



Qualification Specification:

OCN NI Level 4 Certificate in Industrial Science

- Qualification No: 610/1240/3

Version: 2.0



1. Specification Updates

Key changes have been listed below:

Section	Detail of change	Version and date of Issue
Qualification	On new specification	V2.0 – March 2026
Qualification	Extended to 31 July 2032	V2.0 – March 2026

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3. Introduction to Open College Network Northern Ireland (OCN NI)

The Open College Network Northern Ireland (OCN NI) is a UK recognised awarding organisation based in Northern Ireland. We are regulated by CCEA Regulation to develop and award regulated professional and technical (vocational) qualifications from Entry Level up to and including Level 5 across all sector areas. In addition, OCN NI is also regulated by Ofqual to award qualifications in England.

OCN NI is also an educational charity that advances education by developing nationally recognised qualifications and recognising the achievements of learners. We work with centres such as Further Education Colleges, Private Training Organisations, Voluntary & Community Organisations, Schools, SME's and Public Sector bodies to provide learners with opportunities to progress into further learning and/or employment. OCN NI's Strategic Plan can be found on the OCN NI website www.ocnni.org.uk.

For further information on OCN NI qualifications or to contact us, you can visit our website at www.ocnni.org.uk. The website should provide you with details about our qualifications, courses, contact information, and any other relevant information you may need.

OCN NI Contact Details

Open College Network Northern Ireland
Sirius House
10 Heron Road
Belfast
BT3 9LE

Phone: 028 90 463990
Website: www.ocnni.org.uk
Email: info@ocnni.org.uk

4. About this Specification

This specification details OCN NI's specific requirements for the delivery and assessment of the **OCN NI Level 4 Certificate in Industrial Science**.

This specification will provide guidelines for centres to ensure the effective and correct delivery of this qualification. OCN NI qualification specifications are based on research and engagement with the practitioner community to ensure they provide appropriate skills and knowledge for learners.

The qualification specification will detail the following aspects of the OCN NI Level 4 Certificate in Industrial Science.

- **Qualification Features:** this includes the key characteristics and features of this qualification, such as its intended audience, purpose, and credit value.
- **Centre Requirements:** this details the prerequisites and obligations that centres must fulfil to be eligible to deliver and assess this qualification. These include guidelines on staff qualifications, resources, and required procedures.
- **Structure and Content:** this details the structure and content of the qualification including units, and any specific content that learners will be required to study.
- **Assessment Requirements:** this details assessment criteria and assessment methods for this qualification, ensuring that summative assessment approaches are clear.
- **Quality Assurance:** the quality and consistency of delivery and assessment of this qualification are of paramount importance to OCN NI. The mandatory quality assurance arrangements including processes for internal and external quality assurance that all centres offering this qualification must adhere to are detailed.
- **Administration:** guidance on the administrative aspects of delivering this qualification, including registration, certification and record-keeping.
- Reference to other handbooks and policies as appropriate to the qualifications.

It is important to note that OCN NI will communicate any significant updates or changes to this specification in writing to our centres. Additionally, we will make these changes available on our official website at www.ocnni.org.uk.

To stay current, please refer to the online version of this specification as it is the most authoritative and up-to-date publication. Be aware that downloaded and printed copies may not reflect the latest revisions.

4.1 Additional Support

OCN NI offers a comprehensive range of support services designed to assist centres in meeting the delivery and quality assurance requirements of OCN NI qualifications. These services include:

- **Specimen Assessment Materials**: These booklets are created to assist learners in demonstrating the fulfilment of assessment criteria and organising the quality assurance prerequisites for each individual unit.
- **Qualification Support Pack**: A support pack has been developed to support centres in the delivery of this qualification. The pack includes planning and assessment templates, guides to best practice, etc.
- **Professional Development for Educators**: OCN NI provides opportunities for professional development tailored to meet the various needs of practitioners and quality assurance staff. Centres can join our training sessions, available in both face-to-face and online formats, or explore a wealth of training materials by visiting www.ocnni.org.uk
- **OCN NI Subject Advisors**: Our team of subject advisors offers vital information and support to centres. They provide guidance on specification details, non-exam assessment advice, updates on resource developments, and various training opportunities. They actively engage with subject communities through an array of networks to facilitate the exchange of ideas and expertise, to support practitioners to provide quality education programs to learners.

All centres can access information, support and guidance to support the delivery and quality assurance of this qualification by contacting their designated Business Development Advisor or by contacting us on [Contact Us | OCN NI](#)

5. About this Qualification

5.1 Qualification Regulation Information

OCN NI Level 4 Certificate in Industrial Science

Qualification Number: 610/1240/3

Operational start date: 01 August 2022

Review date: 31 July 2032

The qualification's operational start and end dates define the regulated qualification's lifecycle. The operational end date is the final date for learner registration, while learners have until the certificate end date to complete the qualification and receive their certificates.

It is important to note that all OCN NI regulated qualifications are listed on the Register of Regulated Qualifications (RQF), which can be found at [Ofqual Register](#). This register is maintained by Ofqual in England and CCEA Regulation in Northern Ireland. It contains information about qualifications that are regulated and accredited. It is a key resource for learners, employers, and educational institutions to verify the status and recognition of qualifications.

Centres must adhere to administrative guidelines diligently, with special attention to the fact that fees, registration, and certification end dates for the qualification may be subject to changes. It is a centre's responsibility to make itself aware of updates on any modifications to ensure compliance with the latest requirements. OCN NI provides centres with timely updates through various channels including website, newsletters and through this specification. Information on qualification fees can be found on the Centre Login section of the OCN NI website www.ocnni.org.uk.

5.2 Sector Subject Area

A subject sector area is a specific category used to classify academic and vocational qualifications. Subject sector areas are part of the educational and qualifications framework to organise and categorise qualifications. The sector subject for this qualification is:

Subject Area: 2.1 Science

NOS: [Laboratory Skills - Cogent Skills](#)

5.3 Grading

Grading for this qualification is pass/fail.

5.4 Qualification's Aim and Objectives

Qualification's Aim

The aim of the OCN NI Level 4 Certificate in Industrial Science is to provide learners with the skills and knowledge to work competently and safely in accordance with appropriate regulation and guidelines in an industrial laboratory environment.

Qualification's Objectives

The objectives of the OCN NI Level 4 Certificate 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

5.5 Target Learners

This qualification is targeted at learners who are currently working in or who wish to work in laboratory based occupations.

5.6 Entry Requirements

The learner entry requirements for this qualification include the following:

- 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

5.7 Resource Requirements

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

5.8 Progression

The OCN NI Level 4 Certificate in Industrial Science allows for progression to higher level qualifications in science and related areas.

5.9 Delivery Language

This qualification is exclusively available in English. If there is a desire to offer this qualification in Welsh or Irish (Gaeilge), we encourage you to get in touch with OCN NI. They will assess the demand for such provisions and, if feasible, provide the qualification in the requested language as appropriate.

6. Centre Requirements for Delivering this Qualification

6.1 Centre Recognition

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

6.2 Qualification Approval

Once a centre has successfully undergone the Centre Recognition process, it becomes eligible to apply for qualification approval. The centre's capability to meet and sustain the qualification criteria will be assessed. Throughout the qualification approval process, OCN NI will aim to ensure that:

- centres possess suitable physical resources (e.g., equipment, IT, learning materials, teaching rooms) to support qualification delivery and assessment
- centre staff involved in the assessment process have relevant expertise and/or occupational experience
- robust systems are in place for ensuring ongoing professional development for staff delivering the qualification
- centres have appropriate health and safety policies concerning learner equipment use
- qualification delivery by centres complies with current equality and diversity legislation and regulations
- as a part of the assessment process for this qualification it may be useful for learners to have access to a practical work setting

6.3 Centre Staffing

To offer this qualification centres are mandated to establish the following roles as a minimum, although a single staff member may serve in more than one capacity*:

- Centre contact
- Programme Co-ordinator
- Assessor
- Internal Quality Assurance (IQA)

*Note: An individual cannot serve as an IQA for their own assessments.

6.4 Tutor Requirements

Tutors responsible for delivering this qualification are expected to possess a high degree of occupational competency. They should meet the following criteria:

- **Occupational Competency:** Tutors should demonstrate a clear understanding of the subject matter, including up-to-date knowledge. They should also have a minimum of one year's relevant experience in this area. This competence should enable them to effectively impart knowledge and practical skills to learners.
- **Qualifications:** Tutors should hold qualifications at a level that is at least one level higher than the qualification they are teaching. This ensures that they have the necessary academic foundation to provide in-depth guidance and support to learners.

These requirements collectively ensure that learners receive instruction from highly qualified and experienced instructors, thereby enhancing the quality and effectiveness of their educational experience.

6.5 Assessor Requirements

The assessment of this qualification takes place within the centre and is subjected to OCN NI's rigorous quality assurance procedures. The achievement of individual units is based on the criteria defined in each unit.

Assessors play a pivotal role in ensuring the validity and fairness of assessments. They are required to meet the following criteria:

- **Occupational Competency:** Assessors should possess a high degree of occupational competency in the relevant subject matter. This expertise enables them to accurately evaluate and measure a learner's knowledge and skills. Additionally, they should hold qualifications at a level that is at least one level higher than the qualification and have a minimum of one year's experience in the areas they are assessing, ensuring their in-depth understanding of the subject matter.
- **Assessment Expertise:** Assessors should have direct or related experience in the field of assessment. This includes knowledge of best practices in designing, conducting, and grading assessments. Their expertise ensures that assessments are both fair and valid.
- **Assessors Qualification:** Assessors should hold or be currently undertaking a recognised assessor's qualification; or must have attended the OCN NI Assessment Training.
- **Comprehensive Assessment Oversight:** Assessors are responsible for evaluating all assessment tasks and activities comprehensively. They must thoroughly review and assess each element to ensure a fair and accurate representation of a learner's skills and knowledge.

These rigorous requirements uphold the quality and integrity of the qualification's assessment process, ensuring that learners receive a fair and reliable evaluation of their competencies.

6.6 Internal Quality Assurer Requirements

The Internal Quality Assurer plays a crucial role in the centre's internal quality assurance processes. The centre must designate a skilled and trained IQA who assumes the role of an internal quality monitor responsible for verifying the delivery and assessment of the qualification.

The Internal Quality Assurer for this qualification must meet the following criteria:

- **IQA Expertise:** IQA should have direct or related experience in the field of internal assurance and have at least one year's occupational experience in the areas they are internally quality assuring. This includes knowledge of best practices in designing, conducting, and grading assessments. Their expertise ensures that assessments are both fair and valid.
- **IQA Qualification:** IQA should hold or be currently undertaking a recognised IQA qualification or must have attended the OCN NI IQA Training.
- **Thorough Evaluation of Assessment Tasks and Activities:** IQAs are tasked with conducting in-depth reviews and assessments of all assessment tasks and activities. Their responsibility is to ensure a comprehensive and meticulous oversight of each element to guarantee a just and precise reflection of a learner's abilities and knowledge and to ensure that all assessment and quality assurance requirements are fulfilled.

7. Qualification Structure

7.1 Qualification Purpose

The **OCN NI Level 4 Certificate in Industrial Science** is a unitised qualification assessed on a pass/fail basis, requiring learners to demonstrate a comprehensive understanding of key scientific principles and their application within industrial environments.

Its purpose is to develop learners' knowledge and practical competence across core areas of industrial science, enabling them to apply scientific methods, operate safely and effectively in technical settings, and interpret data with accuracy and professional judgement. Through a combination of theoretical learning and applied skills development, the qualification prepares individuals to contribute confidently to scientific, manufacturing, and process-driven industries. It also provides a strong platform for progression into higher-level study, technical roles, or sector-specific training within the wider industrial science field.

7.2 Qualification Level

In the context of the OCN NI Level 4 Certificate in Industrial Science it is essential to understand the significance of qualification levels, as they play a pivotal role in assessing the depth and complexity of knowledge and skills required for successful attainment. This qualification aligns with Level 4, which signifies a complex level of difficulty and intricacy. It's important to note that qualification levels in the educational framework range from Level 1 to Level 8, complemented by three 'entry' levels, namely Entry 1 to Entry 3.

7.3 Qualification Size

Total Qualification Time (TQT)

This represents the total amount of time a learner is expected to spend to complete the qualification successfully. It includes both guided learning hours (GLH) and independent study or additional learning time.

Guided Learning Hours (GLH)

These are the hours of guided instruction and teaching provided to learners. This may include classroom instruction, tutorials, or other forms of structured learning.

OCN NI Level 4 Certificate in Industrial Science	
Total Qualification Time (TQT):	540 hours
Total Credits Required:	54 credits
Guided Learning Hours (GLH):	240 hours

7.4 How to Achieve the Qualification

To achieve the **OCN NI Level 4 Certificate in Industrial Science** learners must complete 54 credits from any of the units.

8. Assessment Structure

This qualification is assessed through internal assessment and each unit is accompanied by specific assessment criteria that define the requirements for achievement.

8.1 Assessment Guidance: Portfolio

The portfolio for this qualification is designed to provide a comprehensive view of a learner's skills and knowledge. It is a holistic collection of evidence that may include a single piece of evidence that satisfies multiple assessment criteria. There is no requirement for learners to maintain separate evidence for each assessment criterion.

It is essential that the evidence in the portfolio reflects the application of skills in real-world situations. Learners should ensure that they provide multiple examples or references whenever the assessment criteria require it.

8.2 Understanding the Units

The units outlined in this specification establish clear assessment expectations. They serve as a valuable guide for conducting assessments and ensuring quality assurance efficiently. Each unit within this specification follows a consistent structure. This section explains the operational framework of these units. It is imperative that all educators, assessors, Internal Quality Assurers, and other personnel overseeing the qualification review and familiarise themselves with this section to ensure a comprehensive understanding of how these units function.

- **Title:** The title will reflect the content of the unit and should be clear and concise.
- **Level:** A unit can have one of six RQF levels: Entry, One, Two, Three, Four or Five. All units within this qualification are Level 4.
- **Credit Value:** This describes the number of credits ascribed to a unit. It identifies the number of credits a learner is awarded upon successful achievement of the unit. One credit is awarded for the learning outcomes which a learner, on average, might reasonably be expected to achieve in a notional 10 hours of learning.
- **Learning Outcome:** A coherent set of measurable achievements.
- **Assessment Criteria:** These enable a judgement to be made about whether or not, and how well, the students have achieved the learning outcomes.
- **Assessment Guidance and Methods:** These detail the different assessment methods within the unit that may be used.
- **Unit Content:** This provides indicative content to assist in teaching and learning.

9. Qualification Summary by Unit

OCN NI Level 4 Certificate in Industrial Science

In order to achieve the OCN NI Level 4 Certificate in Industrial Science the learner must successfully complete 54 credits from any of the units below.

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

10. Unit Content

10.1 Laboratory Skills for Industry

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
<i>Unit purpose and aim(s):</i> 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: - adhering to SOPs - completing required documentation - performing required calculations - analysing test results to determine if equipment meets pass criteria 1.2. Develop a SOP for an item of standard industry laboratory equipment including: - method development - testing - 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: - acid-base - oxidation-reduction reaction (REDOX) - indicator electrode 3.2. To determine the concentration of a secondary standard including: - recording data on an analytical method sheet - calculating the concentration of the secondary standard 3.3. Analyse results of titrations carried out in AC 3.1 to include the following: - trends in data - potentials source of error and anomalies - 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: - calculation of the masses and volumes required - prepare buffer from using the amounts calculated - 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

10.2 Chemistry for the Pharmaceutical and Life Science Industries

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
<i>Unit purpose and aim(s):</i> 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 hybridisation 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, K_c , from given initial and equilibrium amounts of substances. 4.2. Use calculations to determine concentrations from a given reaction constant, K_c . 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.
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	Learner notes/written work Learner log/diary

	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	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

10.3 Pharmaceutical Analytical Quality Control and Analysis

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
<i>Unit purpose and aim(s):</i> 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 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

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

10.4 Scientific Mathematics

Title	Scientific Mathematics
Level	Four
Credit Value	18
Guided Learning Hours (GLH)	80
OCN NI Unit Code	CBF878
Unit Reference No	D/650/3491
<i>Unit purpose and aim(s):</i> 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.

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

10.5 Pharmaceutical Industry Regulation

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.	
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	Learner notes/written work Learner log/diary Peer notes Record of observation Record of discussion

	OR A collection of documents containing work that shows the learner's progression through the course	
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

11. Quality Assurance of Centre Performance

11.1 Internal Assessment

When delivering and assessing this qualification, centres must align with stakeholders' expectations and address learners' needs by implementing a practical and applied programme. Centres have the flexibility to customise programmes to meet local requirements and establish connections with local employers and the broader vocational sector.

The Assessor should work with the Internal Quality Assurer to ensure that the assessment is planned in line with OCN NI requirements. Assessment Plans must be developed and approved by the Internal Quality Assurer prior to the delivery of the qualification.

All units within this qualification must undergo internal assessment. Learners must provide evidence that they have appropriately met all assessment criteria required for that grade.

The assessment format for all units involves a task conducted after the delivery of the unit's content, or part of it, if multiple tasks are used. Tasks may exhibit in various forms, encompassing practical and written types. Please refer to 'OCN NI's Assessment Definitions Guide' for additional details.

A task constitutes a distinct activity completed independently by learners, separated from teaching, practice, exploration, and other activities guided by tutors. Tasks are assigned to learners with a specified start date, completion date, and explicit requirements for the evidence to be produced. Some tasks may include observed practical components and require diverse forms of evidence.

A valid assignment will enable a clear and formal assessment outcome which meets the requirements of the assessment criteria. Assessment decisions are based on the specific assessment criteria given in each unit and set at each grade level. The way in which individual units are written provides a balance of assessment of understanding, practical skills and vocational attributes appropriate to the purpose of qualification.

It is the Assessor's role to ensure that learners are appropriately prepared for assessment, this begins from induction onwards. Assessors should ensure that learners understand how assessment tasks are used to determine the award of credit, the importance of meeting assessment timelines, and that all learners work must be independently created, where source documents are used this should be appropriately referenced, learners should be aware of what would constitute plagiarism and the possible consequences.

When conducting the assessment, Assessors must ensure they do not provide direct input, instructions or specific feedback which may compromise the authenticity of the work submitted.

Once the Assessor has authenticated the learners work, they must transparently demonstrate the rationale behind their assessment decisions. Once a learner completes all assigned tasks for a unit, the Assessor will allocate a grade for the unit. Refer to the 'Unit Grading Matrix' for additional information on the grading process.

Once the Assessor has completed the assessment process for the task, the assessment decision is recorded formally, and feedback is provided to the learner. The feedback should show the learner the outcome of the assessment decision, how it was determined or where the criteria has been met, it may indicate to the learner why achievement of the assessment criteria has not been met. It must be clear to the learner that this Assessment outcome is subject to verification.

For further information on assessment practice, please see the 'OCN NI Centre Handbook'. Assessment Training is also available and can be booked through the OCN NI Website.

11.2 Internal Quality Assurance

The role of the Internal Quality Assurer is to ensure appropriate internal quality assurance processes are carried out. The Internal Quality Assurer must oversee that assessments are conducted in accordance with relevant OCN NI policies, regulations, and this specification.

The Internal Quality Assurer must ensure assessments are fair, reliable, and uniform, thereby providing a consistent standard for all learners.

Internal Quality Assurers are required to provide constructive feedback to Assessors, identifying areas of strength and those that may require improvement. This feedback contributes to the ongoing professional development of Assessors.

Contributing to the standardisation of assessment practices within the centre is an important function of this role. This entails aligning assessment methods, grading criteria, and decision-making processes to maintain fairness and equity.

Internal Quality Assurers will actively engage in the sampling and monitoring of assessments to ensure the consistency and accuracy of assessment decisions. This process helps identify trends, areas for improvement, and ensures the robustness of the overall assessment system.

For further information on Internal Quality Assurance practice, please see the 'OCN NI Centre Handbook'. Internal Quality Assurance Training is also available and can be booked through the OCN NI Website.

11.3 Documentation

For internal quality assurance processes to be effective, the internal assessment and Internal Quality Assurance team needs to keep effective records.

- The programme must have an assessment and Internal Quality Assurance plan. When producing a plan, they should consider:
 - the time required for training and standardisation activities
 - the time available to undertake teaching and carry out assessment,
 - consider when learners may complete assessments and when quality assurance will take place
 - the completion dates for different assessment tasks
 - the date by which the assignment needs to be internally verified
 - sampling strategies
 - how to manage the assessment and verification of learners' work so that they can be given formal decisions promptly
 - how resubmission opportunities can be scheduled.

The following documents are available from OCN NI and document templates can be found in the Centre Login section of the OCN NI website www.ocnni.org.uk:

- A1 – Learner Assessment Record per Learner
- Learner Authentication Declarations
- Records of any reasonable adjustments applied for and the outcome – please see 'OCN NI's Reasonable Adjustments and Special Consideration Policy' for further information
- M1 Internal Quality Assurance Sample Record
- M2 Feedback to Assessor
- Records of any complaints or appeals

11.4 External Quality Assurance

All OCN NI recognised centres are subject to External Quality Assurance. External quality assurance activities will be conducted to confirm continued compliance with the CCEA Regulation General Conditions of Recognition, OCN NI terms and conditions and the requirements outlined within this qualification specification.

The External Quality Assurer is assigned by OCN NI. The External Quality Assurer will review the delivery and assessment of this qualification. This will include, but is not limited to, the review of a sample of assessment evidence and evidence of the internal quality assurance of assessment and assessment decisions. This will form the basis of the External Quality Assurance report and will help OCN NI determine the centre's risk.

The role of the External Quality Assurer serves as an external overseer of assessment quality, working to uphold consistency, compliance, and continuous improvement within the assessment process. Their role is crucial in ensuring that assessments are valid, reliable, fair, and aligned with the required standards and regulations.

For further information on OCN NI Centre Assessments Standards Scrutiny (CASS) Strategy, please see the OCN NI Centre Handbook.

11.5 Standardisation

As a process, standardisation is designed to ensure consistency and promote good practice in understanding and the 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 Quality Assurance

Centres offering this qualification must carry out internal standardisation activities prior to the claim for certification.

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 Quality Assurer documentation). OCN NI will make standardisation summary reports available and correspond directly with centres regarding event outcomes.

12. Administration

12.1 Registration

A centre must register learners for this qualification within 20 days of commencement of the delivery of the programme.

For further information on learner registration please see the OCN NI Centre Handbook and the QuartzWeb Manual, available through the Centre Login section of the OCN NI website. Administration training is also available and can be booked through www.ocnni.org.uk.

12.2 Certification

Once all internal quality assurance activities have been successfully completed, the centre can claim certification for the learner(s).

Certificates will be issued to centres within 20 working days from completion of a satisfactory external quality assurance activity, if appropriate, alternatively from the submission of an accurate and complete marksheet.

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.

For further information on the uploading of results please see the QuartzWeb Manual for guidance, administration training is also available and can be booked through [OCN NI](#)

12.3 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.

12.4 Equality, Fairness and Inclusion

OCN NI's are committed to ensuring all learners have an equal opportunity to access our qualifications and assessment, and that our qualifications are awarded in a way that is fair to every learner.

OCN NI is committed to making sure that:

- learners with a protected characteristic are not, when they are undertaking one of our qualifications, disadvantaged in comparison to learners who do not share that characteristic
- all learners achieve the recognition they deserve for undertaking a qualification and that this achievement can be compared fairly to the achievement of their peers

For information on reasonable adjustments and special considerations please see the OCN NI Centre Handbook and Reasonable Adjustments and Special Considerations Policy held in the back office of the OCN NI website.

12.5 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.

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

Operational start date: 01 August 2022

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Open College Network Northern Ireland (OCN NI)

Sirius House

10 Heron Road

Belfast

BT3 9LE

Phone: 028 90 463990

Email: info@ocnni.org.ukWeb: www.ocnni.org.uk