

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Legislation, Regulations and Standards in Aseptic Pharmaceuticals

Unit Reference Number: R/617/0957

Level: Three (3)

Credit Value: Six (6)

Minimum Guided Learning Hours: 36

| Learning Outcome (The Learner will): | Assessment Criterion (The Learner can): |
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| 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 |
| 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. |

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| | 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

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| LO1 | <p>AC1.1 Medicines legislation and regulations must include at least:-</p> <ul style="list-style-type: none"> • 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 <p>AC1.2 Radiation protection legislation must include:-</p> <ul style="list-style-type: none"> • The Ionising Radiation Regulations 1999(IRR) • Transport of Dangerous Goods (2017 ADR) <p>AC1.3 Regulatory frameworks should include:</p> <ul style="list-style-type: none"> • Manufacturing licenses <p>AC1.5 UK and international regulators should refer to the role & remit of:-</p> <ul style="list-style-type: none"> • Medicines & Healthcare Products Regulatory Authority • General Pharmaceutical Council • Veterinary Medicines Directorate |
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| | <ul style="list-style-type: none"> • European Medicines Agency |
| LO2 | <p>AC2.1 Standards must include at least:-</p> <ul style="list-style-type: none"> • 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) <p>AC2.3 Organisations must refer to the role & remit of:-</p> <ul style="list-style-type: none"> • Medicines & Healthcare Products Regulatory Authority • Eudralex • EL97 Auditors |
| LO3 | <p>AC3.1 Guidance must include at least:-</p> <ul style="list-style-type: none"> • NHS Pharmaceutical QA Committee “Yellow Cover” guidance documents • MHRA guidance on Specials (GN 14 and Q&As 2015) <p>AC3.3 Organisations must refer to the role & remit of:-</p> <ul style="list-style-type: none"> • Regional NHS QA Auditors • Medicines & Healthcare Products Regulatory Authority |
| LO4 | <p>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</p> |
| LO5 | <p>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</p> |

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): |
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| 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 deddfwriaeth 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 |
| 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 |

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| | 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

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| LO1 | <p>AC 1.1</p> <p>Rhaid i deddfwriaeth a rheoliadau meddyginiaethau gynnwys o leiaf:</p> <ul style="list-style-type: none"> • 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 <p>AC 1.2</p> <p>Rhaid i deddfwriaeth amddiffyn rhag ymbelydredd gynnwys:-</p> <ul style="list-style-type: none"> • Rheoliadau Ymbelydredd Ioneiddio 1999 (IRR) • Cludo Nwyddau Peryglus (2017 ADR) <p>AC 1.3</p> <p>Dylai fframweithiau rheoleiddiol gynnwys:</p> <ul style="list-style-type: none"> • Trwyddedau gweithgynhyrchu <p>AC 1.5</p> <p>Dylai rheoleiddwyr y DU a rhyngwladol gyfeirio at rôl a chylch gwaith:-</p> <ul style="list-style-type: none"> • Awdurdod Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd • Y Cyngor Fferyllol Cyffredinol • Cyfarwyddiaeth Meddyginiaethau Milfeddygol • Asiantaeth Meddyginiaethau Ewropeaidd |
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| LO2 | <p>AC 2.1</p> <p>Rhaid i safonau gynnwys o leiaf:-</p> <ul style="list-style-type: none"> • 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) <p>AC 2.3</p> <p>Rhaid i sefydliadau gyfeirio at rôl a chylch gwaith:-</p> <ul style="list-style-type: none"> • Awdurdod Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd • Eudralex • Archwilwyr EL97 |
| LO3 | <p>AC 3.1</p> <p>Rhaid i ganllawiau gynnwys o leiaf:-</p> <ul style="list-style-type: none"> • Dogfennau canllaw "Yellow Cover Pwyllgor Sicrhau Ansawdd Fferyllol y GIG • Canllaw MHRA ae Gynhyrchion Arbenig (GN 14 a Q&As 2015) <p>AC 3.3</p> <p>Rhaid i sefydliadau gyfeirio at rôl a chylch gwaith:-</p> <ul style="list-style-type: none"> • Archwilwyr Sicrhau Ansawdd GIG Rhanbarthol • Awdurdod Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd |
| LO4 | <p>AC 4.1</p> <p>Dylai cymhwyster gwybodaeth gyflwyno egwyddorion GMP a'ch prosesau sefydliadol eich hun. Dylid gwneud dysgwyr yn ymwybodol y gall fod angen hyfforddiant mewnol manwl</p> |
| LO5 | <p>AC 5.1</p> <p>Dylai cymhwyster gwybodaeth gyflwyno egwyddorion GCP a'ch prosesau sefydliadol eich hun. Dylid gwneud dysgwyr yn ymwybodol y gall fod angen hyfforddiant mewnol manwl</p> |