Qualification Specification for:

OCN NI Level 5 Certificate in Regulation in Pharmaceutical Manufacturing and Distribution

- **Qualification No: 610/1256/7**

Qualification Regulation Information

OCN NI Level 5 Certificate in Regulation in Pharmaceutical Manufacturing and Distribution
Qualification Number: 610/1256/7

Operational start date: 01 August 2022
Operational end date: 31 July 2027
Certification end date: 31 July 2032

Qualification operational start and end dates indicate the lifecycle of a regulated qualification. The operational end date is the last date by which learners can be registered on a qualification and the certification end date is the last date by which learners can claim their certificate.

All OCN NI regulated qualifications are published to the Register of Regulated Qualifications (**http://register.ofqual.gov.uk/**). This site shows the qualifications and awarding organisations regulated by CCEA Regulation and Ofqual.

OCN NI Contact Details

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Foreword

This document explains OCN NI's requirements for the delivery and assessment of the following regulated qualifications:

→ **OCN NI Level 5 Certificate in Regulation in Pharmaceutical Manufacturing and Distribution**

This specification sets out:

- Qualification features
- Centre requirements for delivering and assessing the qualification
- The structure and content of the qualification
- Unit details
- Assessment requirements for the qualification
- OCN NI's quality assurance arrangements for the qualification
- Administration

OCN NI will notify centres in writing of any major changes to this specification. We will also publish changes on our website at **www.ocnni.org.uk**

This specification is provided online, so the version available on our website is the most up to date publication. It is important to note that copies of the specification that have been downloaded and printed may be different from this authoritative online version.

Contents

About Regulation

OCN NI

Open College Network Northern Ireland (OCN NI) is a regulated Awarding Organisation based in Northern Ireland. OCN NI is regulated by CCEA Regulation to develop and award professional and technical (vocational) qualifications from Entry Level up to and including Level 5 across all sector areas. In addition, OCN NI is regulated by Ofqual to award similar qualification types in England.

The Regulated Qualifications Framework: an overview

The Regulated Qualifications Framework (RQF) was introduced on 1st October 2015: the RQF provides a single framework for all regulated qualifications.

Qualification Level

The level indicates the difficulty and complexity of the knowledge and skills associated with any qualification. There are eight levels (Levels 1-8) supported by three 'entry' levels (Entry 1-3).

Qualification Size

Size refers to the estimated total amount of time it could typically take to study and be assessed for a qualification. Size is expressed in terms of Total Qualification Time (TQT), and the part of that time typically spent being taught or supervised, rather than studying alone, is known as Guided Learning Hours (GLH).

Qualification Features

Sector Subject Area

2.1 Science

NOS - Cogent Laboratory Skills

Qualification Aim

The OCN NI Level 5 Certificate in Regulation in Pharmaceutical Manufacturing and Distribution will enable learners to develop an understanding of regulation requirements, procedures and how they are applied within pharmaceutical manufacturing and distribution.

Qualification Objectives

The objectives of the OCN NI Level 5 Certificate in Regulation in Pharmaceutical Manufacturing and Distribution are to enable learners to have an understanding of the following procedures, processes and systems used in the pharmaceutical manufacturing and distribution sector:

- Good Laboratory Practice
- Good Manufacturing Practice in industry manufacturing and distribution
- systematic approaches for in-process control tests

Grading

Grading for this qualification is pass/fail.

Qualification Target Group

This qualification is targeted at learners who are currently working in or who wish to work in areas of pharmaceutical manufacturing and distribution impacted by regulation.

Progression Opportunities

The OCN NI Level 5 Certificate in Regulation in Pharmaceutical Manufacturing and Distribution qualification will allow learners to progress to higher level qualifications in science and related areas.

Entry Requirements

The entry requirements for this qualification include the following:

- learners should be at least 18 years old
- have five GCSEs or equivalent including English and Maths at Grade C or above
- have a level 4 qualification in a science related area
- a level 3 qualification in a science related area with at least one year's relevant experience

Resource Requirements

Learners must have access to appropriate equipment typically found in an industrial/scientific laboratory workplace.

Qualification Support

A Qualification Support pack is available for OCN NI centres within the login area of the OCN NI website (https://www.ocnni.org.uk/my-account/), which includes additional support for teachers, eg planning and assessment templates, guides to best practice, etc.

Delivery Languages

This qualification is available in English only at this time. If you wish to offer this qualification in Welsh or Irish (Gaeilge) then please contact OCN NI who will review demand and provide as appropriate.

Centre Requirements for Delivering the Qualification

Centre Recognition and Qualification Approval

New and existing OCN NI recognised centres must apply for and be granted approval to deliver the qualification prior to the commencement of delivery.

Centre Staffing

Centres are required to have the following roles in place as a minimum, although a member of staff may hold more than one role*:

- Centre contact
- Programme Co-ordinator
- Tutor
- Assessor
- Internal Verifier

*Note: A person cannot be an internal verifier for their own assessments.

Tutors

Tutors delivering the qualification should be occupationally competent and qualified to at least one level higher than the qualification and have a minimum of one year's relevant experience.

Assessors

The qualification is assessed within the centre and is subject to OCN NI's quality assurance processes. Units are achieved through internally set, internally assessed, and internally verified evidence.

Assessors must:

- be occupationally competent to at least one level higher than the qualification
- have a minimum of one year's experience in the area they are assessing
- have direct or related relevant experience in assessment
- assess all assessment tasks and activities

Internal Verification

OCN NI qualifications must be scrutinised through the centre's internal quality assurance processes as part of the recognised centre agreement with OCN NI. The centre must appoint an experienced and trained centre internal verifier whose responsibility is to act as the internal quality monitor for the verification of the delivery and assessment of the qualifications.

The centre must agree a working model for internal verification with OCN NI prior to delivery of the qualifications.

Internal Verifiers must:

- have at least one year's experience in the areas they are internally verifying
- attend OCN NI's internal verifier training if not already completed

Internal verifiers are required to:

- support tutors and assessors
- sample assessments according to the centre's sampling strategy
- ensure tasks are appropriate to the level being assessed
- maintain up-to-date records supporting the verification of assessment and learner achievement

Structure and Content

OCN NI Level 5 Certificate in Regulation in Pharmaceutical Manufacturing and Distribution

In order to achieve the qualification learners must successfully complete 18 credits.

Total Qualification Time (TQT) for this qualification:	180 hours
Guided Learning Hours (GLH) for this qualification:	80 hours

Unit Reference Number	OCN NI Unit Code	Unit Title	Credit Value	GLH	Level
L/650/3053	CBF853	Regulation in the Pharmaceutical Industry: Manufacturing and Distribution	18	80	Five

Unit Details

Title	Regulation in the Pharmaceutical Industry: Manufacturing and Distribution
Level	Five
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF853
Unit Reference No	L/650/3053
Unit purpose and aim(s): This unit will enable the learner to understand regulation requirements, procedures and how they are applied within pharmaceutical manufacturing and distribution.	

Learning Outcomes	Assessment Criteria
1. Understand the procedures required to ensure Good Laboratory Practice (GLP) in the pharmaceutical industry.	1.1. Explain and evaluate a standard operating procedure (SOP) for a given laboratory process which supports GLP including the following: a) purpose b) background c) policy d) responsibilities e) definitions f) references g) effective date h) change control table 1.2. Explain and evaluate the procedures required and their role in ensuring laboratory equipment is properly designed and maintained including: a) equipment list b) maintenance and calibration schedule c) information on the calibration status d) investigating calibration failures or deviations e) systems required to ensure equipment validation and qualification f) auditing 1.3. Explain the main areas which should form part of equipment record or logbook documentation which supports GLP.
2. Understand the procedures required to ensure Good Manufacturing Practice (GMP) in the pharmaceutical industry.	2.1. Explain and evaluate an SOP for a given laboratory process which supports GMP including the following: a) purpose b) background c) policy d) responsibilities e) definitions f) references g) effective date h) change control table 2.2. Explain and evaluate the procedures required and their role in ensuring laboratory equipment is properly designed and maintained including: a) equipment list b) maintenance and calibration schedule c) information on the calibration status

	d) investigating calibration failures or deviations e) systems required to ensure equipment validation and qualification f) auditing 2.3. Critically compare and contrast the procedures required to ensure laboratory equipment is properly designed and maintained in GLP and GMP guidelines. 2.4. Explain the main areas which should form part of equipment record or logbook documentation which supports GMP, highlighting the differences with GLP. 2.5. Explain and evaluate regulatory requirements in relation to the validation and qualification of manufacturing processes. 2.6. Explain the role of deviation handling and quality risk management.
3. Be able to develop a systematic approach for in-process control (IPC) tests in the pharmaceutical industry.	3.1. Develop a systematic approach for IPC tests including test or criteria used to monitor the progress of the manufacturing of active pharmaceutical ingredients (APIs) and intermediates.
4. Understand the procedures and systems required to ensure GMP in a distribution setting in the pharmaceutical industry.	4.1. Analyse an SOP from a given distribution setting which supports GMP including the following: a) purpose b) background c) policy d) responsibilities e) definitions f) references g) effective date h) change control table 4.2. Critically compare and contrast distribution and manufacturing GMP in relation to: a) quality management b) personnel c) premises and equipment d) documentation e) operations f) complaints, returns, recalls g) transportation

Assessment Guidance

The following assessment method/s may be used to ensure all learning outcomes and assessment criteria are fully covered.

Assessment Method	Definition	Possible Content
Portfolio of evidence	A collection of documents containing work undertaken to be assessed as evidence to meet required skills outcomes OR A collection of documents containing work that shows the learner's progression through the course	Learner notes/written work Learner log/diary Peer notes Record of observation Record of discussion

Practical demonstration/assignment	A practical demonstration of a skill/situation selected by the tutor or by learners, to enable learners to practise and apply skills and knowledge	Record of observation Learner notes/written work Learner log
Coursework	Research or projects that count towards a learner's final outcome and demonstrate the skills and/or knowledge gained throughout the course	Record of observation Learner notes/written work Tutor notes/record Learner log/diary
E-assessment	The use of information technology to assess learners' work	Electronic portfolio E-tests

Quality Assurance of Centre Performance

External Verification

All OCN NI recognised centres are subject to External Verification. External verification visits and monitoring activities will be conducted annually to confirm continued compliance with the conditions of recognition, review the centre's risk rating for the qualifications and to assure OCN NI of the maintenance of the integrity of the qualifications.

The External Verifier will review the delivery and assessment of the qualifications. This will include the review of a sample of assessment evidence and evidence of the internal verification of assessment and assessment decisions. This will form the basis of the EV report and will inform OCN NI's annual assessment of centre compliance and risk. The External Verifier is appointed by OCN NI.

Standardisation

As a process, standardisation is designed to ensure consistency and promote good practice in understanding and application of standards. Standardisation events:

- make qualified statements about the level of consistency in assessment across centres delivering a qualification
- make statements on the standard of evidence that is required to meet the assessment criteria for units in a qualification
- make recommendations on assessment practice
- produce advice and guidance for the assessment of units
- identify good practice in assessment and internal verification

Centres offering units of an OCN NI qualification must attend and contribute assessment materials and learner evidence for standardisation events if requested.

OCN NI will notify centres of the nature of sample evidence required for standardisation events (this will include assessment materials, learner evidence and relevant assessor and internal verifier documentation). OCN NI will make standardisation summary reports available and correspond directly with centres regarding event outcomes.

Administration

Registration

A centre must register learners within 20 working days of commencement of a qualification.

Certification

Certificates will be issued to centres within 20 working days of receipt of correctly completed results marksheets. It is the responsibility of the centre to ensure that certificates received from OCN NI are held securely and distributed to learners promptly and securely.

Charges

OCN NI publishes all up to date qualification fees in its Fees and Invoicing Policy document. Further information can be found on the centre login area of the OCN NI website.

Equality, Fairness and Inclusion

OCN NI has considered the requirements of equalities legislation in developing the specification for these qualifications. For further information and guidance relating to access to fair assessment and the OCN NI Reasonable Adjustments and Special Considerations policies, centres should refer to the OCN NI website.

Retention of Evidence

OCN NI has published guidance for centres on the retention of evidence. Details are provided in the OCN NI Centre Handbook and can be accessed via the OCN NI website.

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