



# **1. Title of the certificate** <sup>(1)</sup> Life Sciences Manufacturing Operations <sup>(1)</sup> In the original language

# 2. Translated title of the certificate <sup>(1)</sup>

<sup>(1)</sup> If applicable. This translation has no legal status.

3. Profile of skills and competences					
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.				
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.				

# 4. Range of occupations accessible to the holder of the certificate <sup>(1)</sup>

<sup>(1)</sup> If applicable

# <sup>(\*)</sup> Explanatory note

This document is designed to provide additional information about the specified certificate and does not have any legal status in itself. The format of the description is based on the following texts: Council Resolution 93/C 49/01 of 3 December

1992 on the transparency of qualifications, Council Resolution 96/C 224/04 of 15 July 1996 on the transparency of vocational training certificates, Recommendation 2001/613/EC of the European Parliament and of the Council of 10 July 2001 on mobility within the Community for students, persons undergoing training, volunteers, teachers and trainers and Recommendation of the European Parliament and of the Council 2008/C 111/01 of 23 April 2008 on the establishment of the European Qualifications Framework for lifelong learning.

More information available at: <u>http://europass.cedefop.europa.eu</u>

Quality and Qualifications Ireland (QQI)Pri26-27 Denzille LaneD02 P266, IrelandThTel:00 353 1 9058100FraWebsite:www.qqi.ieQuQuality and Qualifications Ireland (QQI) was established inTrNovember 2012 under the Qualifications and Quality Assurance(Education and Training) Act 2012. It is the state agencyresponsible for quality assurance and qualifications in bothfurther and higher education and training in Ireland.Prior to QQI's establishment the Further Education and Training)Act 1999 and dissolved on the establishment of QQI.Level of the certificate (national or international)GrEQF level 4LeNFQ level 5PaLearning outcomes at this level include a broad range of skillsMithat require some theoretical understanding. The outcomesDimay relate to engaging in a specific activity, with the capacity toawuse the instruments and techniques relating to an occupation.CeThey are associated with work being undertaken independently,awsubject to general direction.Actievement of this award will enable the learner to progress toother appropriate programmes leading to awards at the next orFreihigher levels of the National Framework of Qualifications.Thuse to the soft the National Framework of Qualifications.Thuse to the soft the National Framework of Qualifications.Thuse to the soft the National Framework of Qualifications.ThNote the soft the National Framework of Qualifications.Th<		
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	eland, Scotland, England, Wales and Northern Ireland	
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The Qualifications and Quality Assurance (Education and Training) Act 2012.

Certificates issued between 2001 and 2012 were issued by the Further Education and Training Awards Council (FETAC) on the basis of the Qualifications (Education and Training) Act 1999.

#### 6. Officially recognised ways of acquiring the certificate

Programmes of further education and training are provided in Ireland by a wide range of providers in diverse settings including publicly and privately funded institutions and workplace or community and youth settings.

Awards standards are expressed as expected learning outcomes and all are available online:

## http://qsearch.qqi.ie/WebPart/Search?searchtype=awards

Programmes of education and training that lead to certificates are validated by QQI for that purpose.

#### Workplace-based learning

Work experience or equivalent is mandatory in all major awards specifications. Refer to the award specification at <a href="http://gsearch.qqi.ie/WebPart/Search?searchtype=awards">http://gsearch.qqi.ie/WebPart/Search?searchtype=awards</a> for further information.

## Accredited prior learning

Accreditation of prior learning is available for the purposes of access to a programme leading to a further education and training award and for exemptions within the programme. The assessment is carried out by a provider of the validated programme. Award components for which exemptions have been granted through prior certification are noted on the learner's transcript. Those achieved through the accreditation of prior learning are not noted on the certificate.

## **Directed Hours:**

Directed hours are the hours the provider spends directly delivering the content of the programme to the learner. They include class contact, direct online contact, assessment and laboratory time. They can include work-based direction, where there is a tutor/instructor on-site delivering content.

# Self-Directed Hours

Self-directed hours are the hours where the learning is learner-led. They include practice time, work experience, preparation, study time and reflection time.

# **Entry requirements**

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.

# Additional information

Information on validated programmes is available on the relevant provider's website and on <a href="http://gsearch.qqi.ie/WebPart/Search?searchtype=programmes">http://gsearch.qqi.ie/WebPart/Search?searchtype=programmes</a>

#### More information (including a description of the national qualifications system) available at:

http://www.qqi.ie/Pages/National-Framework-of-Qualifications-%28NFQ%29.aspx and www.QQI.ie

# National reference point

Quality and Qualifications Ireland (QQI) hosts NARIC Ireland which is part of the European Network of Information Centres / National Academic Recognition Information Centres (ENIC/NARIC) and acts as the National Reference Point (NRP) for academic further education qualifications. Please see <u>http://www.qqi.ie/Pages/Qualifications-Recognition-Service.aspx</u> for further information.

	Major Awards						
Level	Major award credits	Total Learner Effort (credit value x 10) in Hours	Programme Directed Hours Range	Programme Self-directed Hours Range			
L3	60	600	300-550	50-300			
L 4	90	900	400-800	100-500			
L 5	120	1200	500-1000	200-700			
L 6	120	1200	500-1000	200-700			

Special Purpose, Supplemental and Minor Awards							
	Credit Values	Total learner Effort (credit value x 10) in hours	Programme Directed Hours Range	Programme Self-directed Hours Range			
Levels 1 - 6	5	50	15-50	0-35			
	10	100	30-100	0-70			
	15	150	50-130	20-100			
	20	200	80-160	40-120			
	30	300	100-260	40-200			

Europass (<u>www.europass.ie</u>) supports EU citizens accessing employment or study opportunities across Europe. It is an electronic portfolio of five standardised documents to aid understanding and comparison of qualifications, work and study experiences. The portfolio contains

- Europass Curriculum Vitae
- Europass Language Passport
- Europass Mobility
- Europass Diploma Supplement
- Europass Certificate Supplement

This Europass Certificate Supplement is made available by Quality and Qualifications Ireland (QQI) to support EU wide recognition and understanding of further education and training awards made by QQI on the National Framework of Qualifications (NFQ).

The NFQ (see illustration below) is a system of ten levels and different kinds of qualifications, known as award classes. Each level is based on nationally agreed ranges of knowledge, skill and competence that must be demonstrated by learners so as to achieve a particular qualification. The award class indicates the purpose, volume and progression opportunities associated with the award. Certificate Supplements are only issued for major and special purpose awards.

The NFQ contains four award classes as follows:

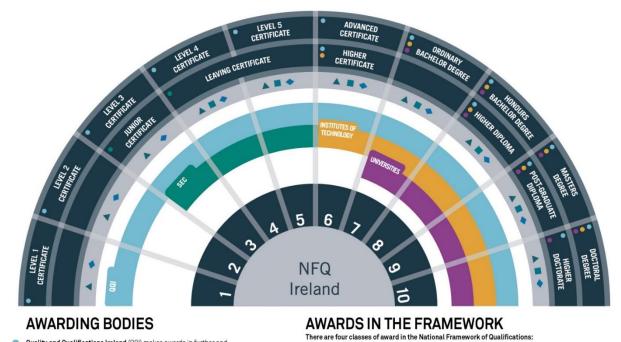
A **major award** represents a significant volume of learning outcomes and prepares learners for employment, participation in society and for access to higher levels of education and training.

A **minor award** is an award derived from and links to, at least one major, special purpose or supplemental award. Minor awards are smaller than their parent award(s). Achievement of a minor award provides for recognition of learning that has relevance and value in its own right.

A **special purpose award** is made for specific and relatively narrow purposes. All special purpose awards comprise one or more components. The learner must successfully achieve all the stated requirements to achieve the special purpose award.

A **supplemental award** recognises learning which involves updating/up-skilling and/or continuing education and training with specific regard to occupations. All supplemental awards comprise one or more components. The learner must successfully achieve all the stated requirements to achieve the supplemental award.

All qualifications in the NFQ are recognised nationally and internationally, are referenced to the EQF and are quality assured. Providers offering programmes of education and training leading to further education and training awards are currently quality assured by QQI.



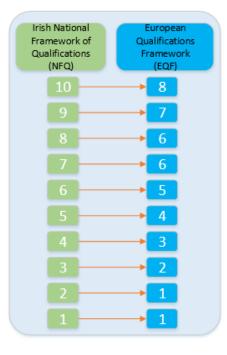
- Quality and Qualifications Ireland (QQI) makes awards in further and higher education and training
- SEC State Examinations Commission (Department of Education and Skills)
- Institutes of Technology
- Universities



For further Information consult: www.nfq.ie www.QQI.ie

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Major Awards: named in the outer rings, are the principal class of awards made at a level

Special Purpose Awards: are for relatively narrow or purpose-specific achievement

Minor Awards: are for partial completion of the outcomes for a Major Award

Supplemental Awards: are for learning that is additional to a Major Award