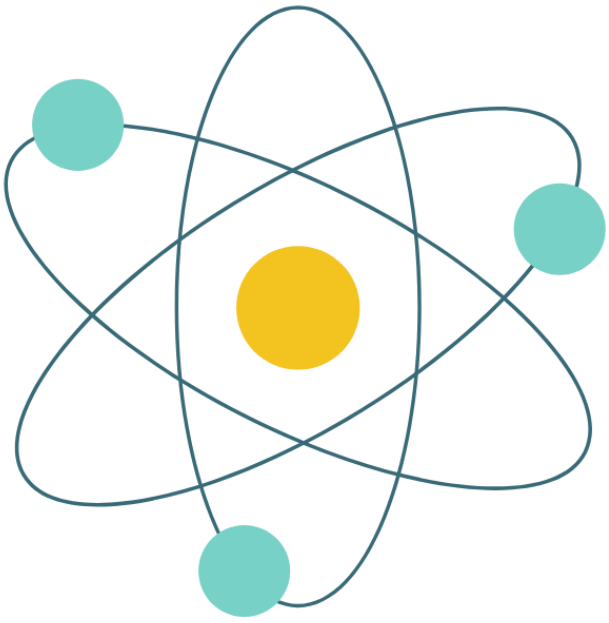
QUALIFICATION GUIDE

Level 3 Diploma in the Principles of Aseptic Pharmaceuticals Processing (RQF)

QAN: 603/3312/1



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About the Qualification

Title	Open Awards Level 3 Diploma in the Principles of Aseptic Pharmaceuticals Processing (RQF)
QAN	603/3312/1
Sector	1.2 Nursing and Subjects and Vocations Allied to Medicine
Level	Level 3
Funding	Please click here for more information
Pricing Information	Please click here for more information
Review Date	30/06/2023

Ofqual Purpose	Prepare for further learning or training and/or develop knowledge and/or skills in a subject area
Ofqual Sub-Purpose	B2 – Develop knowledge and/or skills in a subject area

Total Qualification Time/Guided Learning	
Certificate	
Total Qualification Time (hours)	560
Guided Learning (hours)	352

Age Range and Restrictions:	
Pre -16	x
16 – 18	✓
19+	✓
Any other restrictions specific to the qualification(s)	None

Any specified entry requirements
This qualification is suitable for learners aged 16+ Due to the level and content of the qualification, you are required to have a Level 2 Maths or English qualification (or be working towards this). A Science qualification at Level 2 would also be advantageous.

Recommended Assessment Method Summary
Learners will be required to complete a portfolio of evidence set and marked by the education provider and externally quality assured by Open Awards. Candidates must provide sufficient evidence that they have the required knowledge, skills and understanding of the assessment criteria and that it is their own work. Types of evidence could include: a) Observation of performance b) Questioning (written or oral) c) Practical Activities d) Photographs or videos e) Personal statements f) Project work g) Witness testimonies h) Group discussion i) Recognition of Prior Learning Assessment practices must reflect the Equality and Diversity Policy of Open Awards. Reasonable adjustments may be required for individual learners to enable them to undertake assessments fairly. Please see our Access to Fair Assessment Policy, which includes our Reasonable Adjustments guidance, for applying for Access to Fair Assessment. Further information on the assessment methodology can be found here.

Purpose Statement

The primary purpose of this qualification is to support you to develop knowledge in the subject area of Aseptic Pharmaceuticals Processing. This qualification is designed to enable you to develop the underpinning knowledge required to undertake the Aseptic Processing Technician role in Pharmaceutical Aseptic units. This qualification will provide the underpinning knowledge to support the Science Manufacturing Technician Apprenticeship Standard.

Who is it for?

This qualification is for you if you are on the Level 3 Science Manufacturing Technician Apprenticeship Standard and want to complete an Aseptics specialism.

This qualification is also for you if you are currently working in an Aseptic unit and want to develop knowledge to support progression within this specialism.

What does this qualification cover?

To achieve this qualification you will be required to complete 10 mandatory units and commit to approximately 570 hours of learning.

These units are:

- Understanding Aseptic Preparation Processes
- Understanding Clean Room Design and Behaviours
- Understanding Documentation in Aseptic Processing
- Understanding Health, Safety and Reducing Risk in Aseptic Pharmaceuticals
- Maintenance and Calibration in Aseptic Pharmaceuticals
- Roles, Responsibilities and Professional Development in Aseptic Pharmaceuticals
- Understanding Quality Assurance in Aseptic Pharmaceuticals
- Regulations and Legislation in Aseptic Pharmaceuticals
- Stock Management in Aseptic Pharmaceuticals
- Science in Aseptic Pharmaceuticals

What are the Entry Requirements?

Due to the level and content of the qualification, you are required to have a Level 2 Maths or English qualification (or be working towards this). A Science qualification at Level 2 would also be advantageous.

What are the Progression Opportunities?

The primary progression route for this qualification is employment as it has been delivered as part of the Science Manufacturing Technician Apprenticeship Standard.

On successful completion of the Apprenticeship, you will be able to undertake a Science Manufacturing Technician role.

A Science Manufacturing Technician will operate the systems and equipment involved in the production of products. They may work in varied conditions including wearing specialist safety equipment, shift work and on sites running 365 day operations. Many companies operate under highly regulated conditions and a premium is placed on appropriate attitudes and behaviours to ensure employees comply with organisational safety and regulatory requirements.

Science Manufacturing Technicians are expected to work both individually and as part of a manufacturing team. They are able to work with minimum supervision, taking responsibility for the quality and accuracy of the work they undertake. They are proactive in finding solutions to problems and identifying areas for improving their work environment.[1]

[1] IfA Overview of Science Manufacturing Technician Role
https://www.instituteforapprenticeships.org/apprenticeship-standards/science-manufacturing-technician/

What are the Assessment Methods?

This qualification will be assessed by a portfolio of evidence. Indicative content has been agreed as part of the development to ensure that tutors and assessors are able to put together robust and meaningful assessments to meet the criteria.

Due to the level and knowledge-based focus of the qualification, appropriate forms of assessment could include:

- Coursework
- Written examinations
- Assignments/essays
- Record of Q&A
- Task-based assessments including risk assessments, processes and procedures

Who supports this qualification?

This qualification has been developed in partnership with, and is supported by, a range of stakeholders including: Skills for Health; Health Education England; Barts Health NHS Trust; Pennine Acute Hospitals; University College London Hospitals; University Hospital Southampton.

Qualification Structure

Rules of Combination	
Mandatory Unit Group A:	56 credits to be achieved

Mandatory Units A			
Unit Reference Number	**Unit Name**	**Credits**	**Level**
F/617/0954	Aseptic Manufacture and Preparation Processes	12	Level Three
J/617/0955	Clean Room Design and Behaviours	3	Level Three
L/617/0956	Health, Safety and Reducing Risk in Aseptic Pharmaceuticals	4	Level Three
R/617/0957	Legislation, Regulations and Standards in Aseptic Pharmaceuticals	6	Level Three
Y/617/0958	Maintenance and Calibration in Aseptic Pharmaceuticals	3	Level Three
D/617/0959	Quality Management in Aseptic Pharmaceuticals	6	Level Three
R/617/0960	Roles, Responsibilities and Professional Development in Aseptic Pharmaceuticals	4	Level Three
Y/617/0961	Science in Aseptic Processing	12	Level Three
D/617/0962	Stock Management in Aseptic Pharmaceuticals	3	Level Three
H/617/0963	Documentation in Aseptic Processing	3	Level Three

Delivering this Qualification

Becoming a Centre

To deliver this qualification you must be a recognised Open Awards centre. For more information, click here or contact the team on 0151 494 2072

Already Recognised? How to Deliver

If you are already a recognised Open Awards centre, you can deliver this qualification by completing a New Qualification Notification Form via the Open Awards portal. For more information, see the Centre Handbook, or contact the team on 0151 494 2072.

Registering Learners

Once you are ready to deliver this qualification, you will need to register your learners in line with the timescales below:

Short courses (15 weeks or less) within 25 working days of the course start date. Full year long courses (over 15 weeks) within 60 working days of the course start date.

You will need to register your learners via the Open Awards portal. More information can be found in our Centre Handbook.

Quality Assurance

Delivery of this qualification must be done so in accordance with Ofqual regulatory guidelines and in line with Open Awards' quality assurance processes. Please see our website for more information.

Centre Staff Requirements

It is expected that centres will have occupationally competent staff with relevant sector experience for their role in the delivery of the units/qualifications being offered.

For the delivery and assessment of this qualification, it is expected that staff have a qualification at the level or higher in a related Aseptic Pharmacy subject and have up-to-date working knowledge and experience of best practice in assessment and quality assurance.

Centres are responsible for ensuring that their staff are occupationally competent and have access to appropriate training and support. They are also responsible for notifying Open Awards of staff changes.

Assessment

Open Awards units and qualifications have been designed around the principle that the learner will build evidence towards the achievement of the assessment criteria over a period of time.

Each learner is required to build a portfolio of evidence to demonstrate that all the assessment criteria associated with each unit has been met.

Tutors and Assessors need to ensure that all evidence presented in a portfolio is:

Valid: it should be clearly demonstrating the knowledge or skills that are set out in the assessment criteria. It should be clearly the work of the learner.

Reliable: which means that it will in general, produce the same range of responses from learners, as long as they are used in similar circumstances and with similar groups of learners.

Inclusive: so that no individual learner is excluded from the opportunity to show their achievement because of their individual background or experience.

Assessors are required to review and assess all learner evidence and must be satisfied that learners have achieved all learning outcomes and assessment criteria relating to the unit being assessed prior to deciding the learner has completed the unit. Assessors will also ensure that the evidence produced by the learner is their own work.

Assessors retain records (e.g. Feedback Sheets, Individual Progress Records, Group Progress Records) on behalf of the centre which are made available and used by the centre's internal verifier / AIV and Open Awards Quality Reviewer / External Verifier.

Verification and Standardisation

Verification is the process by which assessment decisions are confirmed. Centres delivering this qualification have a responsibility to conduct internal verification led by a trained internal verifier.

Centre approval compliance monitoring and External verification is carried out by Open Awards Quality Reviewers/External Verifiers who will confirm that the centre is assessing to standard and ensure that there are robust quality assurance systems embedded.

Further guidance on Internal Verification and Training Support for centres can be found on our website

Centres are required to contribute to national standardisation as requested by Open Awards and also to carry out appropriate internal standardisation. Open Awards offers Standardisation events that are held throughout the year. Such events will also provide an opportunity to identify and share best practice. Up to date details of training and standardisation events can be found on our website

Internal standardisation involves ensuring that, where there is more than one tutor/assessor delivering Open Awards provision or more than one site, internally set tasks and the outcomes of internal assessment are consistent across the range of courses.

Recognition of Prior Learning and Achievement (RPL)

RPL is a method of assessment (leading to the award of credit) that considers whether a learner can demonstrate that they can meet the assessment requirements for a unit through knowledge, understanding or skills they may already possess. RPL enables recognition of achievement from a range of achievements and experiences whether at work, home and at leisure and is acceptable for accrediting a unit, units or a whole qualification. Evidence of learning must be sufficient, reliable and valid.

Credit based qualifications enable learners to avoid duplication of learning and assessment through equivalences or exemptions. It is the responsibility of the centre to inform Open Awards at registration of any exemptions and/or equivalences for which a claim may be made. These claims will be subject to external verification by the Open Awards Quality Reviewer for the centre.
For more information, please see our Recognition of Prior Learning Policy.

Health and Safety

Due to the practical requirements of some of the units within this qualification, centres must ensure that appropriate risk assessments are in place for both the activities and individual learners to ensure the learners and staff safety throughout the course. As part of this, centres must ensure that learners and staff have access to appropriate clothing and personal protective equipment (PPE).

Appendices and Links

Appendix Name
Glossary of Terms
Malpractice and Maladministration Policy
Sanctions Policy
Standardisation Policy
Marketing Your Open Awards Course
Centre Handbook
Recognition of Prior Learning Policy and Procedures
Plagiarism Policy
Invoicing Policy
Equality and Diversity Policy
Customer Service Statement
Complaints Policy and Procedures
Enquiries and Appeals Policy and Procedures
Access to Fair Assessment Policy
Report of Suspected Malpractice (M1 Form)

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