

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Aseptic Manufacture and Preparation Processes

Unit Reference Number: F/617/0954

Level: Three (3)

Credit Value: 12

Minimum Guided Learning Hours: 90

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand the principles of practice for Aseptic manufacture and preparation	1.1 Explain the difference between licensed manufacture and non-licensed preparation
	1.2 Identify the different types of products prepared within aseptic manufacture and preparation
	1.3 Outline the range of consumables relevant to Aseptic manufacture and preparation
	1.4 For either Aseptic manufacture or preparation, review: a) Process maps b) Risk Assessments
	1.5 Analyse the impact of not following correct procedures when manufacturing / preparing the product on: a) The patient b) Colleagues/other operators c) Self d) The product
	1.6 Explain the importance of product segregation
	1.7 Use formulae calculations to calculate given weights and measures
	1.8 Explain the importance of carrying out in process checks on calculations, weights and measures
	1.9 List other checks carried out

2. Understand the process of prescription verification for unlicensed Aseptic preparation	2.1 Summarise the process for prescription verification
	2.2 Assess the importance of prescription verification
3. Understand work area start-up checks	3.1 Assess the potential impact of the work area not being clean and organised
	3.2 Identify potential sources of contamination within the assembly area
	3.3 Summarise procedures for preventing contamination when starting up
	3.4 Describe the start-up checks of equipment
	3.5 Assess the potential consequences of not completing required start up checks
4. Understand the organisational transfer process	4.1 Describe own organisational transfer process, including: a) Starting material assembly b) Consumable assembly c) Transfer to support room d) Transfer to preparation room e) Transfer to work zone
	4.2 Explain the effect of different agents used in the transfer process
	4.3 Assess the impact of not following the transfer process correctly
5. Understand the importance of reconciliation of labels, materials and packaging in Aseptic Pharmaceuticals	5.1 Summarise the process for reconciliation
	5.2 Assess the effect of not following identified processes on: a) Product quality b) Patient c) Own organisation
6. Know how to dismantle, clean, decontaminate equipment and the work area correctly	6.1 Summarise the procedures for dismantling, cleaning and decontaminating equipment and the work area
	6.2 Assess the potential risk of not following procedures to: a) The patient b) The product c) Colleagues/other operators d) Self
7. Know how to dispose of waste and cleaning materials	7.1 Summarise procedures for the safe disposal of waste and cleaning materials
	7.2 Describe the risks related to the disposal of materials and cleaning materials

8. Understand the causes and consequences of deviations from standard operational procedures	8.1	Outline causes of deviations from recognised procedures
	8.2	Assess the potential impact of deviations on the: a) Patient b) Product c) Organisation
	8.3	Describe the limitations of own role and competency
	8.4	Understand deviations in the context of change Management
	8.5	Explain reasons for accurate completion of documentation
9. Understand problem solving techniques in Aseptic Pharmaceuticals	9.1	Describe typical problems which may arise during the processing of Aseptic Pharmaceuticals
	9.2	Evaluate problem solving techniques
	9.3	Explain circumstances when they would be expected to: a) Resolve issues b) Escalate problems

Indicative Content

LO1	<p>1.2 Types of products should include:</p> <ul style="list-style-type: none"> • Chemotherapy • Antibiotics • Parenteral Nutrition • Radio Pharmaceuticals • Clinical Trials • Consider clinical indication <p>1.3 Consumables should include:</p> <ul style="list-style-type: none"> • Filters • Pumps • Giving sets <p>1.8 other checks to include:</p> <ul style="list-style-type: none"> • transcription check for unlicensed preparation (prescription) • in-process checks – volumes, identity • final accuracy checks, • final release checks e.g. standard operating procedures have been followed, visual inspection, product complies with prescription, prepared by validated staff, ensuring all monitoring daily performed and aware of retrospective testing, all required checks are present and any deviation reported to authorising pharmacist.
LO2	<p>2.1 Examples of verification could include:</p> <ul style="list-style-type: none"> • Ensures prescriptions have been clinically verified • Prescribers constituents are compatible and the formulation is stable • Product is the correct presentation for the intended route for administration
LO3	<p>a) 3.1 equipment could include:</p> <ul style="list-style-type: none"> a) isolator b) laminar flow cabinet

	<p>c) compounder</p> <p>3.6 documentation could include:</p> <ul style="list-style-type: none"> a) worksheets b) labels c) equipment records – pressure differentials, air velocity, air change rate, glove/sleeve changes d) clean room records – pressure differentials e) cleaning records
LO4	<p>4.2 Examples of different agents may include:</p> <ul style="list-style-type: none"> • Sporocides • Alcohols • Vaporised Hydrogen Peroxide (VHP) • Sprays/wipes
LO5	<p>5.1 Reconciliation:</p> <ul style="list-style-type: none"> • Labels • Materials • Packaging <p>5.2 Include impact of having incorrectly labelled products</p>
LO6	<p>6.1 equipment could include:</p> <ul style="list-style-type: none"> a) Isolator b) laminar flow cabinet c) compounder d) pump
LO7	<p>7.1 Waste should include:</p> <ul style="list-style-type: none"> a) general waste b) clinical waste c) sharps d) drug
LO8	<p>For the learning outcome to be achieved learners should include both Aseptic Manufacture and preparation.</p>
LO9	<p>9.1 Problems could include:</p> <ul style="list-style-type: none"> a) microbiological contamination – environment / product b) operator injury c) breakdown of drug e.g. foaming d) filtration a) e) precipitation

Uned Cymhwyster

Mae'r uned hon yn rhan o gymhwyster rheoleiddiedig.

Teitl yr Uned: Prosesau Gweithgynhyrchu a Pharatoi Aseptig

Lefel: Three (3)

Gwerth Credyd: 12

GLH Lleiafswm: 90

Deilliant Dysgu (Bydd y Dysgwr yn):	Maen Prawf Asesu (Gall y Dysgwr):
1. Deall egwyddorion ymarfer ar gyfer gweithgynhyrchu a pharatoi aseptig	1.1 Egluro'r gwahaniaeth rhwng gweithgynhyrchu trwyddedig a pharatoi di-drwydded
	1.2 Nodi'r gwahanol fathau o gynhyrchion sy'n cael eu paratoi o fewn gweithgynhyrchu a pharatoi aseptig
	1.3 Amlinellu'r ystod o nwyddau traul sy'n berthnasol i weithgynhyrchu a pharatoi aseptig
	1.4 Ar gyfer gweithgynhyrchu neu baratoi aseptig, adolygu: a) Map y broses b) Aseidiadau risg
	1.5 Dadansoddi effaith peidio â dilyn y gweithdrefnau cywir wrth weithgynhyrchu/paratoi'r cynnyrch ar: a) Y claf b) Cydweithwyr / gweithredwyr eraill c) Eich hun d) Y cynnyrch
	1.6 Egluro pwysigrwydd gwahanu cynnyrch
	1.7 Defnyddio cyfrifiadau fformiwlâu i gyfrifo pwysau a mesurau penodol
	1.8 Egluro pwysigrwydd cynnal gwiriadau ar gyfrifiadau, pwysau a mesurau yn y broses
	1.9 Rhestru gwiriadau eraill a wneir
2. Deall y broses o ddilysu presgripsiwn ar gyfer paratoad aseptig didrwydded	2.1 Crynhoi'r broses ar gyfer dilysu presgripsiwn

	2.2	Asesu pwysigrwydd dilysu presgripsiwn
3. Deall gwiriadau cychwyn ardal waith	3.1	Asesu effaith bosibl y man gwaith ddim yn lân a threfnus
	3.2	Nodi ffynonellau halogi posibl yn yr ardal casglu ynghyd
	3.3	Crynhoi gweithdrefnau ar gyfer atal halogiad wrth gychwyn
	3.4	Disgrifio gwiriadau cychwyn offer
	3.5	Asesu canlyniadau posibl peidio â chwblhau'r gwiriadau cychwyn gofynnol
4. Deall y broses drosglwyddo sefydliadol	4.1	Disgrifio proses drosglwyddo eich sefydliad, gan gynnwys: <ul style="list-style-type: none"> a) Casglu ynghyd ddeunydd cychwyn b) Casglu ynghyd nwyddau traul c) Trosglwyddo i'r ystafell gefnogi d) Trosglwyddo i'r ystafell baratoi e) Trosglwyddo i'r parth gwaith
	4.2	Egluro effaith y gwahanol gyfryngau a ddefnyddir yn y broses drosglwyddo
	4.3	Asesu effaith peidio â dilyn y broses drosglwyddo yn gywir
5. Deall pwysigrwydd cysoni labeli, deunyddiau a phecynnu mewn Cynhyrchion Fferyllol Aseptig	5.1	Crynhoi'r broses ar gyfer cysoni
	5.2	Asesu effaith peidio â dilyn prosesau a nodwyd ar: <ul style="list-style-type: none"> a) Ansawdd y cynnyrch b) Glaf c) Eich sefydliad
6. Gwybod sut i ddatgymalu, glanhau, diheintio offer a'r ardal waith yn gywir	6.1	Crynhoi'r gweithdrefnau ar gyfer datgymalu, glanhau a diheintio offer a'r man gwaith
	6.2	Asesu'r risg bosibl o beidio â dilyn gweithdrefnau ar gyfer: <ul style="list-style-type: none"> a) Y claf b) Y cynnyrch c) Cydweithwyr / gweithredwyr eraill d) Eich hun
7. Gwybod sut i gael gwared ar wastraff a deunyddiau glanhau	7.1	Crynhoi gweithdrefnau ar gyfer gwaredu wastraff a deunyddiau glanhau yn ddiogel
	7.2	Disgrifio'r risgiau sy'n gysylltiedig â gwaredu deunyddiau a deunyddiau glanhau
8. Deall achosion a chanlyniadau gwyro o weithdrefnau gweithredu safonol	8.1	Amlinellu achosion a gwiriadau oddi wrth weithdrefnau cydnabyddedig

	8.2	Asesu effaith bosibl gwyradau ar: a) Glaf b) Y cynnyrch c) c) Sefydliad
	8.3	Disgrifio cyfyngiadau eich rôl a'ch cymhwysedd eich hun
	8.4	Deall gwyradau yng nghyd-destun rheoli newid
	8.5	Egluro'r rhesymau dros gwblhau dogfennaeth yn gywir
9.	Deall technegau datrys problemau mewn Cynhyrchion Fferyllol Aseptig	9.1 Disgrifio problemau nodweddiadol a all godi wrth brosesu Cynhyrchion Fferyllol Aseptig
	9.2	Gwerthuso technegau datrys problemau
	9.3	Egluro amgylchiadau pan fyddai disgwyl iddynt: a) Ddatrys materion b) b) Gwaethygu problemau

Cynnwys Mynegol	
LO1	<p>1.2 Dylai mathau o gynhyrchion gynnwys:</p> <ul style="list-style-type: none"> • Cemotherapi • Gwrthfotigau • Maeth Parenterol: • Cynnyrch Fferyllol Radio • Treialon clinigol • Ystyried Dynodiad Clinigol <p>1.3 Dylai nwyddau traul gynnwys:</p> <ul style="list-style-type: none"> • Hidlyddion • Pympiâu • Setiau Rhoddi <p>1.8 Gwiriadau eraill i gynnwys:</p> <ul style="list-style-type: none"> • Gwiriad trawsgrifio ar gyfer paratoad didrwydded (presgripsiwn) • Gwiriadau yn y broses – symiau, hunaniaeth • Gwiriadau cywirdeb terfynol • Gwiriadau rhyddhau terfynol e.e. - mae gweithdrefnau gweithredu safonol wedi'u dilyn, archwiliad gweledol, cynnyrch yn cydymffurfio â'r presgripsiwn, wedi'i baratoi gan staff dilys, sicrhau bod yr holl fonitro yn cael ei wneud yn ddyddiol ac yn ymwybodol o brofion ôl-weithredol, bod yr holl wiriadau gofynnol yn bresennol a bod unrhyw wiriad wedi'i adrodd wrth y fferylllydd awdurdodi
LO2	<p>2.1 Gallai enghreifftiau o ddilysu gynnwys:</p> <ul style="list-style-type: none"> • Sicrhau bod presgripsiynau wedi'u dilysu'n glinigol • Mae cyfansoddion y rhagnodwr yn gydnaws ac mae'r fformiwleiddiad yn sefydlog • Y cynnyrch yw'r un cywir ar gyfer y llwybr arfaethedig ar gyfer gweinyddu
LO3	<p>3.1 Gallai offer gynnwys:</p> <ul style="list-style-type: none"> a) Ynysydd b) Cabinet llif laminaidd c) Cymysgwr

	<p>3.6 Gallai dogfennaeth gynnwys:</p> <ol style="list-style-type: none"> Taflenni gwaith Labeli Cofnodion offer – gwahaniaethau pwysedd, cyflymder aer, cyfradd newidiadau aer, newidiadau maneg/llawes Cofnodion ystafell lân - gwahaniaethau mewn pwysedd Cofnodion glanhau
LO4	<p>4.2 Gall enghreifftiau o gyfryngau gwahanol gynnwys:</p> <ul style="list-style-type: none"> Sporosidau Alcoholau Perocsid Hydrogen Anweddol (VHP) Chwistrelliadau / cadachau
LO5	<p>5.1 Cysoni:</p> <ul style="list-style-type: none"> Labeli Deunyddiau Pecynnu <p>5.2 Cynnwys effaith bod cynhyrchion wedi'u labelu'n anghywir</p>
LO6	<p>6.1 Gallai offer gynnwys:</p> <ol style="list-style-type: none"> Ynysydd Cabinet llif laminaidd Cymysgwr d) Pwmp
LO7	<p>7.1 Dylai gwastraff gynnwys:</p> <ol style="list-style-type: none"> Gwastraff cyffredinol Gwastraff clinigol Eitemau miniog Cyffur
LO8	Er mwyn cyflawni'r deilliant dysgu dylai dysgwyr gynnwys Gweithgynhyrchu a Pharatoi Aseptig
LO9	<p>9.1 Gall problemau gynnwys:</p> <ol style="list-style-type: none"> Halogiad microbiolegol – amgylchedd / cynnyrch Anaf i'r gweithredwr Cyffur yn methu e.e. ewynnu Hidliad a) e) Dyddodiad