Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Principles of Safe Manufacture of Quality Medicines in the Pharmaceutical Environment

Unit Reference Number: Y/617/8946

Level: Three (3)

Credit Value: 10

Minimum Guided Learning Hours: 70

Learning Outcome (The Learner will):		Assessment Criterion (The Learner can):
1. Understand the governance requirements for the manufacture of pharmaceutical products	1.1	Explain why pharmaceutical preparation and manufacture is highly controlled by **legislation and standards**
	1.2	Explain how legislation governs the manufacture and supply of **clinical trial** materials
	1.3	Outline the roles and responsibilities of **key personnel** in pharmaceutical preparation and manufacture
	1.4	Explain why it is important to have a robust recording system in pharmacy preparation and manufacturing
	1.5	Explain the difference between **preparation and manufacture**
	1.6	Describe the use of **documentation** in the preparation and manufacture of medicines
2. Understand the importance of maintaining environments for pharmaceutical manufacture in relation to **Good Manufacturing Practice (GMP)**	2.1	Explain why **different environments** are used for pharmaceutical manufacturing
	2.2	Explain the importance of **hygiene** in pharmaceutical manufacture
	2.3	Explain the importance of the following in the manufacture of pharmaceutical products: a) Process design b) Workflow
	2.4	Discuss the different **sources of contamination** which could be present in a manufacturing environment

	2.5	Explain the **potential consequences** of different sources of contamination within pharmaceutical manufacturing
	2.6	Describe the importance of **planned preventative maintenance** in pharmaceutical manufacturing
	2.7	Describe the procedures for **preparing the environment** for the manufacture of medicines
	2.8	Explain the difference between sterile, non-sterile and aseptic techniques in the manufacturing of pharmaceutical products
3. Understand how medicines are manufactured	3.1	Describe the different **types of pharmaceutical products**
	3.2	Describe different **pharmaceutical manufacturing techniques**
	3.3	Explain the use of different **equipment** in the manufacturing environment
	3.4	Outline the governance in relation to the principles of **labelling and packaging**
	3.5	Explain the importance of correctly **labelling and packaging** pharmaceutical products
	3.6	Describe the different methods of sterilisation
4. Understand how to perform calculations for pharmaceutical formulae	4.1	Explain the importance of performing accurate **calculations**
	4.2	Explain how to calculate accurate **dosages and quantities** for individuals in accordance with prescriptions
5. Understand the principles of pharmaceutical quality systems in the manufacture of pharmaceutical products	5.1	Explain the role of the following in **pharmaceutical quality systems**: **a) Quality assurance** **b) Quality control**
	5.2	Describe how manufactured products are tested for quality
	5.3	Describe **types of validation** that are carried out in pharmaceutical manufacturing
	5.4	Discuss safe systems and error reduction strategies in the context of medicines manufacture
	5.5	Describe different **audit processes** in: a) Licensed units b) Unlicensed unit

Indicative Content	
LO1	**Legislation and standards**: Medicines Act 1968; Human Medicines Regulations 2012; licensing and requirements process; EU Directive on Good Manufacturing Practice for Human Medicinal Products; Rules and Guidance for Pharmaceutical Manufacturers and Distributors and current appendices thereof (Orange guide); Quality Assurance of Aseptic Preparation Services (current edition) EL(97) 52; Good Distribution Practice; Good Automated Manufacturing Practice (GAMP) **Clinical trial:** purpose, design of trials; different types of trials; phases of trials, good clinical practice (GCP) and clinical trials regulation; protection of the public; Investigational Medicinal Products (IMPs). **Key personnel:** Roles and responsibilities of Qualified Person (QP); production manager; Quality Assurance (QA) Manager; Regional QA Officer; quality controller; Accountable Pharmacist; Authorised pharmacist; accredited product approver. **Preparation and manufacture:** Non-sterile; extemporaneous products; sterile and aseptic; large batch production: scaling up of quantities; scaling up of methods of manufacture; scaling up of packaging and transport operations. **Documentation:** Certificates of analysis and conformity; Data integrity; Documentation and system control in pharmacy manufacturing: Local Standard Operating Procedures; working procedure manuals, batch worksheets or records and associated documents; storage, distribution and transport of pharmaceutical products; dispensing units.
LO2	**Good Manufacturing Practice** applied in preparation and manufacturing areas; Preparation versus manufacturing: the difference between extemporaneous and named patient dispensing items and licensed manufacturing; how this is implemented in the workplace. **Different environments** must include: classification of cleanrooms and support rooms; classification of isolators; air handling units; High Efficient Particulate Air (HEPA) filters; essential requirements for sterile, non-sterile and aseptically prepared products in the manufacturing environment, fabric and fittings of buildings, layout of preparation areas. **Hygiene** and its potential effects on environment, products and therefore safety of individuals. **Sources of contamination:** Particles; Microorganisms; Chemical/cross contamination **Potential consequences:** failed batches; harm to individuals; waste; cost; delay to treatment; reputation. **Planned preventative maintenance:** use and scheduled maintenance to premises and equipment. **Preparing the environment:** environmental monitoring and recording of results in relation to: product quality; safe parameters of the clean room; cleaning; changing procedures.
LO3	**Types of pharmaceutical products** Eye drops, injections; antibiotic reconstitutions; cytotoxic products; monoclonal antibodies (MABs), advanced therapy medicinal product (ATMP) parenteral nutrition (PN); radiopharmaceutical products; CIVAS (Centralised Intravenous Additive Service); syringe drivers; gene therapy, radiopharmacy; extemporaneous products. **Pharmaceutical manufacturing techniques**: mixing; size reduction; doubling up; filtration; asepsis. **Equipment:** practical use of autoclaves, stills, mixing equipment, filling and sealing

	equipment, pumps, unidirectional air flow and isolator cabinets, filters. **Labelling and packing:** in line with legislation.
LO4	**Calculations for:** weights; volumes; percentages; ratios; dilutions; displacement values; small quantity calculations; concentration; use of formulae for extemporaneous dispensing. **Dosages and quantities** for individuals based on: age, weight, surface area and blood volume; quantity of medicine based on number of prescribed doses and time intervals.
LO5	**Pharmaceutical Quality Systems (PQS):** implementation of Quality Management; philosophy or operations management; process control, process validation, personal validation, product definition, specifications, safe systems, corrective and preventative actions (CAPA), continuous improvement record keeping; health and safety reporting procedures; validation, e.g. broth and process validation **Quality assurance:** standards in the dispensing or manufacturing process, master formulae and worksheets, official standards relating to containers, raw materials and finished products, quality and product specifications; product contamination by personnel, environment and personnel monitoring; shelf life and stability testing; statutory requirements on quality of pharmaceutical raw materials and formulated products; packaging, labelling and quarantine of completed products, release procedure; batch reconciliation and product recall Procedures; quality assurance issues particular to large scale production Manufacture. **Quality control**: contamination or impurities in pharmaceutical materials and formulated products, their sources and control; in-process testing, degradation of pharmaceutical products; chemical analysis of raw materials and final products; reasons for product sampling and reliability, sterility and pyrogen testing. **Types of validation:** operator validation; process validation; change validation; transfer validation. **Audit processes**: Medicines and Healthcare products Regulatory Agency (MHRA); EL(97)52 Aseptic Dispensing in NHS Hospitals.