JOINT PROGRAMMES BOARD
LONDON, EAST AND SOUTH EAST ENGLAND

Postgraduate Diploma
in
General Pharmacy Practice

TECHNICAL PHARMACY CURRICULUM GUIDE Supporting Information 2013 - 2014

In association with the Joint Programmes Board:

London, Eastern & SE Specialist Pharmacy Services
King's College
Kingston University
Medway School of Pharmacy
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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 on how such experience could be achieved to illustrate where perhaps this is not immediately clear. The information in these columns is not prescriptive and is intended to give ideas of possible practical experience. Where the task relates to a clearly defined area eg knowledge of certain standards or legislation these columns have been left intentionally blank.

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.

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.

Resources

Practitioners are directed to the following resources for general 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 Services Study Day delivered by Specialists in Technical Services & QA (dates will be advertised to all Training Centres)

Section 1: Generic Practice Learning Outcomes

1. Knowledge of relevant pharmaceutical law, regulation and guidance

	Useful Resources (for guidance only)	Examples of how to meet the LOs if no technical services rotation (for guidance and not exhaustive)	Examples of evidence that LOs have been met
1.1 Demonstrate knowledge of the sections of the Medicines Act 1968 relevant to technical pharmacy	http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1 Section 10 www.mhra.gov.uk Technical services study day	Medicines Act Access relevant information from MHRA website	Demonstrate in all areas of practice Questioning DOPS
1.2 Describe the key functions of the MHRA	www.mhra.gov.uk Technical services study day	Access relevant information from MHRA website	Questioning
1.3 Understand the licensing framework within the UK for premises and products as described by the MHRA	www.mhra.gov.uk Pharmacy Law and Ethics Dale and Appleby Trust Unlicensed Medicines Policy Technical services study day Guidance Note 14 - The supply of unlicensed relevant medicinal products for individual patients	Access relevant information from MHRA website	Questioning DOPS Extended intervention relating to an UMP
1.4 Understand the regulatory framework for the conduct of clinical trials within the UK	www.mhra.gov.uk CPPE Clinical trials learning @ lunch	ICH GCP training CPPE Clinical trials learning @ lunch	Completion of GCP training CPPE Clinical trials L @ L
1.5 Be aware of NHS guidance governing aseptic preparation services and their governance	www.dh.gov.uk www.medicinescomplete.com (for access to the Orange Guide) Technical services study day Quality Assurance of Aseptic Preparation Services Edited by Alison Beaney		
1.6 Be aware of the regulatory requirements for the preparation of different categories of medicinal products	www.medicinescomplete.com (for access to the Orange Guide) Technical services study day	Orange Guide requirements for different product classes and need to determine how and where outsourced products are manufactured	

1.7 Knowledge of the data that is used to assess compliance of a supplier with regulatory requirements	www.mhra.gov.uk Guidance Note 14 - The supply of unlicensed relevant medicinal products for individual patients Technical services study day	Supplier audit, assessment and approval process	Quality assure the procurement of an UMP
1.8 Describe COSHH assessment and its relevance to medicines	http://www.hse.gov.uk/coshh/ Trust policy	Risk assessment of handling of potentially hazardous substances in the dispensary or clinical areas	Completion of a COSHH assessment
*1.9 Describe the role of the NPSA and the range and status of the various types of safety alerts that it issues	www.npsa.nhs.uk www.bmjelearning.co.uk	Access NPSA website	Questioning Completion of training relating to NPSA alerts (e.g. anticoagulation, oxygen, insulin)
1.10 Demonstrate knowledge of labelling requirements for licensed and unlicensed products	www.mhra.gov.uk www.npsa.nhs.uk British Pharmacopoeia NHS Pharmaceutical QA Committee via http://www.nelm.nhs.uk/en/Communities/NeLM/UKQAInfoZone/		DOPS with UMP CbD Questioning
1.11 Be aware of relevant waste management regulations as applied to technical pharmacy	Trust policies and procedures relating to waste management. Departmental SOPs on handling pharmaceutical waste	Pharmaceutical waste management	Questioning on relevant SOPs

*Learning outcome in place as long as NPSA in existence

2. The role and professional duties of the pharmacist within technical pharmacy

	Useful Resources (for guidance only)	**Examples of how to meet the LOs if no technical services rotation (for guidance and not exhaustive)**	**Examples of evidence that LOs have been met**
2.1 Describe how both NHS and commercial manufacturing services can respond to individual patient's needs	Pharmaceutical Compounding and Dispensing Handbook of Extemporaneous Preparation- a Guide to Pharmaceutical Compounding Both available via www.pharmpress.com	Product sourcing, specifications and supplier assessment and approval Procurement experience	Examples of prescriptions dispensed (out-sourced products or inhouse preparation): Clinical trials, OPD-dermatology, chemo, TPN, Paeds CbD
2.2 Know the risks, implications and liabilities associated with the use of unlicensed medicines and apply these to ensure patient safety	www.mhra.gov.uk Trust policy Unlicensed Medicines http://www.rpsgb.org/pdfs/restoolsupplyunlic.pdf	NPSA 20 implications. Unlicensed Medicines policy Paediatrics rotation Medicines Information	DOPS Questioning on policy CbD involving UMP Risk assessment of an UMP
2.3 Describe the type and spectrum of risk associated with products made under different regulatory frameworks	Technical services study day	Licensed – Special – Section 10 – clinical area with examples and how risks can be decreased by moving from clinical area to licensed product	Questioning: Clinical trials Licensed versus Special versus section 10
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	Technical services study day Final release SOP Local SOPs & worksheets for Extemporaneous products	Product specifications and approval. Supplier assessment and approval. Product release	Questioning- final check e.g. chemo/ TPN/ CIVAS/ extemps DOPS
2.5 Describe the common reasons why a prepared product may be deemed unfit for purpose	Technical services study day	Clinical: ward preparation of IVs Final release of outsourced products	Drug alert DOPS: Checking prescriptions- product/ wrong label/deviation from specification or description

3. Product Quality and Patient Safety

	Useful Resources (for guidance only)	Examples of how to meet the LOs if no technical services rotation (for guidance and not exhaustive)	Examples of evidence that LOs have been met
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	Technical services study day	All areas of practice. Observe a nurse preparing IVs on the ward. IV aseptic preparation course for nurses	DOPS Assessment of the risks observed.
3.2 Define the terms Quality Assurance, Quality Control and GMP and describe how they apply to the preparation of medicines	Technical services study day	Relevant section of Orange Guide	Questioning
3.3 Describe the key characteristics of the different types of documentation (forms, procedures and policies) required within a Quality Management System	Technical services study day	Audit documentation used in a section of the pharmacy e.g. dispensary or medicines information for compliance with Quality Management Systems	
3.4 Demonstrate an understanding of the need for Standard Operating Procedures (SOPs) and the importance of documentation control in the workplace	www.medicinescomplete.com (for access to the Orange Guide) Quality Assurance of Aseptic Preparation Services Edited by Alison Beaney Technical services study day	Undertake review of an SOP Write an SOP	Undertake review of an SOP Write an SOP
3.5 Demonstrate an understanding of the change control process as it affects product quality and patient safety		Access supplier change control procedures	Participate in a change control process
3.6 Describe the processes of deviation and incident management	Technical services study day Local SOPs	Example of review of a critical incident has led to an improvement in the department's quality system	Incident reporting e.g Datix Undertake root cause analysis of an incident
3.7 Demonstrate an understanding of the role of training to ensure staff are competent to perform their role in assuring product quality	www.medicinescomplete.com (for access to the Orange Guide) Quality Assurance of Aseptic Preparation Services Edited by Alison Beaney Technical services study day		Reflect on a critical incident relating to staff training

Section 2: Specific Practice Learning Outcomes

	Useful Resources (for guidance only)	Examples of how to meet the LOs if no technical services rotation (for guidance and not exhaustive)	Examples of evidence that LOs have been met
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	Handbook of Extemporaneous Preparation- a Guide to Pharmaceutical Compounding available via www.pharmpress.com SPC NEWT Guide	Assessment of suitability of product for paediatric use Intrathecal training Medicines Information	Dispensary TPN stability issues, volume required, chemo stability MI enquiry
2. Describe the factors related to drug compatibility that must be considered during administration of medicines	Handbook of Injectable Drugs Trissel Trust Parenteral Therapy Guide BNF Appendix 6 SPC BPC	Advise on administration protocols in clinical areas	CbD MI-SC syringe driver queries
3. Define aseptic preparation and give examples of good and bad aseptic technique	Nurse IV study day	Access local nurse IV study day Observation of preparation of parenteral medicines on the ward	Questioning DOPS
4. Describe the different sources of particulate and microbial contamination	Fundamentals of Aseptics, LPET study day		Questioning
5. Define the concepts of cleaning, sanitisation (disinfection) and sterilisation	Fundamentals of Aseptics, LPET study day Trust Infection Control training		Questioning
6. Understand the sources of contamination e.g. bacteria, yeasts, moulds, fungi and viruses and give a relevant example of each	Fundamentals of Aseptics, LPET study day		Questioning
7. Describe the origin and significance of spores and the methods commonly used to eradicate them	Fundamentals of Aseptics, LPET study day		Questioning
8. Undertake all mathematical calculations involved in the preparation and administration of parenteral products accurately		Providing advice to paediatric nurses preparing IVs. Work through examples.	TPN/Chemo screening examples
9. To be able to identify the product factors to consider that influence choice of peripheral or central intravenous use		Clinical rotations/MI advice on administering IVs	TPN/Chemo screening examples

10. Describe the key aspects of preparing and administering an intravenous product		Observe the preparation and administration of at least one intravenous product in a clinical setting	Discussion/ write up of key elements to consider.
11. Name the devices commonly used for the administration of intravenous medicines and the circumstances affecting selection		Clinical rotations	Questioning about pumps, syringe drivers
12. Name the devices commonly used to facilitate safe administration of intravenous preparations and the circumstances affecting selection		Clinical rotations	Questioning about types of lines and giving sets
13. Describe the factors influencing the stability of medicines and how these relate to the determination of product shelf life		Assessment of suitability of stability data supplied by manufacturer of outsourced product or IMP	Licensed /unlicensed units Temp excursions Tablet crushing/cutting, reconstituting medicines
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	Technical services study day SOPs on transporting medicines	Assessment and approval or rejection of product stored incorrectly	Questioning on policy MI Receipt of IMPs
15. Describe the factors, as they relate to excipients and preservatives, that should be considered before administering a medicine to a patient		Assessment of suitability of outsourced product for intended use	Examples prescriptions from OPD/Chemo
16. Describe the common errors and their causes associated with pharmaceutical packaging and labelling	Technical services study day	Labelling error investigation in dispensary	Examples of error investigations
17. Describe the factors as they relate to the packaging of medicines which could affect product stability		Assessment of suitability of medicines in a compliance aid Assessment of outsourced product	Example of prescriptions checked: dosette box/ original containers/ protect from light

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	Technical services study day	MHRA website Procurement	Questioning