Changing lives through learning

Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: In Process Operations in Pharmaceutical Technical Services

Unit Reference Number: D/650/7514

Level: Two (2)

Credit Value: Five (5)

Minimum Guided Learning Hours: 40

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Be able to prepare the working area prior to manufacture	1.1 Explain the **importance** of maintaining a clean working environment
	1.2 Explain the importance of **personal hygiene** and use of protective equipment
	1.3 Demonstrate gowning appropriately for the working environment
	1.4 **Disinfect and transfer** products, equipment and consumables into the controlled area
	1.5 Complete any necessary **documentation** in the operation process
	1.6 Demonstrate working within limitations of own role including referring to **an appropriate member of staff**
2. Be able to identify to preparation and processing techniques	2.1 Explain the different preparation/ manufacturing methods relevant to own role
	2.2 Identify **different products** that might be manufactured
	2.3 Carry out product, equipment and consumable checks to ensure items are present and fit for purpose
	2.4 Prepare products in line with standard operating procedures
	2.5 Complete **visual checks** on own work during the preparation process

	2.6	Explain the importance of in-process checks
	2.7	Label prepared product and complete documentation in line with standard operating procedures
	2.8	Forward prepared products for final checking and product release

Indicative Content	
LO1	AC 1.1 should include: Contamination Control and Line Clearance AC 1.2 should include: PPE; Handwashing; Validations; Dress Code AC 1.4 should include: Spray and Wipe Technique; Gassing; Other transfer techniques AC 1.5 should include: Worksheets; Reconciliation; Equipment checks AC 1.6 **appropriate member of the team** could include: Pharmacist; Pharmacy Technician; Quality Assurance officer; Science Manufacturing Technician
LO2	AC 2.2 and 2.4 could include: Chemotherapy; PN; MABs; CIVAS; Clinical Trials; Sterile; Non-sterile; Clinical Trials; Radiopharmaceuticals; Broth/Validations. AC 2.3 could include referring when out of specification. **Visual Checks** (Ac 2.5 – 2.8) should include: volume; Visual product check (particles, precipitation, discolouration, leaks); reconciliation checks; isolating with Quality Assurance Officer for sampling; cold-chain maintenance; light protection; product approver checks; responsible person for release.