Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Start-Up Operations in Pharmaceutical Technical Services

Unit Reference Number: A/650/7513

Level: Two (2)

Credit Value: Five (5)

Minimum Guided Learning Hours: 40

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Know the principles and legislation regarding manufacturing in Pharmaceutical Technical Services	1.1 Summarise **key legislation and guidance** regarding manufacturing in Pharmaceutical Technical Services
	1.2 Outline the difference between **licenced and unlicenced preparation**
	1.3 Explain how different **types of sterile and non-sterile equipment and consumables** are used to prepare the pharmaceutical product
	1.4 Describe **chemical and physical properties** of raw materials relevant to preparation of products
	1.5 Identify different forms of contamination in relation to a Technical services environment
2. Be able to complete start-up procedures - product set-up	2.1 Produce worksheets and labels in accordance with legislation, guidelines and **Standard Operating Procedures (SOPs)**
	2.2 Explain the **importance** of using quality assured (QA) approved documentation
	2.3 Explain the principles and importance of pharmaceutical calculations, weights and measures
	2.4 Demonstrate completing pharmaceutical calculations relevant to Technical services
	2.5 Assemble components for the preparation of products

	2.6	Carry out self-checking in line with **Standard Operating Procedures (SOPs)**
	27	Identify and resolve any near-misses or errors
3. Carry out start-up procedures – sterilisation and decontamination	3.1	Explain the **importance** of maintaining a clean and tidy working environment during the start-up process
	3.2	Describe the **importance** of personal hygiene and use of protective equipment
	3.3	Identify the **procedures** for preparing, cleaning and decontaminating work areas before use
	3.4	Demonstrate gowning appropriately for the working environment
	3.5	Disinfect and transfer **products, equipment and consumables**
	3.6	Complete **documentation** related to the start-up process
	3.7	Refer any issues outside limitations of job role to the **appropriate team member**

Indicative Content	
LO1	AC 1.1 should be assessed holistically with the criteria in unit 1 (Roles, Responsibilities and Professional Development in Pharmaceutical Technical Services). It could include: Standard Operating Procedures (SOP's); COSHH; GPhC Standards; Good Manufacturing Practices (GMP); Good Clinical Practice (GCP); The Medicines Act 1968; Good Distribution Practice (GDP); Rules and Guidance for Pharmaceutical Manufacturers and Distributors (The Orange Guide); Human Medicines Regulation 2012; Quality Assurance of Aseptic Preparation Services (QAAPS) AC 1.2 should include: Quality Assurance of Aseptic Preparation Services (QAAPS); Rules and Guidance for Pharmaceutical Manufacturers and Distributors (The Orange Guide); Differing roles and responsibilities AC 1.3 **Different types of sterile** should include: Filters; Needles; Pumps; Syringes; Caps; Infusions; Dispensing pins (Vented/Non-Vented); Other **Non-sterile** should include: peristaltic pumps, vessels, scales, measuring equipment, spatula. AC 1.4 should include: Components, excipients; solvents; diluents; vehicles; packaging. AC 1.5 should include: Microbial; Particulate; Chemical; Radiation
LO2	AC 2.2 should include: version control; accuracy checked; validation AC 24 **Calculations** can be completed in context of completing a manufacturing process, or simulated in a classroom setting. This could include, for example raw material quantity and production calculations.
LO3	AC 3.1 should include: Bench and area checking logs; cleaning documentation; line

	clearance; other AC 3.2 should include: PPE; Handwashing; Validations; Dress Code AC 3.3 should include: standard operating procedures; Good Manufacturing Practices; Quality Assurance of Aseptic Preparation Services (QAAPS) AC 3.5 should include: Spray and Wipe techniques; Validations; Hydrogen peroxide gassing; Other transfer techniques AC 3.6 **Documentation** should include: Worksheets; reconciliation; environmental monitoring; calibrations AC 3.7 **Appropriate team members** could include: pharmacist; pharmacy technician; Quality Assurance Officer; other team member