Australian Government

Department of Education, Employment and Workplace Relations

FDFPHGMP3A Monitor the implementation of Good Manufacturing Practice procedures

Release: 1

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Modification History

Not applicable.

Unit Descriptor

This is a Core unit for pharmaceutical processing. It covers the skills and knowledge required to provide a leadership role in supporting day-to-day implementation of Good Manufacturing Practices (GMP) in a work area. It also involves supporting others to implement the requirements of GMP. This unit applies to those with formal responsibility for others and to those required to model workplace policies and procedures but who have no formal management role.
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Application of the Unit

Not applicable.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Not applicable.

Employability Skills Information

Not applicable.

Elements and Performance Criteria Pre-Content

Not applicable.

Elements and Performance Criteria

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Element	Performance Criteria
1 Ensure others in the work area are able to meet GMP requirements	1.1 Relevant clothing and equipment appropriate towork requirements are available, functional and correctlyfitted
	1.2 Advice on GMP responsibilities and proceduresis accessible and clearly explained
	1.3 GMP control measures used in the work area canbe identified by those in the work area
	1.4 Mentoring and coaching support is available tosupport individuals/groups to implement GMP and relatedprocedures
	1.5 Training needs are identified and addressedwithin level of responsibility
2 Monitor personal hygiene and conduct of team members in the work area	2.1 Personal hygiene of work team meets GMPrequirements
	2.2 Clothing is prepared, used, stored anddisposed of according to GMP and workplace procedures
	2.3 Personal movement around the workplacecomplies with area entry and exit procedures
3 Monitor implementation of GMP requirements in the work area	3.1 GMP procedures in the work area are clearlydefined, documented and followed
	3.2 Non-compliance with identified procedures isreported and addressed within level of responsibility
	3.3 Personal behaviour is consistent withworkplace policies and procedures that support GMP
	3.4 Workplace procedures to control resourceallocation and process are followed to meet GMP requirements
	3.5 GMP non-conformance is identified and reportedaccording to workplace procedure
	3.6 GMP information is recorded to meet

		workplacereporting requirements
		3.7 The workplace is maintained in a clean andtidy order to meet GMP housekeeping standards
4	Contribute to validation processes	4.1 Validation practices and procedures arereviewed in consultation with relevant personnel
		4.2 Validation results and issues are identifiedand corrective action taken within level of responsibility
		4.3 Documentation and recording requirements meetGMP code and company requirements
5	Take corrective action in response to GMP non-compliance	5.1 Processes, practices or conditions which couldresult in non-compliance with GMP are identified and reportedaccording to workplace reporting requirements
		5.2 Corrective action is taken in accordancewithin level of responsibility
		5.3 GMP issues are raised with designatedpersonnel
6	Maintain and improve GMP in the work area	6.1 Processes or conditions which could result innon-conformance with GMP are identified, reported and correctedwithin level of responsibility
		6.2 Matters raised relating to GMP are promptlyresolved and/or referred to appropriate personnel
		6.3 Effectiveness of control measures aremonitored within level of responsibility
		6.4 Others in the work area are advised of GMPmatters relevant to work role
		6.5 Changes to documentation are proposed inaccordance with workplace procedures to maintain GMP
		6.6 GMP audits are conducted to meet company andlegislative requirements
		6.7 Action is taken to respond to auditrecommendations within level of responsibility

Required Skills and Knowledge

Not applicable.

Evidence Guide

The assessment process must address all of the following items of evidence.
Ability to:
1. Communicate information about GMP requirements and related procedures to others in the work area. This requires demonstration of two-way communication including active listening and constructive response to feedback
2. Provide access to GMP documentation
3. Model personal conduct and work activities to meet requirements of GMP
4. Identify control points in work area and demonstrate monitoring techniques used
5. Support others to identify control points and demonstrate monitoring and control methods
6. Support others to follow GMP procedures. This includes validation procedures within level of responsibility
7. Ensure that appropriate and timely action is taken in response to non-compliance
8. Determine action required to respond to GMP non-compliance within level of responsibility
9. Participate in consultation processes to improve GMP. This may include investigating actual and potential GMP non-compliance
10. Participate in and/or review practices and procedures to prevent or minimise the likelihood of unacceptable performance
11. Ensure that housekeeping standards are maintained and that equipment is in operational order. This may include participating in the management of equipment calibration
12. Monitor the recording of GMP information to confirm that records accurately reflect performance and meet the requirements of the workplace and legislation
Knowledge of:
13. The role of GMP in preventing contamination, its relationship to legislative responsibilities and potential implications of non-compliance
14. GMP arrangements in the workplace. This includes awareness of relevant GMP codes of practice and related workplace policies and procedures to implement these responsibilities
15. The relationship between GMP and the quality system, personnel responsible for designing and managing GMP, personal role to maintain GMP, the role of internal and external auditors as appropriate
16. Procedures followed to investigate contamination events and performance improvement processes
17. Clothing and footwear requirements for working in and/or moving between work areas
18. Current technical and process knowledge required to monitor GMP and participate in investigating GMP non-compliance within level of responsibility. This includes an understanding of common micro-biological, physical and chemical contaminants, conditions under which types of contamination are likely to occur, related control methods and validation procedures and responsibilities
19. Basic concepts of quality assurance including quality specifications, operating parameters, validation procedures and control methods. This includes an understanding of related documentation including Standard Operating Procedures and/or batch instructions
20. Control methods and procedures used in the work area to maintain GMP. This includes an understanding of the purpose of control, the consequence if not controlled and the method of control where relevant. It also includes an understanding of the methods used to monitor process control.
21. Purpose and requirements of validation procedures and purpose of equipment calibration

22. Recall and traceability procedures relevant to work area
23. GMP responsibilities and requirements relating to the work area
24. Properties, handling and storage requirements of raw materials, packaging components and final product handled and used in the work area
25. Standards for materials, equipment and utensils used in the work area
26. Procedures for responding to out-of-specification or unacceptable performance/outcomes. This includes procedures for identifying and isolating or quarantining materials or product of unacceptable quality
27. Documentation system and procedures. This includes record keeping to meet both company and legal requirements, procedures for developing and/or reviewing workplace procedures and document control systems used in the workplace
28. Auditing arrangements, roles and responsibilities as they relate to own work responsibilities. This may include an understanding of the purpose and process for internal and external audit processes
29. Appropriate communication skills and techniques to convey information appropriate to audience
30. Housekeeping requirements and responsibilities relating to own work. Where relevant this includes use and storage of housekeeping/cleaning equipment
31. Waste collection, recycling, handling and disposal. This may include handling/disposal requirements for different types of waste such as hazardous waste where relevant

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Range Statement

The range statement indicates the context for demonstrating competence. This statement is a guide and unless otherwise indicated, items may or may not apply as required by the work context.
- Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements and industrial awards and agreements
- Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes relevant Good Manufacturing Practice (GMP) codes, the Therapeutic Goods Act, labelling, weights and measures legislation and legislation covering environmental management, occupational health and safety, anti-discrimination and equal opportunity
- Responsibility for applying good manufacturing practice relates to the person's work area
- Products/materials handled and stored can include raw materials, packaging components and consumables, part-processed product, finished product and cleaning materials
- Reporting systems may include electronic and manual data recording and storage systems
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Unit Sector(s)

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