Dearbhú Cáilíochta agus Cáilíochtaí Éireann
Quality and Qualifications Ireland

Certificate Specification NFQ Level 5

Life Sciences Manufacturing Operations 5M2162

1. Certificate Details

Title	Life Sciences Manufacturing Operations
Teideal as Gaeilge	Oibríochtaí Déantúsaíochta ar Eolaíochtaí Beatha
Award Class	Major
Code	5M2162
Level	5
Credit Value	120
Purpose	The purpose of this award is to enable the learner to develop the requisite knowledge, skill and competence to work independently and under supervision whilst working in the life sciences industry and or to progress to further and or higher education and training.
Statements of Knowledge, Skill and Competence	Learners will be able to:
Knowledge	
Breadth	Demonstrate a broad range of knowledge related to pharmaceutical, biopharmaceutical and medical devices production.
Kind	Demonstrate knowledge of processes which are applicable to pharmaceutical, biopharmaceutical and medical devices production.
Know How & Skill	
Range	Demonstrate use of a broad range of practical and interpersonal skills in the production of pharmaceutical, biopharmaceutical and medical devices products.
Selectivity	Exercise judgement in selecting responses to both routine and non-routine situations in a pharmaceutical, biopharmaceutical and medical devices setting.
Competence	

	Context	Perform a variety of tasks in conformance with quality and good manufacturing practice.
	Role	Contribute to the implementation and evaluation of a range of practices which support and improve production processes.
	Learning to Learn	Take responsibility for own learning in structured context.
	Insight	Reflect on personal practice in order to improve self understanding and personal development.
		The learning outcomes associated with this award are outlined in the associated Component Specifications.
Access		To access programmes leading to this award the learner should have reached the standards of knowledge, skill and competence associated with the preceding level of the National Framework of Qualifications. This may have been achieved through a formal qualification or through relevant life and work experience.
Transfer		Achievement of this award will enable the learner to transfer to other appropriate programmes leading to awards at the same level of the National Framework of Qualifications.
Progression		Achievement of this award will enable the learner to progress to other appropriate programmes leading to awards at the next or higher levels of the National Framework of Qualifications.
Progression Awards		Learners who successfully complete this award may progress to a range of different awards.
Grading		Pass Merit Distinction The grade achieved will be determined by the grades achieved on the components

2. Certificate Requirements

The total credit value required for this certificate is 120. This will be achieved by completing:

Award Code	Title	Level	Credit Value
All of the following component(s)			
5N1959	Quality and Good Manufacturing Practice	5	15
5N1915	Continuous Improvement in Manufacturing	5	15
5N2158	Health, Safety and Environmental Awareness	5	15
A minimum credit value of 15 from the following components			
5N2985	Personal and Professional Development	5	15

5N1356	Work Experience	5	15
5N1433	Work Practice	5	15
A minimum credit value of 15 from the following components			
5N0690	Communications	5	15
5N1367	Teamworking	5	15
5N1390	Personal Effectiveness	5	15
A minimum credit value of 15 from the following components			
5N1921	Cleanroom Operations	5	15
5N4546	Bioprocessing	5	15
5N2160	Packaging and Labelling	5	15
5N1968	Process Science Skills	5	15
5N2156	Chemical Processing	5	15
5N2159	Sterile Production	5	15
5N3484	Plant Utilities	5	15

The remaining credit value of 30 can be obtained by using vocationally relevant component(s) from level 5. A maximum of 15 credits may be used from either level 4 or level 6.

3. Supporting Documentation

1. Current national & EU health and safety legislation
2. Current national and EU environmental legislation
3. Current US Code of Federal Regulation (21 cfr) for the manufacture of drug and device products www.fda.org
4. Current European legislation for the manufacture and supply of drug and device products within the EU
5. Current Irish legislation for the manufacture and supply of drug and device products within Ireland
6. Current ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines
7. Current ISO 14001- International standard for Environmental Management Systems
8. Current ISO 13485 - International standard recognised for medical device regulations

4. Specific Validation Requirements

The provider must have all of the following in place to offer this award: Access to appropriate equipment and facilities within a life sciences manufacturing environment

5. Europass Certificate Supplement

The Europass Certificate Supplement for this award can be accessed at: **www.qqi.ie**.

6. FET Award Standards

QQI award standards are determined within the National Framework of Qualifications (NFQ), http://www.nfq-qqi.com. QQI determines standards for the education and training awards that it makes itself and that are made by providers to whom it has delegated authority to

make an award. Providers offering programmes leading to QQI awards **must** have their programme(s) validated in accordance with current validation policy (see www.qqi.ie).

Award standards are designed to be consistent with the NFQ's award classes i.e. major, special purpose, supplemental and minor awards. They are expressed in terms of **learning outcomes** i.e. concise statements of what the learner is expected to know or be able to do in order to achieve a particular award. Learning outcomes for QQI awards are contained within the associated specifications:

AWARD CLASS	STANDARDS	AWARDS
Major Award	Certificate Specification	Certificate (Levels 1 to 5) Advanced Certificate (Level 6)
Supplemental Award	Supplemental Specification	Supplemental Certificate (Level 3 to 6)
Special Purpose	Specific Purpose Specification	Specific Purpose Certificate (Levels 3 to 6)
Minor Award	Component Specification	Component Certificate (Levels 1 to 6)

Award standards are thresholds, they describe standards of knowledge, skill or competence to be acquired, and where appropriate, demonstrated, by a learner before an award may be made.

Award standards will be reviewed from time to time as necessary. Minor changes may be made by the QQI executive outside the review cycle where necessary. Changes to standards are published on QQI's website. Providers with validated programmes and providers with delegated authority to make awards are responsible for monitoring relevant standards and making necessary responses to changes.

7. FET Credit

Every FET certificate and component specification includes an FET credit value (Table 1). FET credit is quantified in multiples of 5 FET credits (up to 50 hours of learner effort). Learner effort is based on the time taken by typical learners at the level of the award to achieve the learning outcomes for the award. It includes all learning time involved including: guided learning hours, self-directed learning and assessment.

Table 1: FET Credit Values

NFQ Level	Major Awards Credit Values	Default Credit Values Minor Awards	Other Permitted Minor Award Credit Values	Special Purpose and Supplemental Award Credit Value Ranges
1	20	5	10	
2	30	5	10	
3	60	10	5,20	>5 and<60
4	90	10	5,15,20	>5 and<90
5	120	15	5,10,30	>5 and <120
6	120	15	5,10,30	>5 and <120

Guide to Level

Learning outcomes at this level include a broad range of skills that require some theoretical understanding. The outcomes may relate to engaging in a specific activity, with the capacity to use the instruments and techniques relating to an occupation. They are associated with work being undertaken independently, subject to general direction.

Strand	Sub-strand	Nature of learning
Knowledge	Breadth	Broad range of knowledge
	Kind	Some theoretical concepts and abstract thinking, with significant depth in some areas.
Know How & Skill	Range	Demonstrate a broad range of specialised skills and tools
	Selectivity	Evaluate and use information to plan and develop investigative strategies and to determine solutions to varied unfamiliar problems
Competence	Context	Act in a range of varied and specific contexts, taking responsibility for the nature and quality of outputs; identify and apply skill and knowledge to a wide variety of contexts
	Role	Exercise some initiative and independence in carrying out defined activities; join and function within multiple, complex and heterogeneous groups
	Learning to Learn	Learn to take responsibility for own learning within a managed environment
	Insight	Assume full responsibility for consistency of self- understanding and behaviour

Extract from 'Determinations for the Outline National Framework of Qualifications': NQAI