Australian Government

MSL977001 Contribute to the development of products and applications

Release: 1

INDUSTRY SKILLS COUNCILS
Creating Australia's Future

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**	1.1	Confirm details of new product/application brief
		1.2	Specify new product/application requirements

	project	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
		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

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Links

MSA Training Package Implementation Guides - http://mskills.org.au/training-packages/info/