Changing lives through learning

Open Awards Level 3 Diploma in the

Principles of Aseptic Pharmaceuticals Processing (Wales)

Diploma Lefel 3 mewn

Egwyddorion Prosesu Fferylliaeth Aseptig (Cymru)

QiW: C00/4840/0

Qualification Guide/ Cannllaw' R Rcymhwyster

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Version Control/ Rheoli Fersiwn	
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About the Qualification/ Ynghylch y Cymhwyster

Title/ Teitl	Open Awards Level 3 Diploma in the Principles of Aseptic Pharmaceuticals Processing (Wales)/ Diploma Lefel 3 mewn Egwyddorion Prosesu Fferylliaeth Aseptig Open Awards (Cymru)
Qualification Accreditation Number/ Rhif Achredu Cymhwyster	C00/4840/0
Sector	1.2 Nursing and Subjects and Vocations Allied to Medicine/ 1.2 Nyrsio a Phynciau a Galwedigaethau sy'n Gysylltiedig â Meddygaeth
Level/ Lefel	Level Three/ Lefel Tri
Funding/ Cyllid	Please click here for more information/ Cliciwch yma i gael mwy o wybodaeth
Pricing Information/ Gwybodaeth am Brisio	Please click here for more information/ Cliciwch yma i gael mwy o wybodaeth
Review Date/ Dyddiad Adolygu	31/08/2028

Purpose/ Pwrpas	Prepare for Further Learning or Training and/or Develop Knowledge and/or Skills in a Subject Area/ Paratoi ar gyfer Dysgu neu Hyfforddiant Pellach a/neu Ddatblygu Gwybodaeth a/neu Sgiliau mewn Maes Pwnc
Sub-Purpose/ Is-ddiben	Develop Knowledge and/or Skills in a Subject Area/ Datblygu Gwybodaeth a/neu Sgiliau mewn Maes Pwnc

Total Qualification Time/Guided Learning Cyfanswm Amser Cymhwyster	
Total Qualification Time (hours)/ Cyfanswm Amser Cymhwyster (oriau)	560
Guided Learning (hours)/ Dysgu o dan Arweiniad (oriau)	362

Age Range and Restrictions/ Ystod Oedran a Chyfyngiadau	
Pre-16/ Cyn -16	x
16 – 18	✓
18+	✓
Any other restrictions specific to the qualification(s)/ Unrhyw gyfyngiadau eraill sy'n benodol i'r cymhwyster (cymwysterau)	None/ Dim

Any Specified Entry Requirements/ Unrhyw ofynion mynediad penodol

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.

Mae'r cymhwyster hwn yn addas ar gyfer dysgwyr 16+ oed

Oherwydd lefel a chynnwys y cymhwyster, mae'n ofynnol i chi fod â chymhwyster Lefel 2 mewn Mathemateg neu Saesneg (neu fod yn gweithio tuag at hyn). Byddai cymhwyster Gwyddoniaeth Lefel 2 hefyd yn fanteisiol.

Recommended Assessment Method Summary/ Crynodeb o'r Dull Asesu a Argymhellir

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.

Bydd gofyn i ddysgwyr gwblhau portffolio o dystiolaeth a osodir ac a farcir gan y darparwr addysg a sicrheir ansawdd yn allanol gan Open Awards.

Mae'n rhaid i ddysgwyr ddarparu digon o dystiolaeth bod ganddynt y wybodaeth, y sgiliau a'r ddealltwriaeth ofynnol o'r meini prawf asesu ac mai eu gwaith eu hunain ydyw.

Mathau o dystiolaeth y gellid eucynnwys:

a) Portffolio o dystiolaeth
b) Arsylwadau
c) Datganiadau tystion
d) Dyraniad
e) Trafodaeth broffesiynol
f) Dyddlyfrau adlewyrchol
g) Cyflwyniadau

Mae'n rhaid i arferion asesu adlewyrchu Polisi Cydraddoldeb ac Amrywiaeth Open Awards.

Qualification Structure/ Strwythur y Cymhwyster

Rules of Combination/ Rheolau Cyfuniad

Credit Value of the Qualification/ Gwerth Credyd y Cymhwyster:	56
Minimum Credits to be achieved at the Level of the Qualification/ Isafswm Credydau i'w cyflawni ar Lefel y Cymhwyster:	56
Mandatory Units A/ Unedau Gorfodol A	56

Qualification Units/ Unedau'r Cymhwyster

Mandatory Units/ Unedau Gorfodol

All units must be achieved to be awarded the qualification.
Rhaid cyflawni pob uned i ennill y cymhwyster.

Unit Reference Number/ Cyfeirnod yr Uned	Unit Name/ Enw'r Uned	Credits/ Credydau	Level/ Lefel
F/617/0954	Aseptic Manufacture and Preparation Processes/ Prosesau Gweithgynhyrchu a Pharatoi Aseptig	12	Level Three/ Lefel Tri
J/617/0955	Clean Room Design and Behaviours/ Prosesau Gweithgynhyrchu a Pharatoi Aseptig	3	Level Three/ Lefel Tri
L/617/0956	Health, Safety and Reducing Risk in Aseptic Pharmaceuticals/ Iechyd, Diogelwch a Lleihau Risg mewn Fferylliaeth Aseptig	4	Level Three/ Lefel Tri
R/617/0957	Legislation, Regulations and Standards in Aseptic Pharmaceuticals/ Deddfwriaeth, Rheoliadau a Safonau mewn Fferylliaeth Aseptig	6	Level Three/ Lefel Tri
Y/617/0958	Maintenance and Calibration in Aseptic Pharmaceuticals/ Cynnal a Chadw a Graddnodi mewn Fferylliaeth Aseptig	3	Level Three/ Lefel Tri
D/617/0959	Quality Management in Aseptic Pharmaceuticals/ Rheoli Ansawdd mewn Fferylliaeth Aseptig	6	Level Three/ Lefel Tri

R/617/0960	Roles, Responsibilities and Professional Development in Aseptic Pharmaceuticals/ Rolau, Cyfrifoldebau a Datblygiad Proffesiynol mewn Fferylliaeth Aseptig	4	Level Three/ Lefel Tri
Y/617/0961	Science in Aseptic Processing/ Gwyddoniaeth mewn Prosesu Aseptig	12	Level Three/ Lefel Tri
D/617/0962	Stock Management in Aseptic Pharmaceuticals/ Rheoli Stoc mewn Fferylliaeth Aseptig	3	Level Three/ Lefel Tri
H/617/0963	Documentation in Aseptic Processing/ Dogfennaeth mewn Prosesu Aseptig	3	Level Three/ Lefel Tri

Delivering this Qualification/ Cyflawni'r Cymhwyster hwn

Becoming a Provider/ Dod yn Ddarparwr

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.

I gyflwyno'r cymhwyster hwn, mae'n rhaid i chi fod yn Ddarparwr Open Awards cydnabyddedig. I gael mwy o wybodaeth, ewch i'n gwefan neu cysylltwch â'r tîm ar 0151 494 2072.

How to Deliver/ Sut i Gyflwyno

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 or 0151 494 2072.

I wneud cais i gyflwyno'r cymhwyster hwn, mewngofnodwch i'r Porth ac yna cliciwch ar 'Tracio' a 'Cychwyn Llif Gwaith'. Yna bydd angen i chi ddewis 'Gwneud Cais i Gyflwyno Cymhwyster(au) a Reoleiddir'.

I gael cefnogaeth gyda'r broses hon, gweler y ddogfen ganlynol yn y Porth 'Arweiniad Porth Darparwr – Cymeradwyo Cymhwyster' neu cysylltwch â'r tîm ar customerservices@openawards.org.uk neu 0151 494 2072.

Registering Learners/ Cofrestru Dysgwyr

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.

Unwaith y byddwch yn barod i gyflwyno'r cymhwyster hwn, bydd angen i chi gofrestru eich dysgwyr yn unol â'r amserlenni isod:

Cyrsiau byr (15 wythnos neu lai) o fewn 25 diwrnod gwaith i ddyddiad dechrau'r cwrs. Cyrsiau hir (dros 15 wythnos) o fewn 60 diwrnod gwaith i ddyddiad dechrau'r cwrs.

Bydd angen i chi gofrestru eich dysgwyr drwy'r Porth.

Quality Assurance and Standardisation/ Sicrhau Ansawdd a Safoni

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.

Mae'n rhaid cyflwyno'r cymhwyster hwn yn ôl canllawiau rheoleiddio Ofqual ac yn unol â phrosesau sicrhau ansawdd Open Awards. Gweler ein gwefan i gael mwy o wybodaeth.

Provider Staff Requirements/ Gofynion Staff y Darparwr

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.

y canolfannau sy'n gyfrifol am sicrhau bod eu staff yn meddu ar y sgiliau a'r profiad addas. Mae'n rhaid i diwtoriaid/aseswyr a staff sicrhau ansawdd mewnol (IQA) fod â gwybodaeth alwedigaethol berthnasol a/neu gymhwysedd galwedigaethol ar yr un lefel neu'n uwch na'r unedau sy'n cael eu cyflwyno.

Y canolfannau sy'n gyfrifol am hysbysu Open Awards ynghylch newidiadau staff.

Training and Support/ Hyfforddiant a chefnogaeth

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.

Mae Open Awards yn cynnig digwyddiadau hyfforddi a chefnogaeth mewn Cyflwyno ac Asesu a Sicrhau Ansawdd. Cynhelir y digwyddiadau hyn drwy gydol y flwyddyn. Bydd digwyddiadau o'r fath hefyd yn gyfle i nodi a rhannu arferion gorau. Mae manylion diweddaraf y digwyddiadau hyfforddi hyn ar ein gwefan.

Internal Quality Assurance/ Sicrhau Ansawdd Mewnol (IQA)

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.

Mae'n rhaid i bob canolfan sy'n cyflwyno darpariaeth Open Awards weithredu systemau sicrhau ansawdd mewnol trylwyr. Mae'n rhaid i ganolfan nodi sut y bydd yn sicrhau ansawdd mewnol a safoni ei darpariaeth a'i hasesiadau cyn cyflwyno cwrs.

External Quality Assurance/ Sicrhau Ansawdd Allanol (EQA)

Provdier 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.

Mae monitro cydymffurfiaeth cymeradwyo'r ganolfan a sicrhau ansawdd allanol yn cael ei gynnal gan Adolygwyr Ansawdd Arweiniol Open Awards/Sicrhawyr Ansawdd Allanol a fydd yn cadarnhau bod y ganolfan yn asesu i'r safon ac yn sicrhau bod systemau sicrhau ansawdd cadarn yn rhan annatod o'r broses.

Cyfeiriwch at Sicrhau Ansawdd Mewnol ac Allanol yn Llawlyfr y Ganolfan.

Standardisation/ Safoni

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.

Mae'n ofynnol i ganolfannau gyfrannu at safoni cenedlaethol fel y gofynnir gan Open Awards. Mae Open Awards yn cynnig digwyddiadau safoni sy'n cael eu cynnal drwy gydol y flwyddyn. Bydd digwyddiadau o'r fath hefyd yn gyfle i nodi a rhannu arferion gorau. Gellir gweld manylion diweddaraf am ddigwyddiadau hyfforddi a safoni ar ein gwefan.

I gael canllawiau pellach ynghylch Sicrhau Ansawdd a Safoni, cyfeiriwch at Lawlyfr darparwr.

Recognition of Prior Learning and Achievement/ Cydnabod Dysgu a Chyflawniad Blaenorol (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.

Dull o asesu yw RPL sy'n ystyried a all dysgwr ddangos ei fod yn bodloni'r gofynion asesu ar gyfer uned trwy wybodaeth, dealltwriaeth neu sgiliau y gallai fod ganddo/ganddi eisoes. Mae'n rhaid i dystiolaeth o ddysgu fod yn ddigonol, yn ddibynadwy ac yn ddilys.

Cyfrifoldeb y Darparwr yw hysbysu Open Awards wrth gofrestru unrhyw eithriadau a/neu gyfwerthedd y gellir gwneud hawliad ar eu cyfer. Bydd yr hawliadau hyn yn destun sicrhau ansawdd allanol gan Dîm Sicrhau Ansawdd Open Awards.

I gael mwy o wybodaeth, gweler ein Polisi Cydnabod Dysgu Blaenorol y gellir ei weld ar y Porth.

Appendices and Links/ Atodiadau a Dolenni

The following documents can be viewed on the Open Awards website/ Gellir gweld y dogfennau canlynol ar wefan Open Awards:

1. Provider Handbook/ Llawlyfr Darparwr
2. Enquiries and Appeals Policy and Procedures/ Polisi Ymholiadau, Cwynion ac Apeliadau
3. Complaints Policy/ Polisi Cwynion
4. Equality and Diversity Policy/ Polisi Cydraddoldeb ac Amrywiaeth
5. Invoicing Policy/ Polisi Anfonebu
6. Privacy Policy/ Polisi Preifatrwydd
7. Reasonable Adjustments and Special Considerations Policy and Procedures/ Polisi a Gweithdrefnau Addasiadau Rhesymol ac Ystyriaethau Arbennig

Additional supporting documents can be viewed in the Open Awards Portal/ Gellir gweld dogfennau ategol ychwanegol ym Mhorth Open Awards.

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Cedwir pob hawl. Rhoddir caniatâd i atgynhyrchu at ddefnydd personol ac addysgol yn unig. Gwaherddir copïo masnachol, llogi neu fenthyca.

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