

# Purpose Statement

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

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?

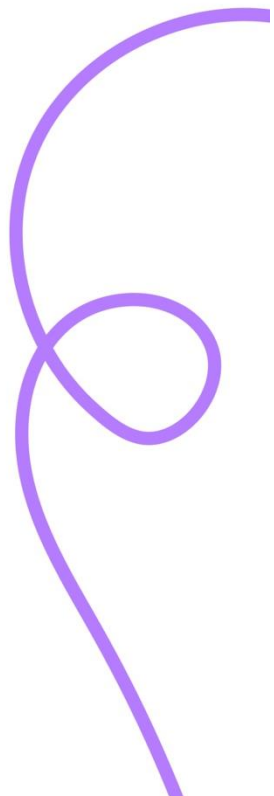
To achieve this qualification you will be required to complete 10 mandatory units and commit to approximately 570 hours of learning.

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

### 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.



## 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.<sup>1</sup>

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

# Datganiad Diben

## Diploma Lefel 3 Open Awards mewn Egwyddorion Prosesu Cynhyrchion Fferyllol Aseptig (RQF)

Prif ddiben y cymhwyster hwn yw eich cefnogi i ddatblygu gwybodaeth ym maes pwnc Prosesu Cynhyrchion Fferyllol Aseptig. Mae'r cymhwyster hwn wedi'i lunio i'ch galluogi i ddatblygu'r wybodaeth sylfaenol sydd ei hangen i ymgymryd â rôl Technegydd Prosesu Aseptig mewn unedau Cynhyrchion Fferyllol Aseptig. Bydd y cymhwyster hwn yn darparu'r wybodaeth sylfaenol i gefnogi Safon Prentisiaeth Technegydd Gweithgynhyrchu Gwyddoniaeth.

### Ar gyfer pwy mae'r cymhwyster?

Mae'r cymhwyster hwn ar eich cyfer chi os ydych yn astudio Safon Prentisiaeth Technegydd Gweithgynhyrchu Gwyddoniaeth Lefel 3 ac yn dymuno bod ag arbenigedd mewn Asepteg.

Mae'r cymhwyster hwn hefyd ar eich cyfer chi os ydych yn gweithio ar hyn o bryd mewn uned Aseptig ac yn dymuno datblygu gwybodaeth i gefnogi dilyniant o fewn yr arbenigedd hwn.

### Beth mae'r cymhwyster hwn yn ei gynnwys?

I ennill y cymhwyster hwn bydd gofyn i chi gwblhau 10 uned orfodol ac ymrwymo i tua 570 awr o ddysgu.

Yr unedau hyn yw:

- Deall Prosesau Paratoi Aseptig; Deall Cynllun ac Ymddygiadau Ystafell Lân; Deall Dogfennaeth mewn Prosesu Aseptig; Deall Iechyd, Diogelwch a Lleihau Risg mewn Cynhyrchion Fferyllol Aseptig;
- Cynnal a Chadw a Graddnodi mewn Cynhyrchion Fferyllol Aseptig;
- Rolau, Cyfrifoldebau a Datblygiad Proffesiynol mewn Cynhyrchion Fferyllol Aseptig;
- Deall Sicrhau Ansawdd mewn Cynhyrchion Fferyllol Aseptig; Rheoliadau a Deddfwriaeth mewn Cynhyrchion Fferyllol Aseptig; Rheoli Stoc mewn Cynhyrchion Fferyllol Aseptig;
- Gwyddoniaeth mewn Cynhyrchion Fferyllol Aseptig

### Pwy sy'n cefnogi'r cymhwyster hwn?

Mae'r cymhwyster hwn wedi'i ddatblygu mewn partneriaeth ag, ac yn cael ei gefnogi gan amrywiaeth o randdeiliaid gan gynnwys: Sgiliau Iechyd; Addysg Iechyd Lloegr; Barts Health NHS Trust; Ysbytai Pennine Acute; Ysbytai Coleg Prifysgol Llundain; Ysbyty Prifysgol Southampton

## Beth yw'r gofynion mynediad?

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

## Beth yw'r gofynion mynediad?

Mae'r asesiad ar gyfer y cymhwyster hwn yn cynnwys portffolio o dystiolaeth Mae cynnwys dangosol wedi'i gytuno fel rhan o'r datblygiad i sicrhau bod tiwtoriaid ac aseswyr yn gallu rhoi asesiadau cadarn ac ystyrlon at ei gilydd i fodloni'r meini prawf.

Oherwydd lefel a ffocws y cymhwyster ar wybodaeth, gallai dulliau asesu priodol gynnwys:

- Gwaith cwrs
- Arholiadau ysgrifenedig
- Aseiniadau/traethodau
- Cofnod o Holi ac Ateb
- Asesiadau sy'n seiliedig ar dasgau gan gynnwys asesiadau, prosesau a gweithdrefnau risg

## Beth yw'r cyfleoedd dilyniant?

Y prif lwybr dilyniant ar gyfer y cymhwyster hwn yw cyflogaeth gan ei fod wedi'i gyflwyno fel rhan o Safon Prentisiaeth Technegydd Gweithgynhyrchu Gwyddoniaeth.

Ar ôl cwblhau'r Brentisiaeth yn llwyddiannus, byddwch yn gallu ymgymryd â rôl Technegydd Gweithgynhyrchu Gwyddoniaeth.

Bydd Technegydd Gweithgynhyrchu Gwyddoniaeth yn gweithredu'r systemau a'r offer sy'n gysylltiedig â chynhyrchu cynhyrchion. Gallent weithio mewn amodau amrywiol gan gynnwys gwisgo offer diogelwch arbenigol, gwaith sifft ac ar safleoedd sy'n gweithredu am 365 o ddiwrnodau. Mae llawer o gwmnïau'n gweithredu o dan amodau rheoledig iawn a rhoddir premiwm ar agweddau ac ymddygiad priodol i sicrhau bod cyflogeion yn cydymffurfio â gofynion diogelwch a rheoliadol y sefydliad.

Disgwylir i Dechnegwyr Gweithgynhyrchu Gwyddoniaeth weithio'n unigol ac fel rhan o dîm gweithgynhyrchu. Gallant weithio gyda chyn lleied o oruchwyliaeth â phosibl, gan gymryd cyfrifoldeb am ansawdd a chywirdeb y gwaith y maent yn ei gyflawni. Maent yn rhagweithiol wrth ddod o hyd i atebion i broblemau a nodi meysydd ar gyfer gwella eu hamgylchedd gwaith.<sup>1</sup>

<sup>1</sup>Trosolwg o Rôl Technegydd Gweithgynhyrchu Gwyddoniaeth

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