supportive approaches to assist colleagues during change
	4.3	Apply constructive approaches to addressing resistance or concerns arising from change
	4.4	Evaluate approaches to maintaining performance and wellbeing during organisational change

Indicative Content	
LO1	1.1 must include leadership styles and approaches relevant to change; characteristics of effective change leadership; suitability of different approaches for technical teams, operational circumstances and organisational requirements. Other examples include transformational, situational and participative leadership. 1.2 must include leadership communication, trust, credibility and role-modelling; colleague engagement and motivation; psychological safety; relationships between leadership behaviours, workplace culture and acceptance of change. 1.3 must include leadership responsibilities in regulated environments; maintaining quality and safety during change; reinforcement of compliant behaviours; alignment of change initiatives with operational objectives and continuous improvement.
LO2	2.1 must include comparison of change management models; their principles, strengths and limitations; selection and justification of an approach appropriate to the scale, complexity and context of the change. Other examples include Kotter's eight-step model, ADKAR and Lewin's change model. 2.2 must include change impact assessment; identification of affected stakeholders, processes and systems; implications for roles, competence, workload, operational performance, quality and regulatory compliance. 2.3 must include change objectives; selected change management approach; stakeholder identification and analysis; communication and engagement activities; responsibilities, timescales and measures for monitoring adoption. Other examples include stakeholder mapping, communication plans and

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	change-readiness assessments. 2.4 must include identification and assessment of implementation risks; potential resistance, resource constraints, skills gaps and operational disruption; development of proportionate mitigating actions and escalation arrangements. 2.5 must include communication of the purpose and implications of change; adaptation of messages to stakeholder needs; opportunities for feedback and consultation; responding to concerns; maintaining appropriate records and communication channels.
LO3	3.1 must include identification of improvement needs using relevant performance or quality evidence; analysis of inefficiencies, recurring problems or process weaknesses; consideration of potential effects on quality, safety, compliance and service performance. 3.2 must include selection and application of a structured improvement approach; analysis of the identified problem; development of objectives, proposed actions and measures of success. Other examples include Lean, Kaizen, Plan–Do–Check–Act (PDCA), process mapping and waste identification. 3.3 must include practical contribution to implementing improvement activities; coordination or communication of agreed actions; consideration of operational and quality requirements; monitoring implementation progress and identifying issues requiring escalation. 3.4 must include evaluation against defined improvement objectives and performance measures; consideration of actual or anticipated effects on efficiency, quality, safety and compliance; identification of unintended consequences, residual issues and further improvement opportunities.
LO4	4.1 must include human factors affecting change adoption; individual and team responses to uncertainty; workload, stress, confidence and competence; identification of support needs and potential barriers to engagement. 4.2 must include selection and application of appropriate support techniques; active listening, questioning and feedback; consideration of individual needs; reinforcement of agreed changes; maintenance of professional boundaries. Other examples include coaching conversations, structured briefings and individual development discussions. 4.3 must include identification and exploration of concerns; professional communication; consideration of the underlying causes of resistance; appropriate consultation, negotiation or escalation; development of proportionate responses. 4.4 must include effects of change on workload, competence, morale, resilience and performance; approaches to maintaining service quality and staff wellbeing during transitions; evaluation of support arrangements and identification of further actions.

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Assessment Requirements

Assessment must demonstrate the application of leadership, change management and continuous improvement knowledge and skills within pharmaceutical manufacturing, aseptic services or pharmacy technical services environments.

Learners must demonstrate Level 5 analytical and evaluative capability, including the ability to select appropriate change management approaches, assess the impact of change, apply improvement methodologies, engage stakeholders and evaluate outcomes.

LO2, LO3 and LO4 require evidence of applied skills. Learners must develop and apply change management arrangements, contribute to improvement activities, and demonstrate appropriate communication and support for colleagues during change.

Assessment may be based on authentic workplace activities or realistic simulated scenarios where opportunities to undertake particular change management activities are unavailable.

For AC 3.3, learners must demonstrate a contribution to implementing improvement actions. Where workplace implementation is unavailable, a structured simulation may be used, provided it includes activities that allow the learner to demonstrate practical implementation skills rather than simply produce an implementation plan.

Learners are not required to hold formal managerial authority, approve organisational changes, manage staff or independently authorise changes to regulated processes.

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

Evidence may include:

- Evaluations of leadership and change management approaches
- Change impact assessments
- Stakeholder analyses and communication plans
- Change management plans
- Risk assessments and mitigation arrangements
- Records of stakeholder engagement activities
- Observations of change-related communications or discussions
- Continuous improvement evaluations and proposals
- Evidence of participation in improvement implementation
- Performance monitoring and improvement evaluations
- Coaching or colleague-support records
- Evaluations of employee responses to change
- Professional discussions supported by relevant workplace evidence

LO1 – Change leadership

Learners should evaluate leadership approaches in the context of organisational change within pharmaceutical technical services.

Assessment should require consideration of how leadership influences engagement, workplace culture, compliance and the adoption of changes.

The focus should be on leadership in change situations rather than general leadership

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theory, which is covered more extensively in Unit 13.

LO2 – Change management

Learners must apply a structured change management approach to a specified initiative.

The assessment should require learners to select and justify an appropriate methodology, evaluate impacts on people, processes and systems, identify barriers, and develop appropriate engagement and communication arrangements.

For AC 2.5, learners must demonstrate a communication or engagement activity. This may involve an authentic workplace interaction or a realistic simulation.

A written communication plan is not sufficient.

LO3 – Continuous improvement

Learners must apply a structured improvement methodology to an identified operational or quality issue.

The assessment must include appropriate evidence to support identification of the improvement opportunity, development of proposed actions and evaluation of outcomes.

Evidence might include contributing to a workplace improvement activity, coordinating an implementation task, communicating revised arrangements or undertaking a structured simulation involving implementation decisions and activities.

Learners are not required to independently lead or complete an entire organisational improvement initiative.

For AC 3.4, evaluation may use actual performance evidence or realistic post-implementation data supplied through a case study.

LO4 – Supporting colleagues through change

Learners must assess individual or team needs arising from change and demonstrate appropriate support and communication skills.

Assessment should include a realistic change-related situation involving uncertainty, resistance, workload pressures or development needs.

For AC 4.2 and 4.3, direct evidence of communication or supportive interaction is required, through workplace activity or simulation.

Learners should also evaluate how change may affect performance and wellbeing, identifying appropriate support measures and recognising the limits of their professional responsibilities.

An integrated change or improvement project could generate evidence across LO2, LO3 and LO4, provided each criterion is clearly demonstrated.

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