Modification history

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| Release | Comments |
| Release 1 | This version released with AHC Agriculture, Horticulture and Conservation and Land Management Training Package Version 5.0. |

| AHCMDC301 | Apply regulatory and quality requirements to the production of medicinal cannabis |
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| Application | This unit of competency describes the skills and knowledge required to ensure that medicinal cannabis production processes comply with regulatory requirements and the organisation's quality system and procedures.  The unit applies to individuals who carry out skilled work in medicinal cannabis production processes. They may not be directly responsible for developing procedures for compliance with regulation and quality systems however are required to be aware of the existence of legislation and the Good Practice Standards framework, including the impact it has on the organisation's arrangements in place to ensure compliance and quality of the product.  No licensing, legislative or certification requirements apply to this unit at the time of publication |
| Prerequisite Unit | Nil |
| Unit Sector | Medicinal Cannabis (MDC) |

| Elements | Performance Criteria |
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| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Identify regulatory requirements for medicinal cannabis production | 1.1 Identify legislation, regulations and standards relevant to the production of medicinal cannabis  1.2 Investigate purpose and intent of regulatory requirements  1.3 Identify roles and responsibilities of authorities responsible for administering requirements  1.4 Identify requirements of licensing for medicinal cannabis cultivators and manufacturers |
| 2. Apply regulatory requirements to work practices | 2.1 Identify workplace policies and procedures in relation to own work responsibilities in medicinal cannabis production processes  2.2 Review work practices to ensure compliance with regulatory requirements  2.3 Identify and report instances of non-compliance and potential problems according to workplace procedures |
| 3. Identify and apply quality practices for production of medicinal cannabis | 3.1 Identify quality requirements for the production of medicinal cannabis  3.2 Determine critical control points for work area  3.3 Conduct a safety hazard analysis and risk assessment  3.4 Monitor work area, materials, processes and crop to ensure compliance with quality requirements, hygiene and health and safety procedures  3.5 Identify and report instances of deviation and potential problems according to workplace procedures |
| 4. Complete records to comply with regulatory and quality requirements | 4.1 Record details of cannabis material receipted at site, stored on site and supplied from the site into and on site, out of production and off site  4.2 Record details of cultivation processes that traces plant batch as it moves through production processes  4.3 Record hygiene and sanitation activities  4.4 Record health and safety requirements, including incident reports  4.5 Record details of plant, pest and disease monitoring, including test methods, results and control  4.6 Record details of fertigation and climate, including environmental control data and inputs  4.7 Identify and report instances of deviation and non-compliance in record keeping according to workplace procedures |

| Foundation Skills  This section describes those language, literacy, numeracy and employment skills that are essential for performance in this unit of competency but are not explicit in the performance criteria. | |
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| Skill | Description |
| Reading | * Interpret legal, and quality documentation from a variety of sources to determine compliance requirements |
| Writing | * Complete workplace documentation using accurate and legible data, appropriate terminology and cross check for errors |
| Numeracy | * Interpret numerical data from sampling results and control gauges |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| AHCMDC301 Apply regulatory and quality requirements to the production of medicinal cannabis | Not applicable | New unit | No equivalent unit |

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| Links | Companion Volumes, including Implementation Guides, are available at VETNet:  <https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=c6399549-9c62-4a5e-bf1a-524b2322cf72> |

| TITLE | Assessment requirements for AHCMDC301 Apply regulatory and quality requirements to the production of medicinal cannabis |
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| Performance Evidence | |
| An individual demonstrating competency in this unit must satisfy all of the elements and performance criteria of this unit.  There must be evidence that the individual has effectively monitored the production of medicinal cannabis to ensure compliance with legislation and quality requirements, including:   * identified and applied legal and regulatory requirements and elements of quality standards that apply to production processes in own area of responsibility * assessed own work area for critical control points, safety and risks * completed accurate records for production processes in own area of responsibility, including records that cover all of the following on at least three occasions: * cultivation processes * traceability * hygiene and sanitation * health and safety * monitoring, sampling and control * identified and reported instances of deviation, potential problems or non-compliance. | |

| Knowledge Evidence |
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| An individual must be able to demonstrate the knowledge required to perform the tasks outlined in the elements and performance criteria of this unit. This includes knowledge of:   * national, state and territory legislation, regulations and standards relevant to the production of medicinal cannabis * legislative and regulatory responsibilities required of licensed cultivators and manufacturers of medicinal cannabis * roles and functions of commonwealth government authorities responsible for administering the legislation, including record requirements * Good Practice Standards and organisation quality systems relevant to the production of medicinal cannabis including: * Good Agricultural and Collection Practices (GACP) in relation to cultivation and harvesting of plants and quality and consistency of products * Good Manufacturing Practices (GMP) in relation to pre-processing and quality of products * principles of GACP and GMP in relation to: * cultivation and production processes * traceability * hygiene and sanitation * health and safety * monitoring, sampling and control * documentation processes * organisational record keeping requirements. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * skills must be demonstrated on a medicinal cannabis production site or an environment that accurately represents workplace conditions * resources, equipment and materials: * workplace quality system * workplace recording system * specifications: * legislation and regulations related to the production of medicinal cannabis * workplace quality procedures * workplace procedures relating to the production of medicinal cannabis, including health and safety, hygiene and sanitation, recording and reporting requirements.   Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards. |

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