



Changing lives through learning

Open Awards Level 3 Diploma in the

# Principles of Aseptic Pharmaceuticals Processing (RQF)

**Ofqual: 603/3312/1**

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### Version Control

v1.0	New document September 2023
v2.0	Document rebranded. No substantive changes to content.

## About the Qualification

<b>Title/ Teitl</b>	Open Awards Level 3 Diploma in the Principles of Aseptic Pharmaceuticals Processing (Wales)
<b>Qualification Accreditation Number/ Rhif Achredu Cymhwyster</b>	603/3312/1
<b>Sector</b>	1.2 Nursing and Subjects and Vocations Allied to Medicine/
<b>Level/ Lefel</b>	Level Three
<b>Funding/ Cyllid</b>	<a href="#">Please click here for more information</a>
<b>Pricing Information/ Gwybodaeth am Briso</b>	<a href="#">Please click here for more information</a>
<b>Review Date/ Dyddiad Adolygu</b>	31/08/2025

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

<b>Total Qualification Time/Guided Learning</b>	
Total Qualification Time (hours)	560
Guided Learning (hours)	362

<b>Age Range and Restrictions</b>	
Pre-16	x
16 – 18	✓
18+	✓
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.

Learners 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) Portfolio of evidence
- b) Observations
- c) Witness statements
- d) Assignment
- e) Professional discussion
- f) Reflective journals
- g) Presentations

Assessment practices must reflect the Equality and Diversity Policy of Open Awards.

## Qualification Structure

### Rules of Combination

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

### Qualification Units

#### Mandatory Units

All units must be achieved to be awarded the qualification.

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 Provider

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

### How to Deliver

To request to deliver this qualification, please login to [the Portal](#) and then click on 'Tracking' and 'Initiate a Workflow'. You will then need to select 'Apply to Deliver Regulated Qualification(s)'.

For support with this process, please see the following document in the Portal 'Provider Portal Guidance – Qualification Approval' or contact the team on [customerservices@openawards.org.uk](mailto:customerservices@openawards.org.uk) or 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.  
Long courses (over 15 weeks) within 60 working days of the course start date.

You will need to register your learners via [the 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. Please see our website for more information.

### Provider Staff Requirements

Providers 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.

Providers 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**

All providers 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**

Provider 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 [Provider 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 Provider 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 quality assurance by the Open Awards Quality Assurance Team.

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



## Appendices and Links

The following documents can be viewed on the Open Awards website:

1. Provider Handbook
2. Enquiries and Appeals Policy and Procedures
3. Complaints Policy
4. Equality and Diversity Policy
5. Invoicing Policy
6. Privacy Policy
7. Reasonable Adjustments and Special Considerations Policy and Procedures

Additional supporting documents can be viewed in the Open Awards Portal.

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