



Australian Government

MSL977001 Contribute to the development of products and applications

Release: 1

MSL977001 Contribute to the development of products and applications

Modification History

Release 1. Supersedes and is equivalent to MSL977001A Contribute to the development of products and applications

Application

This unit of competency covers the ability to evaluate a product/application brief and to contribute to the development of products and applications to meet the requirements of the brief.

This unit of competency is applicable 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.

While no specific licensing or certification requirements apply to this unit at the time of publication, laboratory operations are governed by relevant legislation, regulations and/or external accreditation requirements. Local requirements should be checked.

Pre-requisite Unit

MSL976003 Evaluate and select appropriate test methods and/or procedures

Competency Field

Testing

Unit Sector

Elements and 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/application brief
		1.2	Specify new product/application requirements
		1.3	Analyse existing products (internal and external to workplace) to determine if they meet customer need

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| | | 1.4 | Interpret and apply relevant Acts, regulations and codes of practice |
| | | 1.5 | Prepare product development plan |
| | | 1.6 | Obtain approval for development plan from appropriate personnel |
| 2 | Set scope of project | 2.1 | Estimate resource requirements, including staffing, equipment and materials needed to undertake the project |
| | | 2.2 | Identify roles and responsibilities of project team members |
| | | 2.3 | Identify quality requirements and quality standards |
| | | 2.4 | Prepare project timelines taking into account any constraints |
| 3 | Develop new product formulation | 3.1 | Prepare documentation for new product pilot batch |
| | | 3.2 | Evaluate/recommend materials for new product/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	Assist with preparation of quality/regulatory compliance procedures/materials	4.1	Develop in-process and laboratory testing protocols
		4.2	Prepare product labelling and submit for approval
		4.3	Assist in product and analytical method validation
		4.4	Implement an effective plant hygiene and asepsis program, if applicable
		4.5	Develop good manufacturing principles for medicinal products (GMP)/principles of good laboratory practice (GLP) protocols for approval by appropriate personnel
		4.6	Prepare standard operating procedures (SOPs) for quality and laboratory-related procedures
		4.7	Prepare work health and safety (WHS) procedures for the laboratory and manufacturing environment and submit for approval
5	Document and report project outcomes	5.1	Document and report project outcomes
		5.2	Complete project reporting 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.

Range of Conditions

This field allows for different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Standards, codes, procedures and/or workplace requirements

Standards, codes, procedures and/or workplace requirements include the latest version of one or more of:

- Australian and international standards covering the requirements for the competence of testing and calibration laboratories, laboratory design and construction, physical containment levels and facility types, laboratory safety,

- quality and environmental management systems, and measurement management systems
- national WHS standards and codes of practice, national measurement regulations and guidelines, and intellectual property (IP) and copyright legislation
 - Australian and international standards and guidelines covering specialised analysis, accuracy of measurement methods and results, expression of uncertainty, quantifying uncertainty, Association of Analytical Communities International (AOAC International) Official Methods of Analysis, and Validation of Analytical Procedures
 - specific codes, guidelines, procedures and methods, such as National Association of Testing Authorities (NATA) accreditation programs requirements, Australian code of good manufacturing practice for medicinal products (GMP), principles of good laboratory practice (GLP), Food Standards Australia New Zealand (FSANZ) Code, Australian Dangerous Goods Code, gene technology regulations, National Health and Medical Research Council (NHMRC) Guidelines, and Therapeutic Goods Regulations
 - workplace documents, such as SOPs; quality and equipment manuals; calibration and maintenance schedules; material safety data sheets (MSDS) and safety procedures; material, production and product specifications; production and laboratory schedules; workplace recording and reporting procedures; waste minimisation and safe disposal procedures; cleaning, hygiene and personal hygiene requirements; stock records and inventory; and raw material catalogues
 - sampling procedures (labelling, preparation, storage, transport and disposal)
 - test procedures (validated and authorised)

Product/application briefs Product/application briefs are provided by, but are not limited to, one or more of:

- internal or external customers
- marketing
- production

Materials used to manufacture products/applications

Materials used to manufacture products/applications include, but are not limited to, one or more of:

- solvents
- emulsifiers

- thickeners
- surfactants
- disintegrants
- fillers
- moisturising materials
- colouring materials
- flavours
- perfumes
- opacifiers
- propellants
- sunscreens

Calculations

Calculations are required to adjust properties, such as:

- assay/potency
- viscosity
- application payload
- hardness
- moisture content
- colour

WHS and environmental management requirements

WHS and environmental management requirements include:

- complying with WHS and environmental management requirements at all times, which may be imposed through state/territory or federal legislation. These requirements must not be compromised at any time
- applying standard precautions relating to the potentially hazardous nature of samples
- accessing and applying current industry understanding of infection control issued by the National Health and Medical Research Council (NHMRC) and State and Territory Departments of Health, where relevant

Unit Mapping Information

Release 1. Supersedes and is equivalent to MSL977001A Contribute to the development of products and applications

Links

Companion Volume implementation guides are found in VETNet -

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

Assessment Requirements for MSL977001 Contribute to the development of products and applications

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Performance Evidence

Evidence of competence in this unit must satisfy all of the requirements of the elements and performance criteria, and include demonstration of:

- evaluating at least one (1) product/application brief, preparing the product development plan and contributing significantly to product/application development
- interpreting a brief to determine product or application development requirements
- interpreting and explaining sections of legislation, codes, regulations and Australian Standards that apply to the tasks undertaken in developing products and applications
- applying theoretical knowledge of starting material and formulation principles to develop products or applications
- researching alternative formulations and making formulation recommendations for pilot batch manufacture
- using environment-friendly strategies for formulations
- manufacturing pilot batches
- evaluating pilot batches against the project brief
- evaluating product or application stability
- evaluating the work health and safety (WHS) requirements to be observed for each ingredient during manufacture of product or application
- evaluating the WHS suitability of each ingredient for use in the formulation
- ensuring that the product or application meets regulatory requirements
- documenting the development process in accordance with workplace procedures.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- principles of product or application development
- business goals and their relationship to specific product or application development
- new product/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
- formulation development procedures

- details of regulatory compliance, quality and stability testing protocols and procedures required for new product/application
- relevant hazards, WHS and environment requirements.

Assessment Conditions

- Judgment of competence must be based on holistic assessment of the evidence. Assessment methods must confirm consistency of performance over time, rather than a single assessment event.
- This unit of competency is to be assessed in the workplace or a simulated workplace environment. A simulated workplace environment must reflect realistic operational workplace conditions that cover all aspects of workplace performance, including the environment, task skills, task management skills, contingency management skills and job role environment skills.
- Foundation skills are integral to competent performance of the unit and should not be assessed separately.
- Assessment processes and techniques must be appropriate to the language, literacy and numeracy requirements of the work being performed and the needs of the candidate.
- Knowledge evidence may be collected concurrently with performance evidence or through an independent process, such as workbooks, written assessments or interviews (provided a record is kept in each case).
- This unit of competency may be assessed with:
 - MSL977002 Troubleshoot equipment and/or production processes
 - MSL977003 Contribute to the validation of test methods
 - MSL977004 Develop or adapt analyses and procedures
- Holistic assessment methods include:
 - review of development brief and development plan (budget, timeline, resources and quality requirements) prepared by the candidate
 - review of new product/application documentation (formulation, evaluation and quality/regulatory compliance procedures) prepared by the candidate
 - feedback from supervisors and clients confirming the details of contributions made by the candidate to the development of new product/application
 - oral or written questioning covering principles of product or application development and the candidate's specific contributions to the development of new product/application.
- Access is required to instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - a standard laboratory equipped with appropriate pilot batch manufacturing and testing equipment
 - online data search facilities
 - starting material and product formulation information
 - scheduling charts and project plans
 - standard operating procedures (SOPs) and workplace guidelines.

- Assessors must satisfy the assessor competency requirements that are in place at the time of the assessment as set by the VET regulator.
- The assessor must demonstrate both technical competence and currency.
- Technical competence can be demonstrated through:
 - relevant VET or other qualification/Statement of Attainment AND/OR
 - relevant workplace experience.
- Currency can be demonstrated through:
 - performing the competency being assessed as part of current employment OR
 - having consulted with a laboratory about performing the competency being assessed within the last twelve months.

Links

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