

National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 2)

Level 2

Credits 40

Purpose

The National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 2) [Ref: 1234] is a qualification designed to build on the skills and knowledge acquired in the National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 1) [Ref: 1233]. Holders of this certificate have mastered further core skills for the pharmaceutical and allied products manufacturing sector, and developed some specialisation in roles such as dispensing, manufacturing, packing, quality control, warehousing or engineering.

The qualification comprises compulsory skills and knowledge associated with the compliance requirements for Good Manufacturing Practice as defined in relevant legislation and regulations, as well as critical industry quality control knowledge, problem solving, group participation and report writing skills. In one elective section, individuals may select specific standards to provide some industry specialisation, while the other elective section allows for generic skills and knowledge to be selected to support this specialisation.

Certificate holders are encouraged to undertake further training towards the proposed National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 3), for which this Certificate will be a prerequisite. Certificate holders who wish to change direction and specialise more fully in the engineering aspects of pharmaceutical and allied products manufacture, may undertake the National Certificate in Engineering and Technology (Pharmaceutical and Allied Products) (Level 2) [Ref: 1235], for which some cross crediting is available.

Special Notes

This qualification has a prerequisite qualification (see Requirements for Award of Qualification below). People who do not hold this prerequisite qualification should therefore expect to either complete it, or gain it by demonstration of equivalent knowledge and skills, prior to being awarded this qualification.

Credit Range

| | Compulsory | Elective A | Elective B |
|--------------------------|-------------------|-------------------|-------------------|
| Level 2 or above credits | 14 | 7 | 19 |
| Minimum totals | 14 | 7 | 19 |

Requirements for Award of Qualification

This qualification will be awarded to people who have been awarded the National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 1) [Ref: 1233] and credited with a minimum of 40 credits at Level 2 or above and who have met the requirements of the compulsory and elective sections.

Compulsory

All the standards listed are required.

Elective A

A minimum of 7 credits is required from the list of standards.

Elective B

The balance of credits required, to achieve a minimum total of 40 credits at Level 2 or above, from the list of standards and domains.

Award of NQF Qualifications

Credit gained for a standard may be used only once to meet the requirements of this qualification.

Unit standards and achievement standards that are equivalent in outcome are mutually exclusive for the purpose of award. The table of mutually exclusive standards is provided in the Qualifications Authority *Rules and Procedures* publications available at www.nzqa.govt.nz/ncea/.

Reviewed standards that continue to recognise the same overall outcome are registered as new versions and retain their identification number (Id). Any version of a standard with the same Id may be used to meet qualification requirements that list the Id and/or that specify the past or current classification of the standard.

Detailed Qualification Requirements

Compulsory

All the standards listed below are required.

Field Core Generic
 Subfield Core Generic
 Domain Self-management

| Id | Title | Level | Credit |
|------|---|-------|--------|
| 7123 | Demonstrate knowledge of problem solving and apply a problem solving technique to a problem | 2 | 2 |

Field Humanities
 Subfield Communication Skills
 Domain Interpersonal Communications

| Id | Title | Level | Credit |
|------|--|-------|--------|
| 9677 | Participate in groups and/or teams to gather ideas and information | 2 | 3 |

Domain Writing

| Id | Title | Level | Credit |
|------|----------------------|-------|--------|
| 3492 | Write a short report | 2 | 3 |

Field Manufacturing
 Subfield Pharmaceutical and Allied Products
 Domain Pharmaceutical and Allied Products Quality Assurance

| Id | Title | Level | Credit |
|-------|---|-------|--------|
| 21073 | Apply current good manufacturing practice for pharmaceutical and allied products | 2 | 3 |
| 21361 | Demonstrate knowledge of quality control for pharmaceutical and allied products manufacturing | 2 | 3 |

Elective A

A minimum of 7 credits is required from the following list of standards.

Field Manufacturing
 Subfield Pharmaceutical and Allied Products
 Domain Pharmaceutical and Allied Products Manufacturing

| Id | Title | Level | Credit |
|-------|--|-------|--------|
| 21075 | Receive inwards materials for pharmaceutical and allied products manufacturing | 2 | 3 |
| 21076 | Pick materials for pharmaceutical and allied products manufacturing and receive manufactured product | 2 | 3 |
| 21077 | Pick and assemble finished pharmaceutical and allied products for despatch | 2 | 2 |
| 21364 | Perform basic solids processing operations for pharmaceutical and allied products | 2 | 3 |
| 21366 | Perform secondary product packing operations for pharmaceutical and allied products manufacturing | 2 | 4 |
| 21368 | Dispense starting materials for pharmaceutical and allied products manufacturing | 2 | 4 |
| 21369 | Demonstrate knowledge of solids processing for pharmaceutical and allied products manufacturing | 2 | 4 |
| 21370 | Demonstrate knowledge of liquids mixing for pharmaceutical and allied products manufacturing | 2 | 2 |
| 21371 | Perform basic liquids processing operations for pharmaceutical and allied products manufacturing | 2 | 3 |
| 21943 | Demonstrate basic knowledge of engineering for pharmaceutical and allied products manufacturing | 2 | 4 |
| 21944 | Demonstrate knowledge of air quality for pharmaceutical and allied products manufacturing | 2 | 3 |
| 21945 | Demonstrate knowledge of water for manufacture of pharmaceutical and allied products | 2 | 2 |

Domain Pharmaceutical and Allied Products Quality Assurance

| Id | Title | Level | Credit |
|-------|---|-------|--------|
| 21362 | Perform routine sampling for pharmaceutical and allied products manufacturing | 2 | 3 |
| 21363 | Perform routine testing for pharmaceutical and allied products manufacturing | 2 | 4 |

Elective B

The balance of credits required, to achieve a minimum total of 40 credits at Level 2 or above, from the following standards and domains.

Field Core Generic
 Subfield Core Generic
 Domain Self-management

| Id | Title | Level | Credit |
|-----------|-----------------------------|--------------|---------------|
| 12349 | Demonstrate time management | 2 | 3 |

Field Engineering and Technology
 Subfield Mechanical Engineering
 Domain Maintenance and Diagnostics in Mechanical Engineering

| Id | Title | Level | Credit |
|-----------|--|--------------|---------------|
| 2397 | Service machines and equipment | 2 | 4 |
| 2399 | Dismantle, inspect, assemble and test components under supervision | 3 | 10 |

Domain Mechanical Assembly

| Id | Title | Level | Credit |
|-----------|--|--------------|---------------|
| 2387 | Assemble mechanical components under supervision | 2 | 2 |

Field Humanities
 Subfield Communication Skills
 Domain Interpersonal Communications

| Id | Title | Level | Credit |
|-----------|--|--------------|---------------|
| 1277 | Communicate information in a specified workplace | 2 | 3 |
| 1304 | Communicate with people from other cultures | 2 | 2 |
| 9680 | Communicate within an organisational context | 2 | 2 |

Field Service Sector
 Subfield Lifting Equipment
 Domain Powered Industrial Lift Trucks

| Id | Title | Level | Credit |
|-----------|--|--------------|---------------|
| 10851 | Operate a powered industrial lift truck fitted with forks (forklift) | 3 | 7 |

| Field | Subfield | Domain |
|---|--------------------------------|-------------------|
| Computing and Information Technology Sciences | Computing | Generic Computing |
| | Mathematics | Algebra |
| | Science | Chemistry |
| Service Sector | Statistics and Probability | Statistics |
| | Retail, Distribution and Sales | Distribution |
| | | Stock Control |

NQF Registration Information

| Process | Version | Date | Last Date for Award |
|--------------|---------|------------|---------------------|
| Registration | 1 | March 2006 | N/A |

Standard Setting Body

Competenz
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 Auckland 1149

Telephone 0800 526 1800
 Fax 09 539 9899
 Email info@competenz.org.nz
 Website <http://www.competenz.org.nz/>

Any person or organisation may contribute to the review of this qualification by sending feedback to the standard setting body at the above address.

The review of this qualification is planned to take place in 2010.

Other standard setting bodies whose standards are included in the qualification

Competenz
 NZQA
 Retail Industry Training Organisation Incorporated

Certification

The certificate will display the logos of the Qualifications Authority and Competenz.

Classification

This qualification is classified according to the NQF classification system and the New Zealand Standard Classification of Education (NZSCED) system as specified below.

| NQF Classification | | NZSCED | |
|--------------------|---|--------|--|
| Code | Description | Code | Description |
| 1943 | Manufacturing/Pharmaceutical and Allied Products/Pharmaceutical and Allied Products Manufacturing | 030199 | Engineering and Related Technologies/Manufacturing, Engineering and Technology/Manufacturing Engineering and Technology not elsewhere classified |

Quality Management Systems

A recognised Quality Assurance Body must accredit providers and Industry Training Organisations before they can register credits from assessment against standards. Accredited providers and Industry Training Organisations assessing against standards must engage with the moderation system that applies to those standards. Accreditation requirements and the moderation system are outlined in the associated Accreditation and Moderation Action Plan (AMAP) for each standard.