

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

<b>2. Translated title of the certificate <sup>(1)</sup></b>
<sup>(1)</sup> If applicable. This translation has no legal status.

<b>3. Profile of skills and competences</b>	
<b>Purpose</b>	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.
<b>Knowledge</b>	
<b>Breadth</b>	Demonstrate a broad range of knowledge related to pharmaceutical, biopharmaceutical and medical devices production.
<b>Kind</b>	Demonstrate knowledge of processes which are applicable to pharmaceutical, biopharmaceutical and medical devices production.
<b>Know How &amp; Skill</b>	
<b>Range</b>	Demonstrate use of a broad range of practical and interpersonal skills in the production of pharmaceutical, biopharmaceutical and medical devices products.
<b>Selectivity</b>	Exercise judgement in selecting responses to both routine and non-routine situations in a pharmaceutical, biopharmaceutical and medical devices setting.
<b>Competence</b>	
<b>Context</b>	Perform a variety of tasks in conformance with quality and good manufacturing practice.
<b>Role</b>	Contribute to the implementation and evaluation of a range of practices which support and improve production processes.
<b>Learning to Learn</b>	Take responsibility for own learning in structured context.
<b>Insight</b>	Reflect on personal practice in order to improve self understanding and personal development.

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

**(\*) 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: <http://europass.cedefop.europa.eu>

## 5. Official basis of the certificate

<p><b>Name and status of the body awarding the certificate</b>  Quality and Qualifications Ireland (QQI)  26-27 Denzille Lane  D02 P266, Ireland  Tel: 00 353 1 9058100  Website: <a href="http://www.qqi.ie">www.qqi.ie</a></p> <p>Quality and Qualifications Ireland (QQI) was established in November 2012 under the Qualifications and Quality Assurance (Education and Training) Act 2012. It is the state agency responsible for quality assurance and qualifications in both further and higher education and training in Ireland. Prior to QQI's establishment the Further Education and Training Awards Council was the relevant awarding body (2001-2012) established under the Qualifications (Education and Training) Act 1999 and dissolved on the establishment of QQI.</p>	<p><b>Name and status of the national/regional authority providing accreditation/recognition of the certificate</b></p> <p>The certificate is recognised within the Irish National Framework of Qualifications, <a href="http://www.qqi.ie/Pages/National-Framework-of-Qualifications-%28NFQ%29.aspx">http://www.qqi.ie/Pages/National-Framework-of-Qualifications-%28NFQ%29.aspx</a>, under the Qualifications and Quality Assurance (Education and Training) Act 2012.</p> <p>The programme leading to the award of this certificate has been validated by either QQI or (prior to November 2012) by the Further Education and Training Awards Council and is subject to QQI quality assurance arrangements, or those of the Further Education and Training Awards Council prior to the establishment of QQI.</p>
<p><b>Level of the certificate (national or international)</b>  <b>EQF level 4</b>  <b>NFQ level 5</b>  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.</p>	<p><b>Grading scale / Pass requirements</b></p> <p>Levels 4, 5 and 6 Certificates are graded as follows:  Pass  Merit  Distinction</p> <p>Certificates at levels 1, 2 and 3 are not graded. They are awarded only where the candidate is <b>successful</b> in the applicable assessment.</p>
<p><b>Access to next level of education/training</b></p> <p>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.</p>	<p><b>International agreements</b></p> <p>The Irish National Framework of Qualifications is referenced to the European Qualifications Framework. Please view <a href="http://www.nfq-qqi.com/index.html">http://www.nfq-qqi.com/index.html</a></p> <p>The Irish and United Kingdom awarding and qualifications authorities have established broad comparisons between qualifications and their levels in Ireland, Scotland, England, Wales and Northern Ireland. Please view <a href="https://qhelp.qqi.ie/learners/qualifications-recognition-advice/comparing-qualifications-in-the-uk-and-ireland/Qualifications_Can_Cross_Boundaries.pdf">https://qhelp.qqi.ie/learners/qualifications-recognition-advice/comparing-qualifications-in-the-uk-and-ireland/Qualifications Can Cross Boundaries.pdf</a></p>
<p><b>Legal basis</b></p> <p>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.</p>	

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

**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](http://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 <http://www.qqi.ie/Pages/Qualifications-Recognition-Service.aspx> for further information.

<b>Major Awards</b>				
<b>Level</b>	<b>Major award credits</b>	<b>Total Learner Effort (credit value x 10) in Hours</b>	<b>Programme Directed Hours Range</b>	<b>Programme Self-directed Hours Range</b>
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

<b>Special Purpose, Supplemental and Minor Awards</b>				
<b>Levels 1 - 6</b>	<b>Credit Values</b>	<b>Total learner Effort (credit value x 10) in hours</b>	<b>Programme Directed Hours Range</b>	<b>Programme Self-directed Hours Range</b>
	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 ([www.europass.ie](http://www.europass.ie)) 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.



### AWARDING BODIES

- **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**

### AWARDS IN THE FRAMEWORK

There are four classes of award in the National Framework of Qualifications:

- ⤵ **Major Awards:** named in the outer rings, are the principal class of awards made at a level
- ▲ **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
- ◼ **Special Purpose Awards:** are for relatively narrow or purpose-specific achievement



For further Information consult: [www.nfq.ie](http://www.nfq.ie) [www.QQI.ie](http://www.QQI.ie)

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