Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Legislation, Regulations and Standards in Aseptic Pharmaceuticals

Unit Reference Number: L/652/3060
Level: Three (3)

Credit Value: Six (6)

Minimum Guided Learning Hours: 36

Learning Outcome (The Learner will):		Assessment Criterion (The Learner can):	
1.	Understand legislation and regulations related to the manufacture of Aseptic Processing	1.1	Identify medicines legislation and regulations related to the manufacture of Aseptic Processing
		1.2	Summarise the Radiation Protection Legislation requirements within Radiopharmacy
		1.3	Summarise the regulatory frameworks under which medicines compounding or manufacture can take place
		1.4	Assess the impact of identified legislation and regulations on own role and on the manufacturing unit
		1.5	Identify the UK and international regulators for this legislation, and their role in maintaining safe manufacturing
2.	Understand standards related to the manufacture of Aseptic Pharmaceuticals	2.1	Identify standards applicable to the manufacture of Aseptic Pharmaceuticals
		2.2	Assess impact of these standards on own role and on the manufacturing unit
		2.3	Identify the organisations responsible for setting and monitoring adherence to these standards
		2.4	Explain the requirements for controlled drugs and why they have more secure storage requirements
3.	Understand guidance related to the manufacture of Aseptic Pharmaceuticals	3.1	Identify guidance applicable to the manufacture of Aseptic Pharmaceuticals

		3.2	Assess impact of this guidance on own role and on the manufacturing unit.
		3.3	Outline the organisations responsible for setting this guidance, including: a) How they are established b) How they undertake their role
4.	Know about Good Manufacturing Practice (GMP) in relation to Aseptic Processing	4.1	Summarise the principles of Good Manufacturing Practice (GMP) in relation to aseptic processing
		4.2	Describe organisational processes that support the implementation of Good Manufacturing Practice
5.	Know about Good Clinical Practice (GCP) in relation to Aseptic processing	5.1	Summarise the principles of Good Clinical Practice (GCP) in relation to aseptic processing
		5.2	Describe organisational processes that support the implementation of Good Clinical Practice
6.	Understand how own organisation responds to changes to regulations and legislation related to Aseptic processing	6.1	Summarise audit procedures for monitoring compliance with regulations and legislation
		6.2	Describe how own organisation implements changes to regulations and legislation
		6.3	Explain how to evaluate changes made to compliance relating to regulation and legislation

Indicative Content	
LO1	AC1.1 Medicines legislation and regulations must include at least:- • Human Medicines Regulations 2012 (regs in relation to manufacture, dispensing, wholesaling, distribution, and exemptions for pharmacies) • Veterinary Medicines Regulations 2013 (regs as for human medicines) • Medicines for Human Use (Clinical Trials) regulations 2004 • Advanced Therapy Medicinal Products Regulations 2007 • Medical Devices Regulations 2002 (and new EU regulation 2017) · Controlled Drugs (Supervision of management and use) Regulations 2013 • European source legislation to the above • The Misue of drugs act 1971 & The Misuse of drugs regulations 2001 AC1.2 Radiation protection legislation must include:- • The Ionising Radiation Regulations 1999(IRR) • Transport of Dangerous Goods (2017 ADR) AC1.3 Regulatory frameworks should include: • Manufacturing licenses • Supervision requirements and responsible person/delegated authority AC1.5 UK and international regulators should refer to the role & remit of:- • Medicines & Healthcare Products Regulatory Authority • General Pharmaceutical Council

	• Veterinary Medicines Directorate • European Medicines Agency • Care quality commission
LO2	AC2.1 Standards must include at least:- • Rules & Guidance for Pharmaceutical Manufacturers & Distributors • ISO 14644 Cleanrooms & Associated Controlled Environments • ISO 14698 Cleanrooms and associated controlled environments — Biocontamination control • ISO 13408 Aseptic Processing of Healthcare Products • Quality Assurance of Aseptic Preparation Services (NHS QA Committee / Royal Pharm Soc) AC2.3 Organisations must refer to the role & remit of:- • Medicines & Healthcare Products Regulatory Authority • Eudralex • EL97 Auditors (aka as regional QA auditors)
LO3	AC3.1 Guidance must include at least:- • NHS Pharmaceutical QA Committee “Yellow Cover” guidance documents • MHRA guidance on Specials (GN 14 and Q&As 2015) AC3.3 Organisations must refer to the role & remit of:- • Regional NHS QA Auditors • Medicines & Healthcare Products Regulatory Authority
LO4	AC 4.1 Knowledge qualification should introduce principles of GMP and own organisational processes. Learners should be made aware that in-depth in-house training may be required
LO5	AC 5.1 Knowledge qualification should introduce principles of GCP and own organisational processes. Learners should be made aware that in-depth in-house training may be required

Uned Cymhwyster

Mae'r uned hon yn rhan o gymhwyster rheoleiddiedig.

Teitl yr Uned: Deddfwriaeth, Rheoliadau a Safonau mewn Cynhyrchion Fferyllol Aseptig

Lefel: Three (3)

Gwerth Credyd: Chwech (6)

GLH Lleiafswm: 36

Deilliant Dysgu (Bydd y Dysgwr yn):	Maen Prawf Asesu (Gall y Dysgwr):
1. Deall deddfwriaeth a rheoliadau sy'n ymwneud â gweithgynhyrchu cynhyrchion fferyllol aseptig	1.1 Nodi deddfwriaeth a rheoliadau meddyginiaethau sy'n ymwneud â gweithgynhyrchu prosesu aseptig
	1.2 Crynhoi gofynion deddfwriaeth amddiffyn rhag ymbelydredd o fewn radiofferylliaeth
	1.3 Crynhoi'r fframweithiau rheoleiddio y gall cymysgu neu weithgynhyrchu meddyginiaethau ddigwydd oddi tanynt
	1.4 Asesu effaith deddfwriaeth a rheoliadau a nodwyd ar eich rôl eich hun ac ar yr uned gweithgynhyrchu
	1.5 Nodi rheoleiddwyr yn y DU ac yn rhyngwladol ar gyfer y ddeddfwriaeth hon, a'u rôl wrth weithgynhyrchu'n ddiogel
2. Deall safonau sy'n ymwneud â gweithgynhyrchu cynhyrchion fferyllol aseptig	2.1 Nodi safonau sy'n berthnasol i weithgynhyrchu cynhyrchion fferyllol aseptig
	2.2 Asesu effaith y safonau hyn ar eich rôl eich hun ac ar yr uned weithgynhyrchu
	2.3 Nodi'r sefydliadau sy'n gyfrifol am osod a monitro cydymffurfiaeth â'r safonau hyn
	2.4 Egluro'r gofynion ar gyfer cyffuriau rheoledig a pham fod ganddyn nhw ofynion storio mwy diogel
3. Deall canllaw sy'n ymwneud â gweithgynhyrchu cynhyrchion fferyllol aseptig	3.1 Nodi canllaw sy'n berthnasol i weithgynhyrchu cynhyrchion fferyllol aseptig
	3.2 Asesu effaith y canllaw hwn ar eich rôl eich hun ac ar yr uned weithgynhyrchu

		3.3	Amlinellu'r sefydliadau sy'n gyfrifol am osod y canllaw hwn, gan gynnwys: a) Sut maent wedi'u sefydlu b) Sut maent yn cyflawni eu rôl
4.	Gwybod am Arfer Gweithgynhyrchu Da (GMP) mewn perthynas â phrosesu aseptig	4.1	Crynhoi egwyddorion Arfer Gweithgynhyrchu Da (GMP) mewn perthynas â phrosesu aseptig
		4.2	Disgrifio prosesau sefydliadol sy'n cefnogi gweithrediad Arfer Gweithgynhyrchu Da
5.	Gwybod am Arfer Clinigol Da (GCP) mewn perthynas â phrosesu aseptig	5.1	Crynhoi egwyddorion Arfer Clinigol Da (GCP) mewn perthynas â phrosesu aseptig
		5.2	Disgrifio prosesau sefydliadol sy'n cefnogi gweithrediad Arfer Clinigol Da
6.	Deall sut mae eich sefydliad eich hun yn ymateb i newidiadau i reoliadau a deddfwriaeth sy'n ymwneud â chynhyrchion fferyllol aseptig	6.1	Crynhoi gweithdrefnau archwilio ar gyfer monitro cydymffurfiaeth â rheoliadau a deddfwriaeth
		6.2	Disgrifio sut mae eich sefydliad eich hun yn gweithredu newidiadau i reoliadau a deddfwriaeth
		6.3	Egluro sut i werthuso newidiadau a wnaed i gydymffurfiaeth yn ymwneud â rheoliadau a deddfwriaeth

Cynnwys Mynegol	
LO1	AC 1.1 Rhaid i ddeddfwriaeth a rheoliadau meddyginiaethau gynnwys o leiaf: • Rheoliadau Meddyginiaethau Dynol 2012 (rheoliadau mewn perthynas â gweithgynhyrchu, gweinyddu, cyfanwerthu, dosbarthu, ac eithriadau ar gyfer fferyllfeydd) • Rheoliadau Meddyginiaethau Milfeddygol 2013 (rheoliadau fel ar gyfer meddyginiaethau dynol) • Rheoliadau Meddyginiaethau i'w Defnyddio gan Bobl (Treialon Clinigol) 2004 • Rheoliadau Cynhyrchion Meddyginiaethol Therapi Uwch 2007 • Rheoliadau Dyfeisiau Meddygol 2002 (a rheoliad newydd yr UE 2017) • Rheoliadau Cyffuriau a Reolir (Goruchwylio Rheolaeth a Defnydd) 2013 • Deddfwriaeth ffynhonnell Ewropeaidd i'r uchod • Deddf Camddefnyddio Cyffuriau 1971 a Rheoliadau Camddefnyddio Cyffuriau 2001 AC 1.2 Rhaid i ddeddfwriaeth amddiffyn rhag ymbelydredd gynnwys:- • Rheoliadau Ymbelydredd Ïoneiddio 1999 (IRR) • Cludo Nwyddau Peryglus (2017 ADR) AC 1.3 Dylai fframweithiau rheoleiddiol gynnwys: • Trwyddedau gweithgynhyrchu • Gofynion goruchwylio a pherson cyfrifol/awdurdod dirprwyedig AC 1.5 Dylai rheoleiddwyr y DU a rhyngwladol gyfeirio at rôl a chylch gwaith:- • Awdurdod Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd • Y Cyngor Fferyllol Cyffredinol

	• Cyfarwyddiaeth Meddyginiaethau Milfeddygol • Asiantaeth Meddyginiaethau Ewropeaidd • Comisiwn ansawdd gofal
LO2	AC 2.1 Rhaid i safonau gynnwys o leiaf:- • Rheolau a Chanllawiau ar gyfer Dosbarthwyr a Gwneuthurwyr Fferyllol • ISO 14644 Ystafelloedd Glân ac Amgylcheddau a Reolir Cysylltiedig • ISO 14698 Ystafelloedd glân ac amgylcheddau a reolir cysylltiedig - Rheoli biohalogiad • ISO 13408 Prosesu Aseptig o Gynhyrchion Gofal Iechyd • Sicrwydd Ansawdd Gwasanaethau Paratoi Aseptig (Pwyllgor Sicrhau Ansawdd y GIG / Royal Pharm Soc) AC 2.3 Rhaid i sefydliadau gyfeirio at rôl a chylch gwaith:- • Awdurdod Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd • Eudralex • Archwilwyr EL97 (hynny yw fel archwilwyr rhanbarthol sicrwydd ansawdd)
LO3	AC 3.1 Rhaid i ganllawiau gynnwys o leiaf:- • Dogfennau canllaw “Yellow Cover Pwyllgor Sicrhau Ansawdd Fferyllol y GIG • Canllaw MHRA ae Gynhyrchion Arbenig (GN 14 a Q&As 2015) AC 3.3 Rhaid i sefydliadau gyfeirio at rôl a chylch gwaith:- • Archwilwyr Sicrhau Ansawdd GIG Rhanbarthol • Awdurdod Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd
LO4	AC 4.1 Dylai cymhwyster gwybodaeth gyflwyno egwyddorion GMP a’ch prosesau sefydliadol eich hun. Dylid gwneud dysgwyr yn ymwybodol y gall fod angen hyfforddiant mewnol manwl
LO5	AC 5.1 Dylai cymhwyster gwybodaeth gyflwyno egwyddorion GCP a’ch prosesau sefydliadol eich hun. Dylid gwneud dysgwyr yn ymwybodol y gall fod angen hyfforddiant mewnol manwl