Australian Government

Department of Education, Employment and Workplace Relations

FDFPH4005A Participate in validation processes

Revision Number: 1

ISC INDUSTRY SKILLS COUNCILS
Creating Australia's Future

FDFPH4005A Participate in validation processes

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	The unit is targets content outlined in Annex 15 of the Australian Code of Good Manufacturing Practice for Medicinal Products and should be read in conjunction with this document. It covers the skills and knowledge required to participate in validation processes.

Application of the Unit

Application of the unit	This unit provides an overview of validation processes used to support Good Manufacturing Practice (GMP) in the pharmaceutical sector.
	The unit covers the skills and knowledge required by production/packaging line managers or supervisors to participate in validation processes. This person would not typically have responsibility for validation but would require an understanding of the purpose, procedures and responsibilities for different types of validation.
	This unit applies to people working in a supervisory or line management role. Their involvement in validation would typically be as part of a multi-disciplinary team.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.

Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.

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Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Participate in qualification processes for new or modified facilities, systems or equipment	1.1. Responsibilities and procedures for developing and implementing design qualification, installation qualification, operational qualification and performance qualification are identified
	1.2. Qualification processes and documentation are developed or reviewed within level of responsibility
	1.3. Workplace procedures are documented to support operational requirements
2. Participate in validation processes for new or modified facilities, systems or equipment	2.1. Validation requirements in the work area are identified
	2.2. The validation protocol is followed to support validation activities in the work area
	2.3. Data is collected, analysed and reported to meet GMP requirements

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE
This section describes the skills and knowledge required for this unit.
Required skills
Ability to: • apply principles of risk management to identify critical facilities, systems and equipment   • identify and interpret validation documentation relating to qualification and validation requirements for a work area   • participate in qualification and validation procedures within level of responsibility   • identify and manage the impact of qualification and validation procedures on related processes or work areas/personnel within level of responsibility   • liaise with other relevant departments/functions to coordinate and schedule validation processes   • develop documentation to support qualification and validation according to required formats and within level of responsibility   • ensure that operators in the work area have the   • prepare workplace documentation in plain English and suited to purpose and audience   • use communication skills to interpret and complete work information to support operations of work team or area   • demonstrate and support cooperative work practices within a culturally diverse workforce
Required knowledge
Knowledge of: • principles and purpose of qualification and related procedures and responsibilities   • principles and purpose of validation and related procedures and responsibilities   • purpose and application of prospective, concurrent and retrospective validation   • data collection, analysis and reporting requirements   • scope, application and timing of validation including any relevant circumstances that could trigger the need to validate or re-validate or justify not carrying out a validation process prior to production starting   • relationship between validation and change control   • equipment design drawings and process flow charting   • relevant investigation methods including process capability and root cause analysis   • recording and reporting requirements   • training and assessment arrangements and responsibilities   • workplace documentation and authorisation procedures

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Evidence Guide

EVIDENCE GUIDE	
The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.	
Overview of assessment	Assessment may occur in a real or simulated pharmaceutical or complementary medicine manufacturing workplace where the assessment environment provides access to workplace documentation relating to qualification and validation processes that are typical of commercial manufacturing businesses and meet the requirements of the Therapeutic Goods Act. It will also provide a range of commercial production/packaging equipment and activities typically used in a commercial manufacturing environment. Qualification processes may be simulated to allow a walk through of the process.
Critical aspects for assessment and evidence required to demonstrate competency in this unit	Evidence of participation in a team responsible for validation processes. This includes providing evidence developed by the candidate to: • review the qualification and validation protocols to assess implications for a work area and related departments/functions • participate in qualification procedures - design qualification, installation qualification, operational qualification, and/or performance qualification For example, this could include conducting trials in the work area as part of performance qualification in a work area. The assessment activity requires use and/or development of checklists and tools in required formats to carry out qualification as part of a project team. It also includes monitoring and reporting on outcomes.
Context of and specific resources for assessment	Assessors must be satisfied that the person can consistently perform the unit as a whole, including all elements, performance criteria, and required skills and knowledge. A holistic approach should be taken to the assessment. Assessment of this unit would typically involve responding to 'what if' scenarios, answering questions and conducting workplace projects Resources for assessment:

EVIDENCE GUIDE	
	• copies of the relevant Act, regulations, codes and guides • workplace documentation including procedures relating to qualification and validation • real or simulated workplace context.
Method of assessment	This unit could be assessed concurrently with other units relating to problem solving and process improvement. Examples could be: • FDFOP2015A Apply principles of statistical process control • FDFPH4001A Prepare and review workplace documentation to support Good Manufacturing Practice • FDFPH4002A Facilitate and monitor Good Manufacturing Practice • FDFPH4003A Facilitate contamination control • FDFPH4004A Participate in change control procedures • MSACMT450A Undertake process capability improvements.
Guidance information for assessment	To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

Range Statement

RANGE STATEMENT	
The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.	
Design qualification	Design requirements of facilities and equipment must meet those outlined in Australian Code of Good Manufacturing Practice for Medicinal Products, Chapter 3
Installation qualification	Installation qualification includes but is not limited to: • checking of equipment, piping, instrumentation and services installation checked against current engineering drawings and specifications • piping and instrumentation diagrams (P&IDs), operating manuals and other supplier information relating to operation and maintenance • calibration requirements • cleaning and sanitation inspection requirements • safety issues • environmental issues
Operational qualification	Operational qualification includes but is not limited to: • tests of processes, systems and equipment to confirm that functioning meets agreed criteria within operating conditions • calibration plans • preventative maintenance plans • operating, cleaning and sanitation operating procedures • training programs and schedules • recording requirements
Performance qualification	Performance qualification may include but is not limited to:

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RANGE STATEMENT

	• tests, using production materials, qualified substitutes or simulated product, that have been developed from knowledge of the process, facilities, systems or equipment • tests to include a condition or set of conditions encompassing upper and lower operating limits
Validation requirements	Validation requirements include but are not limited to: • process validation • packaging validation • cleaning validation • calibration validation • test method validation • validation of computerised systems • re-validation of in-use processes
Validation protocol	A validation protocol includes but is not limited to: • a short description of the process • summary of the critical step/s being investigated • list of equipment/facilities to be used (including measuring/monitoring equipment) together with its calibration status • finished product specifications for release • list of analytical methods, as appropriate • proposed in-process controls with acceptance criteria • additional testing to be carried out, with acceptance criteria and analytical validation, as appropriate • sampling plan • methods for recording and evaluating results • roles and responsibilities • proposed timetable
Validation documentation	Documentation may include but is not limited to: • validation master plan • protocols • reports • operating procedures and work instructions

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RANGE STATEMENT	
	• occupational health and safety (OHS) and environmental requirements • manufacturers' specifications

Unit Sector(s)

Unit sector	Pharmaceutical manufacturing

Competency field

Competency field	

Co-requisite units

Co-requisite units		

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