

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Maintenance and Calibration in Aseptic Pharmaceuticals

Unit Reference Number: Y/617/0958

Level: Three (3)

Credit Value: Three (3)

Minimum Guided Learning Hours: 20

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand the requirements for maintenance and calibration of facilities and equipment	1.1 Explain the types of: a) Maintenance b) Calibration
	1.2 Describe the requirements for maintenance and calibration of facilities and equipment in own workplace
2. Understand the procedures for handover of the processes for maintenance in Aseptic processing	2.1 Outline the handover procedures required to allow maintenance and calibration activities to begin
	2.2 Describe how to prepare a work area for maintenance
	2.3 Describe how to reinstate the working area following maintenance and/or calibration of equipment
	2.4 Explain the action to take if unable to reinstate the working area
	2.5 Assess the potential impact of not following the standard operating procedures
3. Understand responsibilities and limitations of own role relating to maintenance and calibration	3.1 Explain the responsibilities of own role
	3.2 Analyse the limitations of own role

Indicative Content

LO1	AC 1.1 Maintenance and calibration of equipment and plant CAPA, CC and EMER's.
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	AC1.2 Planned/unplanned different requirements by grade, cleaning, releasing for use by quality
LO2	AC 2.1 to include Permits to work, deviations, facility/equipment records/log AC 2.4 would include: <ul style="list-style-type: none">• CAPA• Reporting/Referral• Contingency• Outsourcing• Capacity plan

Uned Cymhwyster

Mae'r uned hon yn rhan o gymhwyster rheoleiddiedig.

Teitl yr Uned: Cynnal a Chadw a Graddnodi mewn Cynhyrchion Fferyllol Aseptig

Lefel: Three (3)

Gwerth Credyd: Tri (3)

GLH Lleiafswm: 20

Deilliant Dysgu (Bydd y Dysgwr yn):	Maen Prawf Asesu (Gall y Dysgwr):
1. Deall y gofynion ar gyfer cynnal a chadw a graddnodi cyfleusterau ac offer	1.1 Egluro'r mathau o: a) gynnal a chadw b) graddnodi
	1.2 Disgrifio'r gofynion ar gyfer cynnal a chadw a graddnodi cyfleusterau ac offer yn eich gweithle eich hun
2. Deall y gweithdrefnau ar gyfer trosglwyddo'r prosesau ar gyfer cynnal a chadw mewn Cynhyrchion Fferyllol Aseptig	2.1 Amlinellu'r gweithdrefnau trosglwyddo sydd eu hangen i ganiatáu i weithgareddau cynnal a chadw a graddnodi ddechrau
	2.2 Disgrifio sut i baratoi ardal waith ar gyfer cynnal a chadw
	2.3 Disgrifio sut i ailosod yr ardal waith yn dilyn gwaith cynnal a chadw a/neu raddnodi offer
	2.4 Egluro'r camau i'w cymryd os na allwch ailosod yr ardal waith
	2.5 Asesu effaith bosibl peidio â dilyn y gweithdrefnau gweithredu safonol ar:
3. Deall cyfrifoldebau a chyfyngiadau eich rôl eich hun mewn perthynas â chynnal a chadw a graddnodi	3.1 Egluro cyfrifoldebau eich rôl
	3.2 Dadansoddi cyfyngiadau eich rôl

LO1	<p>AC 1.1 Cynnal a chadw a graddnodi offer a pheiriannau CAPA, CC ac EMER\'.s.</p> <p>AC 1.2 Wedi'i gynllunio/heb ei gynllunio Gofynion gwahanol yn ôl gradd, glanhau, rhyddhau i'w defnyddio yn ôl ansawdd</p>
LO2	<p>AC 2.1 Dylai gynnwys trwyddedau i weithio, gwiriadau, cofnodion/log cyfleuster/offer</p> <p>AC2.4 Dylai gynnwys:</p> <ul style="list-style-type: none"> • CAPA • Adrodd/Cyfeirio • Trefniadau wrth gefn • Rhoi ar gontract allanol • Cynllun capasiti