QQI
Quality and Qualifications Ireland
Dearbhú Cáilíochta agus Cáilíochtaí Éireann

Component Specification NFQ Level 5

Continuous Improvement in Manufacturing 5N1915

1. Component Details

Title	Continuous Improvement in Manufacturing
Teideal as Gaeilge	Feabhsú Leanúnach i nDéantúsaíocht
Award Type	Minor
Code	5N1915
Level	5
Credit Value	15
Purpose	The purpose of this award is to equip the learner with the knowledge, skills and competence to utilise a range of continuous improvement methodologies whilst working at operative level in the life sciences manufacturing sector.
Learning Outcomes	Learners will be able to:
	1 Explain continuous improvement in terms of objectives and benefits
	2 Describe a range of tools which support continuous improvement
	3 Distinguish between added-value and non value-added in relation to products and services
	4 Explain the role of value stream mapping in continuous improvement
	5 Explain the key principles of leading process management strategies including Six Sigma, and

DMAIC (Define, Measure, Analyse, Improve and Control)

6 Participate in a 5S audit utilising the 5S methodology to enhance workplace organisation

7 Demonstrate how a mistake-proofing technique such as Poka-Yoke can be used to minimise manufacturing process defects

8 Complete a task that supports analysis of equipment effectiveness and performance for your area of responsibility such as total preventative maintenance (TPM), overall equipment effectiveness (OEE), single minute exchange of die (SMED) or shift start up checks

9 Contribute to a continuous improvement or Kaizen event in your own area of responsibility

10 Apply a problem solving technique such as Pareto Principle, 5 Why's, Brainstorming, Cause and Effect diagram and Failure, Mode and Effect Analysis (FMEA) appropriate to a range of events

11 Reflect on own performance to inform ongoing continuous improvement activities.

Assessment

General Information

All assessment should be planned in accordance with the programme assessment strategy developed as part of the programme submission for validation. See **Policies and Criteria for Validation of Programmes.** Assessment should be undertaken consistently and reflect current assessment guidelines. See www.qqi.ie.

All FET assessment is criterion referenced. Successful achievement of the award is based on learners attaining the required standards of knowledge, skill or competence consistent with the **minimum intended programme learning outcomes**.

The techniques set out below are considered the optimum approach to assessment for this component. In exceptional circumstances providers may identify alternative assessment techniques through the provider's application for programme validation which are reliable and valid but which are more appropriate to their context.

Assessment of a number of components may be integrated across programmes for delivery, provided that the learning outcomes of each minor award are assessed.

Group or team work may form part of the assessment, provided each learner's achievement is separately assessed.

All providers are required to submit an assessment plan as part of their application for programme validation. Assessment Plans will include information relating to scheduling and integration of assessment. See current FET validation guidelines at www.qqi.ie.

Assessment Techniques

In order to demonstrate that they have reached the standards of knowledge, skill and competence identified in all the learning outcomes, learners are required to complete the assessment(s) below.

The assessor is responsible for devising assessment instruments (e.g. project and assignment briefs, examination papers), assessment criteria and mark sheets, consistent with the techniques identified below and QQI's assessment requirements.

Programme validation will require providers to map each learning outcome to its associated assessment technique. All learning outcomes **must** be assessed and achieved in accordance with the **minimum intended module learning outcomes** set out in the validated programme.

Portfolio / Collection of Work	60%
Examination - Theory	40%

Description

Portfolio / Collection of Work

A portfolio or collection of work is a collection and/or selection of pieces of work produced by the learner over a period of time that demonstrates achievement of a range of learning outcomes. The collection may be self-generated or may be generated in response to a particular brief or tasks/activities devised by the assessor.

The assessor will devise a brief for a Portfolio/Collection of Work based on learning outcomes 6 - 11.

Examination - Theory

An examination provides a means of assessing a learner's ability to recall and apply knowledge, skills and understanding within a set period of time and under clearly specified conditions.

A theory-based examination assesses the ability to recall, apply and understand specific theory and knowledge.

The assessor will devise a brief for an Examination ¿ Theory based on learning outcomes 1 - 5.

Recognition of Prior Learning (RPL)

To support the development and implementation of RPL with regard to access, granting credit/exemptions and achievement of awards/parts of awards, providers should refer to **QQI's Statutory Guidelines for Quality Assurance,** the **Policies and Criteria for Validation of Programmes** and the **Principles and Operational Guidelines for the Recognition of Prior Learning in Further and Higher Education and Training** available at www.qqi.ie

Grading

Pass	50% - 64%
Merit	65% - 79%
Distinction	80% - 100%

Specific Validation Requirements

There are no specific validation requirements for this award

Supporting Documentation

1. Current US Code of Federal Regulation (21 cfr) for the manufacture of drug and device products -www.fda.org
2. Current European legislation for the manufacture and supply of drug and device products within the EU - www.emea.europa.eu
3. Current Irish legislation for the manufacture and supply of drug and device products within Ireland - www.imb.ie
4. Current ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines
5. Current ISO 14001 - International standard for Environmental Management Systems
6. Current ISO 13485 - This is the international standard recognised for medical device regulations

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

Successful completion of this component award enables the learner to transfer to programmes leading to other certificates where this component is a mandatory or an elective requirement.

2. 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 FET 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.

3. 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.
		Some underpinning theory
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