Qualification Specification for:

OCN NI Level 4 Diploma in Industrial Science

- **Qualification No: 610/1240/3**

Qualification Regulation Information

OCN NI Level 4 Diploma in Industrial Science
Qualification Number: 610/1240/3

Operational start date: 01 August 2022
Operational end date: 31 July 2027
Certification end date: 31 July 2031

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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Web: **www.ocnni.org.uk**

Foreword

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

→ **OCN NI Level 4 Diploma in Industrial Science**

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 4 Diploma in Industrial Science will provide learners with the skills and knowledge to work competently and safely in accordance with appropriate regulation and guidelines in an industrial laboratory environment.

Qualifications Objectives

The objectives of the OCN NI Level 4 Diploma in Industrial Science are to provide learners with knowledge and skills in the following areas:

- industrial laboratory techniques
- applied chemistry for life and related sciences
- pharmaceutical analytical quality control
- applied mathematics for science
- pharmaceutical industry regulation

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 laboratory based occupations.

Progression Opportunities

The OCN NI Level 4 Diploma in Industrial Science 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 3 qualification or a level 2 qualification and in addition have at least one year's experience in a science related occupation

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 occupational 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 4 Diploma in Industrial Science

In order to achieve the qualification learners must successfully complete 54 credits from any of the units.

Total Qualification Time (TQT) for this qualification:	540 hours
Guided Learning Hours (GLH) for this qualification:	240 hours

Unit Reference Number	OCN NI Unit Code	Unit Title	Credit Value	GLH	Level
R/650/3489	CBF875	Laboratory Skills for Industry	18	80	Four
A/650/3490	CBF877	Chemistry for the Pharmaceutical and Life Science Industries	18	80	Four
M/650/3488	CBF874	Pharmaceutical Analytical Quality Control and Analysis	18	80	Four
D/650/3491	CBF878	Scientific Mathematics	18	80	Four
K/650/3034	CBF850	Pharmaceutical Industry Regulation	18	80	Four

Unit Details

Title	Laboratory Skills for Industry
Level	Four
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF875
Unit Reference No	R/650/3489
Unit purpose and aim(s): This unit will enable the learner to understand how to carry out industrial laboratory tasks and activities.	
Learning Outcomes	**Assessment Criteria**
1. Be able to calibrate laboratory equipment and develop standard operating procedures (SOP)s.	1.1. Calibrate at least 4 items of standard industry laboratory equipment including the following: a) adhering to SOPs b) completing required documentation c) performing required calculations d) analysing test results to determine if equipment meets pass criteria 1.2. Develop a SOP for an item of standard industry laboratory equipment including: a) method development b) testing c) validation
2. Be able to prepare primary standards and serial dilutions and record results.	2.1. Calculate masses required to prepare a primary standard accurately, recording data on an analytical method sheet. 2.2. Calculate required serial dilutions to given specifications. 2.3. Prepare serial dilutions accurately, recording data on an analytical method sheet.
3. Be able to carry out titration and analyse results.	3.1. Carry out the following types of titrations accurately: a) acid-base b) oxidation-reduction reaction (REDOX) c) indicator electrode 3.2. To determine the concentration of a secondary standard including: a) recording data on an analytical method sheet b) calculating the concentration of the secondary standard 3.3. Analyse results of titrations carried out in AC 3.1 to include the following: a) trends in data b) potentials source of error and anomalies c) determining data validity and relevancy
4. Be able to produce buffer solutions.	4.1. Produce an acid and a base buffer to a given pH including: a) calculation of the masses and volumes required b) prepare buffer from using the amounts calculated c) check and adjust pH of the buffer as required to required pH

5. Be able to carry out a risk assessment.	5.1. Analyse own laboratory environment and tasks to be undertaken to identify potential hazards, control measures and risk rating. 5.2. Carry out a risk assessment to include potential hazards, control measures and risk rating for the following: a) an industrial laboratory environment b) at least three different laboratory tasks
6. Be able work safely and competently within an industrial laboratory environment.	6.1. Adhere to given quality standards and quality management and audit processes whilst working within a laboratory including: a) ensuring consistency in method b) maintaining health and safety c) adhering to appropriate processes and procedures d) maintaining data integrity in line with relevant guidelines 6.2. Adhere to regulatory controls whilst working within a laboratory including: a) Selecting and use appropriate type and level of required personal protective equipment (PPE) to meet requirements identified in AC 5.1 and 5.2 b) standards of health and safety and appropriate housekeeping standards c) requirements for disposal of waste

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

Title	Chemistry for the Pharmaceutical and Life Science Industries
Level	Four
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF877
Unit Reference No	A/650/3490
Unit purpose and aim(s): This unit will enable the learner to understand the application of organic, inorganic and physical chemistry within the pharmaceutical and life sciences industries.	

Learning Outcomes	Assessment Criteria
1. Understand atomic theory, bonding and the shapes of molecules.	1.1. Explain the photoelectric effect to emission of electrons from atoms. 1.2. Explain the observations from atomic spectra to Bohr atoms. 1.3. Determine the 4 unique quantum numbers for a given orbital. 1.4. Explain the electronic configuration of different atoms. 1.5. Explain electronic configuration in terms of rules and quantum numbers. 1.6. Determine Lewis / (Valence Shell Electron Pair Repulsion Theory) VSEPR theory to describe bonding in a range of molecules. 1.7. Explain bonding in organic molecules using the valence bond theory. 1.8. Explain the electronic structure of simple molecules in terms of molecular orbital theory. 1.9. Calculate the formal charge of different molecules. 1.10. Analyse the resonance forms of different molecules. 1.11. Determine the shape of different molecules. 1.12. Determine with justification hybridisaton of atoms based on the number of equivalent molecular orbitals.
2. Be able to carry out chemical calculations.	2.1. Calculate the following for different substances: a) mass b) molar mass c) moles d) molarity e) dilutions 2.2. Determine oxidation numbers to given chemical formula. 2.3. Explain oxidation-reduction reaction (REDOX) processes in terms of oxidation numbers. 2.4. Develop balanced half-equations and overall REDOX equations.
3. Be able to determine factors affecting the progress of industrial and biological reactions.	3.1. Analyse given experimental data from reaction rates and use calculations to determine for at least three given chemical industrial and biological reactions the following: a) order b) rate constant c) rate law

	3.2. Analyse given graphical data to determine reaction order. 3.3. Determine through application of the integrated rate law a) reaction rates b) rate constants c) reactant concentrations d) half-life of reactions 3.4. Use calculations to determine for given industrial and biological chemical reactions: a) activation energy b) enthalpy change c) entropy d) Gibb's Free Energy
4. Understand equilibrium and kinetics in relation to industrial and biological chemical reactions.	4.1. Use calculations to determine the reaction constant, Kc, from given initial and equilibrium amounts of substances. 4.2. Use calculations to determine concentrations from a given reaction constant, Kc. 4.3. Apply Le Chatelier's Principle to determine and/or adjust the position of equilibrium position of given industrial and biological chemical reactions. 4.4. Classify given reaction components as either acid or base. 4.5. Use calculations to determine the pH of the following: a) strong acids b) weak acids c) buffer solutions 4.6. Use calculations to determine the acid/base dissociation constant for a given substance. 4.7. Use calculations to determine the composition of buffer solutions at of a given pH. 4.8. Analyse and interpret given reaction profile diagrams. 4.9. Classify given reactions as exergonic or endergonic. 4.10. Explain the relationship between Gibb's free energy and entropy. 4.11. Analyse given data to determine the spontaneity of a given industrial and biological chemical reaction. 4.12. Estimate the temperature that equilibrium may be achieved for given industrial and biological chemical reactions.

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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

Title	Pharmaceutical Analytical Quality Control and Analysis
Level	Four
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF874
Unit Reference No	M/650/3488
Unit purpose and aim(s): This unit will enable the learner to understand how to carry out different tests on laboratory pharmacological samples including quality analysis and control tests on tablets. Methods and Standard Operating Procedures (SOPs) used in analysis will align to guidelines found in in the Pharmacopeias, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and European Medicines Agency (EMA).	

Learning Outcomes	Assessment Criteria
1. Be able to perform titration to determine the concentration of a sample and analyse data.	1.1. Perform titration in line with pharmacopeia guidelines to determine the concentration of a given sample, accurately recording data on an analytical method sheet. 1.2. Calculate the percentage purity of the sample titrated in AC 1.1. 1.3. Analyse the results obtained in AC 1.1 and AC 1.2 including the following: a) trends in data b) possible sources of error and anomalies c) determining if data is valid and relevant. d) initiating further action for results out of specification
2. Be able to carry out quality control tests on friability of tablets.	2.1. Perform all steps in the appropriate SOP to determine the friability of tablets including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP and provide a revised SOP if required. 2.2. Analyse results obtained in AC 2.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification
3. Be able to carry out quality control tests on hardness of tablets.	3.1. Perform all steps in the SOP to determine the hardness of tablets including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP to provide a revised SOP if required 3.2. Analyse results obtained in AC 3.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification

4. Be able to carry out quality control tests on the uniformity of tablet weight.	4.1. Perform all steps in the SOP to determine the uniformity of tablet weight including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP to provide a revised SOP if required 4.2. Analyse results obtained in AC 4.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification
5. Be able to carry out quality control tests on the disintegration of tablets.	5.1. Perform all steps in the to determine the disintegration of tablets including: a) use of appropriate techniques to safely and effectively handle equipment and reagents b) accurate recording techniques c) critically review and evaluate SOP to provide a revised SOP if required 5.2. Analyse results obtained in AC 5.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification
6. Be able to carry out ultraviolet-visible (UV-Vis) spectroscopy and dissolution tests.	6.1. Perform all steps in the SOP determine % dissolution by UV-Vis including: a) use of appropriate techniques to safely and effectively prepare five samples of various concentrations b) carry out UV-Vis analysis on test samples c) interpret results from UV-Vis analysis to produce a calibration curve d) carry out dissolution tests on samples e) interpret results from dissolution tests to determine percentage dissolution 6.2. Analyse results obtained in AC 6.1 including the following: a) trends in data b) possible sources of error and anomalies c) determining data validity and relevancy d) drawing conclusions with justification

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E-assessment	The use of information technology to assess learners' work	Electronic portfolio E-tests

Title	Scientific Mathematics
Level	Four
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF878
Unit Reference No	D/650/3491
Unit purpose and aim(s): The unit will enable the learner how to apply mathematical methods to scientific data.	
Learning Outcomes	**Assessment Criteria**
1. Be able to interpret, evaluate and communicate scientific data.	1.1 Interpret given quantitative and qualitative scientific data using appropriate software. 1.2 Select appropriate media and information detail to clearly communicate scientific data from a given data set to a selected audience. 1.3 Evaluate scientific results and data in terms of accuracy and errors.
2. Be able to work with standard mathematical form, logarithms, algebraic functions and their graphical representation.	2.1 Perform calculations with given data in standard form and using logarithms. 2.2 Apply transposition of formulae to scientific equations. 2.3 Resolve function-based equations including: a) simplifying expressions b) factorising expressions c) solving algebraic equations d) solving simultaneous equations 2.4 Illustrate graphically the following: a) linear b) quadratic c) cubic functions d) exponential growth and decay curves and gradients 2.5 Interpret graphical representations of the following: a) linear functions b) quadratic functions c) cubic functions d) exponential growth and decay curves and gradients
3. Be able to apply statistical methods to scientific data.	3.1 Calculate and evaluate measures of central tendency and variability in given scientific data sets. 3.2 Determine tendencies and variability in process outputs to scientific data. 3.3 Perform data analysis on given scientific data using appropriate software to include: a) production of scatter plots b) correlation and regression analysis c) simple forecasting association between variables and outputs in science applications 3.4 Demonstrate the application of significance testing to establish correctness of a hypothesis to include the following: a) Z-test b) T-test c) F-test d) Chi-squared test

4. Be able to apply differential and integral calculus to scientific problems.	4.1 Demonstrate the application of methods for differentiating mathematical functions including: a) the use of stationary points to determine maxima and minima b) determining the rate of change of a scientific quantity 4.2 Demonstrate the application of definite and indefinite integration for known functions using integration to determine the area under a curve for given sets of scientific data. 4.3 Demonstrate the application of formulating models of exponential growth and decay, using integration methods to given sets of scientific data.

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E-assessment	The use of information technology to assess learners' work	Electronic portfolio E-tests

Title	Pharmaceutical Industry Regulation
Level	Four
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF850
Unit Reference No	K/650/3034
Unit purpose and aim(s): This unit will enable the learner to understand pharmaceutical regulatory agencies, approval processes and relevant good practice guidelines and requirements.	

Learning Outcomes	Assessment Criteria
1. Understand worldwide pharmaceutical regulatory agencies and approval processes for drugs and medical devices.	1.1 Explain the role of worldwide regulatory agencies. 1.2 Research the regulatory agencies in at least four different world regions 1.3 Critically compare and contrast the drug approval processes in two different world regions identified in AC 1.2. 1.4 Critically compare and contrast medical device approval processes in two different world regions identified in AC 1.2. 1.5 Critically compare the drug approval processes for animals and human drugs in one of the world regions identified in AC 1.2.
2. Understand Good Manufacturing Practice (GMP) for the pharmaceutical industry.	2.1 Research and evaluate the following for GMP: a) principles and requirements b) legal framework and guidance governing two different world regions c) similarities and differences in AC 2.1.b)
3. Understand Good Laboratory Practice (GLP) for the pharmaceutical industry.	3.1 Research and evaluate the following for GLP: a) principles and requirements b) Organisation for Economic Co-operation and Development (OECD) legal framework and guidance
4. Understand Good Clinical Practice (GCP) for the pharmaceutical industry.	4.1 Research and evaluate the following for GCP: a) principles and requirements b) legal framework and guidance governing two different world regions c) similarities and differences in AC 4.1.b)
5. Understand Good Documentation Practice (GDP) for the pharmaceutical industry.	5.1 Research and evaluate the following for GDP: a) principles and requirements in all Good x Practice (GxP) processes b) Attributable Legible Contemporaneous Original Accurate (ALCOA) guidance expectations for paper and electronic records.

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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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Qualification Number: 610/1240/3

Operational start date: 01 August 2022
Operational end date: 31 July 2027
Certification end date: 31 July 2031

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