



Australian Government

MSL977010 Contribute to the development of products or applications

Release: 1

MSL977010 Contribute to the development of products or applications

Modification History

Release 1. Supersedes and not equivalent to MSL977006 Contribute to the development of products and applications. Minor title change for clarity. Scope clarification added to Application. Prerequisite unit removed. Element 5 integrated into Element 4. Other minor changes to Performance Criteria.

Application

This unit of competency describes the skills and knowledge to evaluate a product or application brief from a technical perspective and to contribute to the formulation and development of products or applications to meet the brief requirements.

This unit applies to senior technical officers, laboratory supervisors and technical specialists working in all industry sectors. All operations must comply with relevant standards, appropriate procedures and/or workplace requirements.

No licensing or certification requirements exist at the time of publication. However, regulations and/or external accreditation requirements for laboratory operations exist, so local requirements should be checked. Relevant legislation, industry standards and codes of practice within Australia must also be applied.

Pre-requisite Unit

Nil

Competency Field

Testing

Elements and Performance Criteria

Elements	Performance Criteria
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.
1. Scope the development project	1.1 Confirm details of new product or application brief from consultation and available information 1.2 Specify new product/application requirements according to brief 1.3 Analyse existing products (internal and external to workplace) to determine if they meet customer need 1.4 Interpret and apply relevant Acts, regulations and codes of practice

Elements	Performance Criteria
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.
	1.5 Prepare product/application development plan that reflects internal and external parameters 1.6 Obtain approval for development plan from appropriate personnel
2. Set scope of project	2.1 Estimate resource requirements for staffing, equipment and materials 2.2 Identify roles and responsibilities of project team members 2.3 Identify quality requirements and quality standards 2.4 Identify and document project timelines, taking into account any constraints
3. Develop new product	3.1 Prepare documentation for new product pilot batch 3.2 Evaluate and recommend materials for new product or application 3.3 Calculate required quantities of materials and adjust for properties as appropriate 3.4 Develop/modify products in pilot batch scale in accordance with workplace and regulatory requirements 3.5 Arrange for product evaluation against development brief 3.6 Modify product/application to meet evaluation recommendations 3.7 Edit documentation and issue to appropriate personnel 3.8 Recommend and evaluate packaging for new product/application 3.9 Prepare protocol for stability (shelf) testing of new product/application
4. Contribute to development of procedures and materials	4.1 Develop in-process and laboratory testing protocols relevant to the product 4.2 Prepare accurate and complete product labelling information 4.3 Assist in product and analytical method validation 4.4 Implement a plant hygiene and asepsis program that responds to product/application needs 4.5 Prepare workplace procedures for quality and laboratory-related procedures 4.6 Prepare work health and safety (WHS) procedures for the laboratory and manufacturing environment 4.7 Seek approval for procedures and materials from relevant personnel 4.8 Document and report development outcomes in accordance with

Elements	Performance Criteria
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.
	workplace requirements

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential to performance.

Foundation skills essential to performance are explicit in the performance criteria of this unit of competency.

Unit Mapping Information

Supersedes and not equivalent to MSL977006 Contribute to the development of products and applications.

Links

MSL Laboratory Operations Companion Volume Implementation Guide is available from VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>

Assessment Requirements for MSL977010 Contribute to the development of products or applications

Modification History

Release 1. Supersedes and not equivalent to MSL977006 Contribute to the development of products and applications. Minor title change for clarity. Scope clarification added to Application. Prerequisite unit removed. Element 5 integrated into Element 4. Other minor changes to Performance Criteria.

Performance Evidence

There must be evidence the candidate has completed the tasks outlined in the elements and performance criteria of this unit, and:

- evaluated at least 1 product or application brief, prepared the product development plan and contributed to its development.

Knowledge Evidence

There must be evidence the candidate has knowledge of:

- principles of product or application development, including
- good manufacturing principles for medicinal products (GMP)
- principles of good laboratory practice (GLP)
- business goals and their relationship to specific product or application development
- new product or application requirements, expected performance outcomes and key indicators
- physical and chemical aspects of new product or application development
- details of development plan, budget and timeline for new product/application
- principles and practices of operation of pilot batch equipment
- uses, characteristics and limitations of formulation starting materials
- details of regulatory compliance, quality and stability testing protocols and procedures required for new product/application
- environmental sustainability issues as they relate to the work task
- legal, ethical and work health and safety (WHS) requirements specific to the work task.

Assessment Conditions

Skills must have been demonstrated in the workplace or in a simulated environment that reflects workplace conditions and contingencies. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
 - a standard laboratory equipped with appropriate pilot batch manufacturing and testing equipment

- information technology for research
- starting material and product formulation information
- scheduling charts and project plans
- workplace procedures and guidelines.

Assessors must satisfy the NVR/AQTF mandatory competency requirements for assessors.

Links

MSL Laboratory Operations Companion Volume Implementation Guide is available from VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>