



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

Ofqual (England) 603/3312/1  
Qualification Wales C00/4840/O



QUALIFICATION GUIDE

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## About the Qualification

<b>Title</b>	Open Awards Level 3 Diploma in the Principles of Aseptic Pharmaceuticals Processing (RQF)
<b>QAN</b>	603/3312/1
<b>Sector</b>	1.2 Nursing and Subjects and Vocations Allied to Medicine
<b>Level</b>	Level 3
<b>Funding</b>	<a href="#">Please click here for more information</a>
<b>Pricing Information</b>	<a href="#">Please click here for more information</a>
<b>Review Date</b>	31/07/2025

<b>Ofqual Purpose</b>	Prepare for Further Learning or Training and/or Develop Knowledge and/or Skills in a Subject Area
<b>Ofqual Sub-Purpose</b>	Develop Knowledge and/or Skills in a Subject Area

Total Qualification Time/Guided Learning	
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
<p>This qualification is suitable for learners aged 16+</p> <p>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.</p>

### **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.

## Qualification Units

Rules of Combination	
Diploma	
Credit Value of the Qualification	56
Minimum Credits to be achieved at the Level of the Qualification	56
Mandatory Units A	56

### Mandatory Units A

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

## Delivering this Qualification

### Becoming a Centre

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

### How to Deliver

You can deliver this qualification by requesting approval via the Open Awards portal. For more information, see the Provider 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](#).

### Quality Assurance and Standardisation

Delivery of this qualification must be done so in accordance with Ofqual regulatory guidelines and in line with Open Awards' quality assurance processes. Template forms and guidance documents are available via the Open Awards portal.

#### **Centre Staff Requirements**

Centres are responsible for ensuring that their staff are suitably skilled and experienced. Tutors/ assessors and internal quality assurance (IQA) staff must have relevant occupational knowledge and/or occupational competence at the same level or higher as the units being delivered.

Centres are responsible for notifying Open Awards of staff changes.

#### **Training and support**

Open Awards offers training and support events in Delivery & Assessment and Quality Assurance. These events are held throughout the year. Such events will also provide an opportunity to identify and share best practice. Up to date details of these training events are on our [website](#).

#### **Internal Quality Assurance (IQA)**

All centres delivering Open Awards provision must operate rigorous internal quality assurance systems. A centre must identify how they will internally quality assure and standardise their delivery and assessment before delivering a course.

#### **External Quality Assurance (EQA)**

Centre approval compliance monitoring and external quality assurance is carried out by Open Awards' Lead Quality Reviewers/External Quality Assurers who will

confirm that the centre is assessing to standard and ensure that there are robust quality assurance systems embedded.

Please refer to Internal and External Quality Assurance within the Centre Handbook.

### **Standardisation**

Centres are required to contribute to national standardisation as requested by Open Awards. 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.

Further guidance on Quality Assurance and Standardisation please refer to the [Centre Handbook](#)

### **Recognition of Prior Learning and Achievement (RPL)**

RPL is a method of assessment 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. Evidence of learning must be sufficient, reliable and valid.

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' Lead Quality Reviewer for the centre.

For more information, please see our Recognition of Prior Learning Policy found on the Open Awards [portal](#).

### **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
<a href="#">Centre Handbook</a>
<a href="#">Enquiries, Complaints and Appeals Policy</a>
<a href="#">Equality and Diversity Policy</a>
<a href="#">Invoicing Policy</a>
<a href="#">Privacy Policy</a>

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