

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Health, Safety and Reducing Risk in Aseptic Pharmaceuticals

Unit Reference Number: L/617/0956

Level: Three (3)

Credit Value: Four (4)

Minimum Guided Learning Hours: 24

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand and safety legislation in Aseptic processing	1.1 Summarise the requirements of Health and Safety legislation in relation to Aseptic processing
	1.2 Explain how the requirements of Health and Safety legislation relate to own role
	1.3 Explain the relevance of Control of Substances Hazardous to Health Regulations (COSHH)
2. Understand own roles and responsibilities in relation to Health and Safety	2.1 Assess the importance of good personal hygiene and use of personal protective clothing in own role
	2.2 Explain the importance of following manual handling procedures
	2.3 Explain first aid procedures relevant to own workplace
	2.4 Explain how own health can have an impact on the workplace and the associated risks
	2.5 Explain the Standard Operating Procedures to maintain safe working conditions in relation to own role
	2.6 For one process, assess the potential impact of not following the Standard Operation Procedure on: <ul style="list-style-type: none"> a) The product b) The patient c) Colleagues d) The organisation e) Self

3. Know how to reduce risk in the workplace	3.1	Explain methods of risk assessment used in own workplace
	3.2	Identify risks in own workplace
	3.3	Evaluate control measures to mitigate identified risk
	3.4	Explain the reporting requirements for risks associated with health in the workplace
	3.5	Explain the different types of contamination
	3.6	Summarise emergency response procedures
	3.7	Explain systems to prevent loss of containment

Indicative Content	
LO1	<p>AC 1.1 must include, as a minimum, Health and Safety at Work Act 1974 and Control of Substances Hazardous to Health Regulations (COSHH) Other legislation could include:</p> <ul style="list-style-type: none"> • Dangerous Substances and Explosive Atmospheres Regulations (DSEAR) • The Ionising Radiation Regulations 1999 (IRR) • Radiation Protection Principles • Transport of Dangerous Goods (2017 ADR) <p>AC1.2 should include but is not limited to:</p> <ul style="list-style-type: none"> • fire safety • working at height regulations • manual handling • Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) <p>In AC1.3 COSHH may apply to different types of radiation in radiopharmacy</p>
LO2	<p>AC2.1 For learners working in radiopharmacy, this will include any specialist PPE for operator protection Radiation Protection Guidelines Procedures for treating needlestick injuries should also be covered.</p>
LO3	<p>AC3.2 may include risks such as:</p> <ul style="list-style-type: none"> • cleaning / sterilisation of equipment and components • spillages • exposure to chemical and radioactive emissions • waste management and control · handling needle sticks and sharps • control of the aseptic environment • personnel practices and procedures • environmental monitoring • storage of stock • hazardous substances, for example different types of radiation • production of radiopharmaceuticals <p>AC 3.3 may include:</p> <ul style="list-style-type: none"> • failure mode and effects analysis (FMEA) • fault tree analysis • hazard analysis and critical control points (HACCP) • control measures applicable to the prevention and removal of radioactive contamination

In AC3.5 different types of contamination may include:

- chemical
- microbial
- particulate
- radiation

Uned Cymhwyster

Mae'r uned hon yn rhan o gymhwyster rheoleiddiedig.

Teitl yr Uned: Iechyd, Diogelwch a Lleihau Risg mewn Cynhyrchion Fferyllol Aseptig

Lefel: Three (3)

Gwerth Credyd: Pedwar (4)

GLH Lleiafswm: 24

Deilliant Dysgu (Bydd y Dysgwr yn):	Maen Prawf Asesu (Gall y Dysgwr):
1. Deall deddfwriaeth lechyd a Diogelwch mewn prosesu aseptig	1.1 Crynhoi gofynion deddfwriaeth lechyd a Diogelwch mewn perthynas â phrosesu aseptig
	1.2 Egluro sut mae gofynion deddfwriaeth lechyd a Diogelwch yn berthnasol i'ch rôl eich hun
	1.3 Egluro perthnasedd Rheoliadau Rheoli Sylweddau Peryglus i Iechyd (COSHH)
2. Deall eich rolau a'ch cyfrifoldebau eich hun mewn perthynas ag iechyd a diogelwch	2.1 Asesu pwysigrwydd hylendid personol da a defnyddio dillad diogelu personol yn eich rôl eich hun
	2.2 Egluro pwysigrwydd dilyn gweithdrefnau codi a chario
	2.3 Egluro gweithdrefnau cymorth cyntaf sy'n berthnasol i'ch gweithle
	2.4 Egluro sut y gall eich iechyd eich hun gael effaith ar y gweithle a'r risgiau cysylltiedig
	2.5 Egluro'r Gweithdrefnau Gweithredu Safonol i gynnal amodau gwaith diogel mewn perthynas â'ch rôl ei hun
	2.6 Ar gyfer un proses, asesu effaith bosibl peidio â dilyn y Gweithdrefnau Gweithredu Safonol ar: a) Y cynnyrch b) Y claf c) Cydweithwyr d) Y sefydliad e) Eich hun
3. Gwybod sut i leihau risg yn y gweithle	3.1 Egluro'r dulliau asesu risg a ddefnyddir yn eich gweithle

3.2	Adnabod risgiau yn eich gweithle
3.3	Gwerthuso mesurau rheoli i liniaru risg a nodir
3.4	Egluro'r gofynion adrodd ar gyfer risgiau sy'n gysylltiedig ag iechyd yn y gweithle
3.5	Egluro'r gwahanol fathau o halogiad
3.6	Crynhoi gweithdrefnau ymateb i argyfwng
3.7	Egluro systemau i atal colli ynysiad

Cynnwys Mynegol	
LO1	<p>AC 1.1</p> <p>Rhaid cynnwys, o leiaf, Ddeddf Iechyd a Diogelwch yn y Gwaith 1974 a Rheoliadau Rheoli Sylweddau Peryglus i Iechyd (COSHH). Gallai deddfwriaethau eraill gynnwys:</p> <ul style="list-style-type: none"> • Rheoliadau Sylweddau Peryglus ac Atmosfferau Ffrwydrol (DSEAR) • Rheoliadau Ymbelydredd Ïoneiddio 1999 (IRR) • Egwyddorion Diogelu rhag Ymbelydredd • Cludo Nwyddau Peryglus (2017 ADR) <p>AC 1.2</p> <p>Dylai gynnwys ond heb fod yn gyfyngedig i:</p> <ul style="list-style-type: none"> • ddiogelwch tân • rheoliadau gweithio ar uchder • codi a chario • Rheoliadau Adrodd am Anafiadau, Clefydau a Digwyddiadau Peryglus (RIDDOR) <p>AC 1.3</p> <p>Gall COSHH fod yn berthnasol i wahanol fathau o ymbelydredd mewn radiofferylliaeth</p>
LO2	<p>AC 2.1</p> <p>Ar gyfer dysgwyr sy'n gweithio ym maes radiofferylliaeth, bydd hyn yn cynnwys unrhyw PPE arbenigol ar gyfer amddiffyn gweithredwr Canllawiau Diogelu rhag Ymbelydredd Dylid hefyd gwmpasu gweithdrefnau ar gyfer trin anafiadau nodwyddau</p>
LO3	<p>AC 3.2</p> <p>Gall gynnwys risgiau megis:</p> <ul style="list-style-type: none"> • glanhau / sterileiddio offer a chydrannau • gollyngiadau • dod i gysylltiad ag allyriadau cemegol ac ymbelydrol • rheoli gwastraff • trin ffyn nodwydd ac offer miniog • rheoli'r amgylchedd aseptic • arferion a gweithdrefnau personél • monitro amgylcheddol • storio stoc • sylweddau peryglus, er enghraifft gwahanol fathau o ymbelydredd • cynhyrchu cynnyrch radiofferyllol <p>AC 3.3</p> <p>Gallai gynnwys:</p> <ul style="list-style-type: none"> • dadansoddiad modd ac effeithiau methu (FMEA) • dadansoddiad coeden bai • dadansoddi peryglon a manau rheoli critigol (HACCP)

- mesurau rheoli sy'n berthnasol i atal a chael gwared ar halogiad ymbelydrol

AC 3.5

Gall y gwahanol fathau o halogiad gynnwys:

- cemegol
- microbaidd
- gronynnol
- ymbelydredd