Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Quality Management in Aseptic Pharmaceuticals

Unit Reference Number: D/617/0959

Level: Three (3)

Credit Value: Six (6)

Minimum Guided Learning Hours: 45

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand Quality Management in Aseptic processing	1.1 Explain principles of a Pharmaceutical Quality System
	1.2 Explain how Quality Risk Management applies to Aseptic processing
	1.3 Explain the components of a Risk Management system
	1.4 Explain the role of Quality Assurance at each stage of the aseptic process
	1.5 Summarise the principles of continuous improvement within Aseptic services
	1.6 Explain how principles of continuous improvement are put into practice in own organisation
2. Understand how to maintain product quality through the Pharmaceutical Quality System	2.1 Explain the purpose and practice of validation
	2.2 Outline how to carry out a validation study
	2.3 Assess the role of Standard Operating Procedures (SOPs) and production documentation in maintaining product quality
	2.4 Explain the requirements for internal and external audits & inspections
	2.5 Explain the circumstances when investigations would be carried out
	2.6 Outline the techniques used to carry out Root-Cause Analysis (RCA)

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		2.7	Explain requirements for the Product Release Process
		2.8	Explain own role in maintaining product quality
3.	Understand Change Management	3.1	Summarise Change Management principles
		3.2	Evaluate the impact of change on product quality
4.	Understand the impact of errors and/or deviations in Aseptic processing	4.1	Explain errors and/or deviations which may occur
		4.2	Explain the role of Pharmacovigilance in protecting patient safety
		4.3	Summarise procedures for error and/or deviation reporting
		4.4	Explain the place of Trend Analysis in error reduction
		4.5	Assess the potential impact of errors and/or deviations
		4.6	Summarise techniques used to correct deviations and reduce risk of errors
5.	Understand Quality Control (QC) in the context of Quality Assurance	5.1	Identify methods for Quality Control testing of starting materials and finished products
		5.2	Assess the limits of Quality Control testing in the context of Aseptic compounding

Indicative Content	
LO1	AC1. Pharmaceutical Quality System should refer to: • EU GMP Guide (in Rules & Guidance for Pharmaceutical Manufacturers & Distributors) • ICH Q10 Guidance on Pharmaceutical Quality System • RPS Quality Assurance of Aseptic Preparation Services AC1.2 Quality Risk Management Should refer to: • CH Q9 Quality Risk Management
LO2	AC 2.1 Validation should refer to: • process • operator • computerised systems • facility qualification – and local examples AC2.3 Audits and inspections include: • MHRA inspections • Regional QA audits • Reporting methods

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	• Action planning AC2.6 Products include; • Specials • IMPs • Aseptically dispensed items
LO4	AC4.2 pharmacovigilance to include: • National error reporting/near misses • Local processes
LO5	AC5.1 Quality control testing should include: • TLC • HPLC • UV spec • IR spec • Refractometry • Sterility testing • Endotoxin testing • Radiation calibrators

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Uned Cymhwyster

Mae'r uned hon yn rhan o gymhwyster rheoleiddiedig.

Teitl yr Uned: Rheoli Ansawdd mewn Cynhyrchion Fferyllol Aseptig

Lefel: Three (3)

Gwerth Credyd: Chwech (6)

GLH Lleiafswm: 45

Deilliant Dysgu (Bydd y Dysgwr yn):	Maen Prawf Asesu (Gall y Dysgwr):	
1. Deall Rheoli Ansawdd mewn prosesu aseptig	1.1	Egluro egwyddorion System Ansawdd Fferyllol
	1.2	Egluro sut mae Rheoli Risg Ansawdd yn berthnasol i brosesu aseptig
	1.3	Egluro cydrannau system rheoli risg
	1.4	Egluro rôl sicrhau ansawdd ym mhob cam o'r broses aseptig
	1.5	Crynhoi egwyddorion gwelliant parhaus o fewn gwasanaethau aseptig
	1.6	Egluro sut mae egwyddorion gwelliant parhaus yn cael eu rhoi ar waith yn eich sefydliad
2. Deall sut i gynnal ansawdd cynnyrch trwy'r System Ansawdd Fferyllol	2.1	Egluro diben ac arfer dilysu
	2.2	Amlinellu sut i gynnal astudiaeth ddilysu
	2.3	Asesu rôl Gweithdrefnau Gweithredu Safonol (SOPs) a dogfennaeth gynhyrchu mewn cynnal ansawdd y cynnyrch
	2.4	Egluro'r gofynion ar gyfer archwiliadau mewnol ac allanol
	2.5	Egluro'r amgylchiadau pan fyddai ymchwiliadau'n cael eu cynnal
	2.6	Amlinellu'r technegau a ddefnyddir i wneud Dadansoddiad o Wraidd y Broblem (RCA)
	2.7	Egluro gofynion ar gyfer y broses rhyddhau cynnyrch
	2.8	Egluro eich rôl eich hun wrth gynnal ansawdd cynnyrch

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3.	Deall Rheoli Newid	3.1	Crynhoi egwyddorion Rheoli Newid
		3.2	Gwerthuso effaith newid ar ansawdd cynnyrch
4.	Deall effaith gwallau a/neu wyriadau mewn prosesu Aseptig	4.1	Egluro gwallau a/neu wyriadau a all ddigwydd
		4.2	Egluro rôl Gwyliadwriaeth Fferyllol mewn amddiffyn diogelwch cleifion
		4.3	Crynhoi gweithdrefnau ar gyfer adrodd am wall a/neu wyriad
		4.4	Egluro lle dadansoddiad tueddiadau mewn lleihau gwallau
		4.5	Asesu effaith bosibl gwallau a/neu wyriadau
		4.6	Crynhoi'r technegau a ddefnyddir i gywiro gwyriadau a lleihau'r risg o wallau
5.	Deall Rheoli Ansawdd (QC) yng nghyd-destun Sicrhau Ansawdd	5.1	Nodi dulliau ar gyfer profi rheolaeth ansawdd ar ddeunyddiau cychwynnol a chynhyrchion gorffenedig
		5.2	Asesu terfynau profion QC yng nghyd-destun cyfuno Aseptig

Cynnwys Mynegol	
LO1	AC 1.1 Dylai System Ansawdd Fferyllol gyfeirio at: • Ganllaw GMP yr UE (mewn Rheolau a Chanllawiau ar gyfer Dosbarthwyr a Gwneuthurwyr Fferyllol • ICH C10 Canllaw ar System Ansawdd Fferyllol • Sicrwydd Ansawdd ar gyfer Paratoi Gwasanaethau Aseptig RPS AC 1.2 Dylai Rheoli Risg Ansawdd gyfeirio at: • CH Q9 Rheoli Risg Ansawdd
LO2	AC 2.1 Dylai dilysu gyfeirio at: • broses • gweithredwr • systemau cyfrifiadurol • cymhwyster cyfleuster – ac enghreifftiau lleol AC 2.3 Mae archwiliadau ac arolygiadau yn cynnwys: • Archwiliadau gan MHRA • Archwiliadau sicrhau ansawddrhanbarthol • dulliau adrodd • cynllunio gweithredu AC 2.6 Mae cynhyrchion yn cynnwys: • Cynhyrchion arbennig • IMPs

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	• eitemau a ddosberthir yn aseptig
LO4	AC 4.2 Gwyliadwriaeth fferyllol i gynnwys: • adrodd cenedlaethol ar wallau/achosion y bu ond y dim iddynt ddigwydd • prosesau lleol
LO5	AC 5.1 Dylai profion rheoli ansawdd gynnwys: • TLC • HPLC • Manylion UV • Manylion IR • reffractometreg • profi ddiheintrwydd • profi endotocsin • graddnodwyr ymbelydredd

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