



Australian Government

Department of Education, Employment and Workplace Relations

MSL977001A Contribute to the development of products and applications

Revision Number: 1

MSL977001A Contribute to the development of products and applications

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	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.
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Application of the Unit

Application of the unit	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 enterprise requirements Industry representatives have provided case studies to illustrate the practical application of this unit of competency and to show its relevance in a workplace setting. These can be found at the end of this unit of competency under the section 'This competency in practice'.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		
	MSL976003A	<i>Evaluate and select appropriate test methods</i>

Prerequisite units		
		<i>and/or procedures</i>

Employability Skills Information

Employability skills	This unit contains employability skills.
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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. 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 enterprise) 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 enterprise 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 in 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

ELEMENT	PERFORMANCE CRITERIA
	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 occupational health and safety (OHS) 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

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Required skills include:

- interpreting and explaining sections of legislation, codes, regulations and Australian standards that apply to the tasks undertaken in developing products and applications
- evaluating a product/application brief and contributing to the development of products and applications to meet the requirements of the brief
- interpreting a brief to determine product/application development requirements
- applying theoretical knowledge of starting material and formulation principles to develop product/applications
- using appropriate procedures to research alternative formulations
- using environment friendly strategies for formulations
- making formulation recommendations for pilot batch manufacture
- manufacturing pilot batches
- evaluating pilot batches against project brief
- evaluating product/application stability
- evaluating the OHS requirements to be observed for each ingredient during manufacture of product/application
- evaluating the OHS suitability of each ingredient for use in the formulation
- ensuring that product/application meets regulatory requirements
- following enterprise procedures to document development process

Required knowledge

Required knowledge includes:

- theoretical and practical aspects of product/application development
- physical and chemical aspects of product/application development
- principles and practices of operation of a range of pilot batch equipment
- uses, characteristics and limitations of formulation starting materials
- formulation development procedures
- performance outcomes expected and key indicators
- enterprise and regulatory development, quality and stability testing requirements
- business goals and the impact of their projects on these goals
- operating budgets and plans for work area
- relevant health, safety and environment requirements

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

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Assessors should ensure that candidates can:

- evaluate a product/application brief and contribute to the development of products and applications to meet the requirements of the brief
- interpret a brief to determine product/application development requirements
- apply theoretical knowledge of starting material and formulation principles to develop product/applications
- use appropriate procedures to research alternative formulations
- use environment friendly strategies for formulations
- make formulation recommendations for pilot batch manufacture
- manufacture pilot batches
- evaluate pilot batches against project brief
- evaluate product/application stability
- evaluate the OHS requirements to be observed for each ingredient during manufacture of product/application
- evaluate the OHS suitability of each ingredient for use in the formulation
- ensure that product/application meets regulatory requirements
- follow enterprise procedures to document development process.

Context of and specific resources for assessment

This unit of competency is to be assessed in the workplace or simulated workplace environment.

This unit of competency may be assessed with:

- *MSL977002A Troubleshoot equipment and/or production processes*
- *MSL977003A Contribute to the validation of test methods*
- *MSL977004A Develop or adapt analyses and*

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	<i>procedures.</i> Resources may include: • 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 • appropriate SOPs and enterprise guidelines.
Method of assessment	The following assessment methods are suggested: • review of development work completed by the candidate • review of development briefs completed by the candidate over time to ensure that they were implemented consistently within the required timeframe • feedback from supervisors and/or clients • oral or written questioning to assess development and problem solving approaches. In all cases, practical assessment should be supported by questions to assess underpinning knowledge and those aspects of competency which are difficult to assess directly. Where applicable, reasonable adjustment must be made to work environments and training situations to accommodate ethnicity, age, gender, demographics and disability. Access must be provided to appropriate learning and/or assessment support when required. The language, literacy and numeracy demands of assessment should not be greater than those required to undertake the unit of competency in a work like environment.
This competency in practice	Industry representatives have provided the case studies below to illustrate the practical application of this unit of competency and to show its relevance in a workplace setting. Manufacturing Technical specialists who formulate cosmetics products must apply theoretical and practical knowledge during each stage of the formulation process. This is illustrated

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during the perfuming stage of the product development process for a product range consisting of soap, talc and a water-in-oil emulsion. For example, soaps are alkaline and the selected perfume must be stable under alkaline conditions. Perfumes consist of a large number of components, and any preferential adsorption of some of these components on the surface of the talc will alter the odour. When perfuming an emulsion, the components of the perfume will partition between the water and oil phases of the emulsion, altering the odour reaching the consumer. To get the three products smelling the same after manufacture requires attention to these theoretical concepts. Stability studies must be planned and carried out to ensure that the products are stable in the chosen packs and smell the same throughout their lifetime. When perfuming this rather small range of products, the technical specialists must apply a wide range of theoretical and practical knowledge to satisfy the product brief.

Food processing

Technical specialists in food research laboratories evaluate product briefs provided by marketing. They then develop products to meet the requirements of the brief and convert the brief into a marketable product. After the product is successfully introduced, technical specialists must continue to upgrade the quality and desirability of products because of shortened product life cycles.

As part of their role technical specialists may be required to apply technical knowledge to:

- reduce ingredient costs of existing formulation
- standardise existing formulations and processes for quality and cost control
- identify solutions to existing problems, such as product quality or shelf life
- develop consumer preparation instruction methods
- develop labelling or packaging information
- formulate new or improve existing products
- locate and evaluate new packaging alternatives to meet a range of requirements
- assist in compliance with regulatory standards
- assess consumer preferences
- prepare pilot batches of new products
- assist in scale up of pilot batches to full scale

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- production batches
- test product's shelf life.

This requires an in-depth knowledge of how to select and use various ingredients for specific applications, as well as the chemistry, technology and regulatory aspects of their job.

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.

Codes of practice

Where reference is made to industry codes of practice, and/or Australian/international standards, it is expected the latest version will be used

Standards, codes, procedures and/or enterprise requirements

Standards, codes, procedures and/or enterprise requirements may include:

- Australian and international standards, such as:
 - AS ISO 17025-2005 General requirements for the competence of testing and calibration laboratories
 - AS/NZS 2243 Set:2006 Safety in laboratories set
- AS/NZS ISO 10005:2006 Quality management systems - Guidelines for quality plans
- AS/NZS ISO 10012:2004 Measurement management systems - Requirements for measurement processes and measuring equipment
 - AS/NZS ISO 9000 Set:2008 Quality management systems set
 - ISO 5725 Accuracy (trueness and precision) of measurement methods and results
 - ISO/IEC Guide 98-3:2008 Uncertainty of measurement - Part 3 Guide to the expression of uncertainty in measurement (GUM)
- Eurachem/CITAC Guide CG4 Quantifying uncertainty in analytical measurement
- Australia New Zealand Food Standards (ANZFS) Code
- Association of Analytical Communities

RANGE STATEMENT	
	International (AOAC International) Official methods of analysis • ICH Q2A: Validation of Analytical Procedures - Guideline for industry • Australian code of good manufacturing practice for medicinal products (GMP) • Australian Quarantine and Inspection Service (AQIS) Export Control (Orders) Regulations 1982 and Import Guidelines • calibration and maintenance schedules • enterprise recording and reporting procedures • equipment and quality manuals • gene technology regulations • intellectual property and copyright • maintenance and confidentiality of records • material safety data sheets (MSDS) • material, production and product specifications • national environment protection measures • National Health and Medical Research Council (NHMRC) Guidelines • national measurement regulations and guidelines • OHS national standards and codes of practice • principles of good laboratory practice (GLP) • product formulation documentation • SOPs • suppliers of raw material catalogues • Therapeutic Goods Regulations 1009
Product/application briefs	Product/application briefs may be provided by: • external customers • internal customers • marketing • production
Materials used to manufacture products/applications	Materials used to manufacture products/applications may include: • solvents • emulsifiers • thickeners • surfactants

RANGE STATEMENT	
	• disintegrants • fillers • moisturising materials • colouring materials • flavours • perfumes • opacifiers • propellants • sunscreens
Calculations	• Calculations may be required to adjust properties, such as: • assay/potency • viscosity • application payload • hardness • moisture content • colour
Occupational health and safety (OHS) and environmental management requirements	OHS and environmental management requirements: • all operations must comply with enterprise OHS and environmental management requirements, which may be imposed through state/territory or federal legislation - these requirements must not be compromised at any time • all operations assume the potentially hazardous nature of samples and require standard precautions to be applied • where relevant, users should access and apply current industry understanding of infection control issued by the National Health and Medical Research Council (NHMRC) and State and Territory Departments of Health

Unit Sector(s)

Unit sector	Testing
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Competency field

Competency field	
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Co-requisite units

Co-requisite units		