

Purpose Statement

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

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 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

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/>

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.