School of Pharmacy,
University of London

Postgraduate Diploma
in
General Pharmacy Practice

TECHNICAL PHARMACY CURRICULUM GUIDE 2011/12

In association with the Joint Programmes Board:

East and South East England Specialist Pharmacy Services
King's College
Kingston University
Medway School of Pharmacy
School of Pharmacy, University of London
University of Brighton
University of East Anglia
University of Hertfordshire
University of Portsmouth
University of Reading

Introduction

This guide represents a review of what was formerly referred to as the Technical Services Curriculum Guide within the JPB Postgraduate Diploma in General Pharmacy Practice. This section of the diploma has been recognised as being challenging to deliver in those Trusts where there is either no in house technical services section or where there is limited capacity for the delivery of training for a large number of pharmacists.

The guide was originally tailored to be delivered with at least some time in a technical services unit, however it has become apparent that this is not always a practical or achievable option. There are some absolutely key aspects associated with the technical aspects of pharmacy representing the application of some knowledge and skills that are only found within the pharmacy profession and are vital in the delivery of safe and effective patient care.

We have therefore attempted to identify this key and unique set of skills and knowledge that represent what we have termed "Technical Pharmacy". These are set out in the guide below and it was the consensus of the development group that all of these could equally be delivered within a technical services unit or within the wider area of general pharmacy practice. We have included additional guidance in the Technical Pharmacy Curriculum Guide Support Pack on how such experience could be achieved to illustrate where perhaps this is not immediately clear.

It is important to view the learning outcomes in terms of the link between product and patient safety. Patient safety is at the forefront of technical pharmacy. The product may be licensed or unlicensed (UMP); prepared inhouse in an aseptic unit, on a ward, extemporaneously in the pharmacy or outsourced from a specials manufacturer; it may be an investigational medicinal product (IMP). Each section of the Guide focuses on different elements of the pharmacist's role in assuring the quality of the product being dispensed to the patient irrespective of the product's origin.

It is expected that practitioners will work under the direction of relevant national and local policies, guidelines and Standard Operating Procedures (SOPs) at all times.

Using the Guide:

The technical pharmacy curriculum guide should be used in conjunction with the three other curriculum guides to support learning in pharmacy practice. There are a number of areas of overlap between the curriculum guides which have been signposted to help the learner to achieve learning outcomes across the four core service areas where possible.

In the first instance Training Centres should review the learning outcomes in this guide and consider how each can be met using existing rotations. Some learning outcomes could equally be met in patient services, clinical services and medicines information. Some learning outcomes may require the practitioner to look back at University notes or textbooks in order to revise their knowledge of for example regulations and microbiology.

The four curriculum guides should be brought to the Record of In-service Training Assessment (RITA) meetings that occur at regular intervals throughout the programme. The Guides will be used to review practitioner progress and to assist in planning the focus of learning for the next period of the programme.

In order to facilitate this process, **practitioners** are asked to place a tick against the learning objectives as and when they feel they have been achieved. Practitioners are reminded that **all** learning outcomes are subject to assessment either in the workplace (mini-CEX, CbD, MRCF, DOPS) or at their HEI portfolio review, MCQs or OSCEs.

Resources

Practitioners are directed to the following resources for support in meeting the knowledge-based learning outcomes:

- Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 (The Orange Guide) also accessible via Medicines Complete
- MHRA website
- Aseptic Dispensing for NHS Patients DoH publication 2003
- Quality Assurance of Aseptic Preparation Services Edited by Alison Beaney
- Aseptic Preparation and Dispensing of Medicines (APDM), University of Leeds
- Fundamentals of Aseptics, London Pharmacy Education & Training
- Intermediate Aseptics, London Pharmacy Education & Training
- Technical Pharmacy Study Day delivered by Specialists in Technical Services and QA

Section 1: Generic Practice Learning Outcomes

1. Knowledge of relevant pharmaceutical law, regulation and guidance	**Achieved**
1.1 Demonstrate knowledge of the sections of the Medicines Act 1968 relevant to technical pharmacy	
1.2 Describe the key functions of the MHRA	
1.3 Understand the licensing framework within the UK for premises and products as described by the MHRA	
1.4 Understand the regulatory framework for the conduct of clinical trials within the UK	
1.5 Be aware of NHS guidance governing aseptic preparation services and their governance	
1.6 Be aware of the regulatory requirements for the preparation of different categories of medicinal products	
1.7 Knowledge of the data that is used to assess compliance of a supplier with regulatory requirements	
1.8 Describe COSHH assessment and its relevance to medicines	
1.9 Describe the role of the NPSA and the range and status of the various types of safety alerts that it issues*	
1.10 Demonstrate knowledge of labelling requirements for licensed and unlicensed products	
1.11 Be aware of relevant waste management regulations as applied to technical pharmacy	
2. The role and professional duties of the pharmacist within technical pharmacy	
2.1 Describe how both NHS and commercial manufacturing services can respond to individual patient's needs	
2.2 Know the risks, implications and liabilities associated with the use of unlicensed medicines and apply these to ensure patient safety	
2.3 Describe the type and spectrum of risk associated with products made under different regulatory frameworks	
2.4 Evaluate the process involved in dispensing or preparing a product to determine whether it is fit for purpose and demonstrate application when approving the product for use	
2.5 Describe the common reasons why a prepared product may be deemed unfit for purpose	
3. Product Quality and Patient Safety	
3.1 When considering ward, pharmacy and outsourced preparation describe the main areas of risk associated with product preparation and how these could be managed	
3.2 Define the terms Quality Assurance, Quality Control and GMP and describe how they apply to the preparation of medicines	
3.3 Describe the key characteristics of the different types of documentation (forms, procedures and policies) required within a Quality Management System	
3.4 Demonstrate an understanding of the need for Standard Operating Procedures (SOPs) and the importance of documentation control in the workplace	

3.5 Demonstrate an understanding of the change control process as it affects product quality and patient safety	
3.6 Describe the processes of deviation and incident management	
3.7 Demonstrate an understanding of the role of training to ensure staff are competent to perform their role in assuring product quality	

Section 2: Specific Practice Learning Outcomes

	Achieved
1. Describe the formulation factors that will determine the suitability of a product for administration to a specific patient and apply this information to ensure appropriate use of medicines	
2. Describe the factors related to drug compatibility that must be considered during administration of medicines	
3. Define aseptic preparation and give examples of good and bad aseptic technique	
4. Describe the different sources of particulate and microbial contamination	
5. Define the concepts of cleaning, sanitisation (disinfection) and sterilisation	
6. Understand the sources of contamination e.g. bacteria, yeasts, moulds, fungi and viruses and give a relevant example of each	
7. Describe the origin and significance of spores and the methods commonly used to eradicate them	
8. Undertake all mathematical calculations involved in the preparation and administration of parenteral products accurately	
9. To be able to identify the product factors to consider that influence choice of peripheral or central intravenous use	
10. Describe the key aspects of preparing and administering an intravenous product	
11. Name the devices commonly used for the administration of intravenous medicines and the circumstances affecting selection	
12. Name the devices commonly used to facilitate safe administration of intravenous preparations and the circumstances affecting selection	
13. Describe the factors influencing the stability of medicines and how these relate to the determination of product shelf life	
14. Describe the requirements for the safe storage and transport of medicines (including cold storage items) and how deviation from recommended practice should be assessed and managed	
15. Describe the factors, as they relate to excipients and preservatives, that should be considered before administering a medicine to a patient	
16. Describe the common errors and their causes associated with pharmaceutical packaging and labelling	
17. Describe the factors as they relate to the packaging of medicines which could affect product stability	
18. Describe the issues associated with counterfeit pharmaceuticals in the supply chain and the anti counterfeiting and anti tampering controls that may be used by pharmaceutical companies	