Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Documentation in Aseptic Processing

Unit Reference Number: H/617/0963

Level: Three (3)

Credit Value: Three (3)

Minimum Guided Learning Hours: 22

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand document management in Aseptic Processing	1.1 Summarise legal requirements and organisational policies and procedures relating to document management
	1.2 Summarise sources of documentation
	1.3 Explain restrictions on access to documentation
	1.4 Explain the need for document control systems
2. Understand documentation used in Aseptic Processing	2.1 Summarise the different types of documentation used in Aseptic Processing
	2.2 Explain the purpose of each type of documents used
	2.3 Explain good documentation practice
	2.4 Explain why approved documentation should be used
3. Understand how to produce and use Aseptic Processing documentation	3.1 Explain the documentation used in planning and scheduling
	3.2 Explain how to produce documentation used in Aseptic Processing
	3.3 Summarise what should be included on documentation used
	3.4 Analyse methods of interpreting documentation

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Indicative Content	
LO1	AC1.1 will include information governance, access, retrieval, storage and handover of documentation.
LO2	AC 2.1 should include logs, labels, worksheets, standard operating procedures, permits AC2.3 Good documentation practice will include: • Approved documentation • Correction procedures (error reporting, CAPA, deviations) • Version control • Archiving
LO3	AC 3.1 and AC 3.3 should include: • Order receipt and logging • label generation and worksheets • start-up approvals

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Uned Cymhwyster

Mae'r uned hon yn rhan o gymhwyster rheoleiddiedig.

Teitl yr Uned: Dogfennaeth mewn Prosesu Aseptig

Lefel: Three (3)

Gwerth Credyd: Three (3)

GLH Lleiafswm: 22

Deilliant Dysgu (Bydd y Dysgwr yn):	Maen Prawf Asesu (Gall y Dysgwr):
1. Deall rheoli dogfennau mewn prosesu aseptig	1.1 Crynhoi gofynion cyfreithiol a pholisïau a gweithdrefnau sefydliadol yn ymwneud â rheoli dogfen
	1.2 Crynhoi ffynonellau dogfennaeth
	1.3 Egluro cyfyngiadau ar fynediad at ddogfennau
	1.4 Egluro'r angen am system rheoli dogfennau
2. Deall dogfennaeth a ddefnyddir mewn prosesu aseptig	2.1 Crynhoi'r gwahanol fathau o ddogfennaeth a ddefnyddir mewn prosesu aseptig
	2.2 Egluro pwrpas pob math o ddogfennau a ddefnyddir
	2.3 Egluro arfer da o ran dogfennaeth
	2.4 Egluro pam y dylid defnyddio dogfennau cymeradwy
3. Deall sut i gynhyrchu a defnyddio dogfennaeth prosesu aseptig	3.1 Egluro'r ddogfennaeth a ddefnyddir wrth gynllunio ac amserlennu
	3.2 Esbonio sut i gynhyrchu dogfennaeth a ddefnyddir mewn prosesu aseptig
	3.3 Crynhoi'r hyn y dylid ei gynnwys ar ddogfennaeth a ddefnyddir
	3.4 Dadansoddi dulliau o ddehongli dogfennaeth

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Cynnwys Mynegol	
LO1	AC1.1 I gynnwys rheoli gwybodaeth, cyrchu, adalw, storio a throsglwyddo dogfennaeth
LO2	AC2.1 Dylai gynnwys logiau, labeli, taflenni gwaith, gweithdrefnau gweithredu safonol, trwyddedau AC2.3 Bydd arfer da o ran dogfennaeth yn cynnwys: • Dogfennaeth wedi'i chymeradwyo • Gweithdrefnau cywiro (adrodd ar wallau, CAPA, gwyriadau) • Rheoli fersiwn • Archifo
LO3	AC 3.1, 3.3 Dylai'r ddau gynnwys: • derbynneb archebu a logio • cynhyrchu label a taflenni gwaith • cymeradwyaeth cychwyn

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