OCR
Oxford Cambridge and RSA

Cambridge **TECHNICALS LEVEL 3**

Cambridge TECHNICALS 2016

APPLIED SCIENCE

Unit 11 – Drug development
DELIVERY GUIDE

Version 2

ocr.org.uk/science

CONTENTS

INTRODUCTION

This Delivery Guide has been developed to provide practitioners with a variety of creative and practical ideas to support the delivery of this qualification. The Guide is a collection of lesson ideas with associated activities, which you may find helpful as you plan your lessons.

OCR has collaborated with current practitioners to ensure that the ideas put forward in this Delivery Guide are practical, realistic and dynamic. The Guide is structured by learning outcome so you can see how each activity helps you cover the requirements of this unit.

We appreciate that practitioners are knowledgeable in relation to what works for them and their learners. Therefore, the resources we have produced should not restrict or impact on practitioners' creativity to deliver excellent learning opportunities.

Whether you are an experienced practitioner or new to the sector, we hope you find something in this guide which will help you to deliver excellent learning opportunities.

If you have any feedback on this Delivery Guide or suggestions for other resources you would like OCR to develop, please email resources.feedback@ocr.org.uk.

OPPORTUNITIES FOR ENGLISH AND MATHS SKILLS DEVELOPMENT AND WORK EXPERIENCE

We believe that being able to make good progress in English and maths is essential to learners in both of these contexts and on a range of learning programmes. To help you enable your learners to progress in these subjects, we have signposted opportunities for English and maths skills practice within this resource. We've also identified any potential work experience opportunities within the activities. These suggestions are for guidance only. They are not designed to replace your own subject knowledge and expertise in deciding what is most appropriate for your learners.

English

Maths


Work

Please note

The activities suggested in this Delivery Guide **MUST NOT** be used for assessment purposes. The timings for the suggested activities in this Delivery Guide **DO NOT** relate to the Guided Learning Hours (GLHs) for each unit.

Assessment guidance can be found within the Unit document available from http://www.ocr.org.uk/. The latest version of this Delivery Guide can be downloaded from the OCR website.

UNIT AIM

Drug development describes the process whereby new medicines are discovered and developed, from basic research ('drug discovery') through the various pre-clinical and clinical phases of development and trialling before the drug can be approved for sale. This is a truly multi-disciplinary endeavour involving a wide range of specialists including plant and animal biologists, synthetic organic chemists (medicinal chemistry), analytical chemists, biochemists, pharmacologists, pharmaceutical (formulation) chemists and many others in the pre-clinical stages as well as clinicians and statisticians in the clinical trials phase.

The aim of this unit is for you to develop some of the practical preparative and analytical skills used in the drug development process and to gain an appreciation of the wider context in which you work..

Unit 11 Drug development	
LO1	Understand drug discovery and development principles
LO2	Understand the range of techniques used in drug production
LO3	Be able to carry out a basic extraction, synthesis, isolation and purification of a simple drug or pharmaceutical
LO4	Understand the importance of product formulation and dosage form
LO5	Understand the importance of planning clinical trials when introducing new drugs

To find out more about this qualification, go to: http://www.ocr.org.uk/qualifications/vocational-education-and-skills/cambridge-technicals-applied-science-level-3-certificate-extended-certificate-foundation-diploma-diploma-extended-diploma-05847-05849-05879-05874-2016-suite/

Cambridge TECHNICALS 2016

2016 Suite

- **New suite for first teaching September 2016**
- **Externally assessed content**
- **Eligible for Key Stage 5 performance points from 2018**
- **Designed to meet the DfE technical guidance**

RELATED ACTIVITIES

The Suggested Activities in this Delivery Guide listed below have also been related to other Cambridge Technicals in Applied Science units/Learning Outcomes (LOs). This could help with delivery planning and enable learners to cover multiple parts of units.

This unit (Unit 11)	Title of suggested activity	Other units/LOs	
LO1	Categories of drugs	Unit 1 Fundamentals of science	LO4 Understand the principles of carbon chemistry LO5 Understand the importance of inorganic chemistry in living systems LO6 Understand the structures, properties and uses of materials
		Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
	Stages of drug discovery	Unit 10 Testing consumer products	LO1 Understand the influence of regulatory bodies on development of consumer products
		Unit 11 Drug development	LO2 Understand the range of techniques used in drug production LO4 Understand the importance of product formulation and dosage form
	Modelling techniques in drug development	Unit 1 Fundamentals of science	LO4 Understand the principles of carbon chemistry
		Unit 11 Drug development	LO2 Understand the range of techniques used in drug production
	Pharmacogenomics approach to drug development	Unit 5 Genetics	LO4 Understand the impact of an innovation in an application of genomics
	Combinatorial chemistry	Unit 1 Fundamentals of science	LO4 Understand the principles of carbon chemistry
		Unit 11 Drug development	LO2 Understand the range of techniques used in drug production
	Drug development timeline	Unit 11 Drug development	LO2 Understand the range of techniques used in drug production LO3 Be able to carry out a basic extraction, synthesis, isolation and purification of a simple drug or pharmaceutical LO4 Understand the importance of product formulation and dosage form LO5 Understand the importance of planning clinical trials when introducing new drugs
LO2	Techniques used in drug production: extraction	Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
		Unit 10 Testing consumer products	LO4 Be able to use extraction and separation techniques on consumer products
	Techniques used in drug production: synthesis	Unit 1 Fundamentals of science	LO4 Understand the principles of carbon chemistry
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory
	Techniques used in drug production: purification	Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory
	Analytical techniques	Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
		Unit 3 Scientific analysis and reporting	LO1 Be able to use mathematical techniques to analyse data LO2 Be able to use graphical techniques to analyse data LO4 Be able to analyse and evaluate the quality of data LO5 Be able to draw justified conclusions from data LO6 Be able to use modified, extended or combined laboratory techniques in analytical procedures LO7 Be able to record, report on and review scientific analyses
	Biochemical and immunological screening	Unit 4 Human physiology	LO6 Understand the role and function of the immune system
	Virtual lab tours	Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory LO3 Be able to design a safe functioning laboratory to manage the risk presented by hazards

This unit (Unit 11)	Title of suggested activity	Other units/LOs	
LO3	Extraction of compounds from plants	Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
		Unit 3 Scientific analysis and reporting	LO1 Be able to use mathematical techniques to analyse data
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory LO2 Be able to use health and safety procedures to minimise the risk presented by hazards in a laboratory
		Unit 10 Testing consumer products	LO4 Be able to use extraction and separation techniques on consumer products
	Synthesis of a simple medicine	Unit 1 Fundamentals of science	LO5 Understand the importance of inorganic chemistry in living systems LO6 Understand the structures, properties and uses of materials
		Unit 2 Laboratory techniques	LO3 Be able to determine the concentration of an acid or base using titration LO5 Be able to identify cations and anions in samples
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory LO2 Be able to use health and safety procedures to minimise the risk presented by hazards in a laboratory
	Microscale synthesis of aspirin	Unit 1 Fundamentals of science	LO4 Understand the principles of carbon chemistry
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory LO2 Be able to use health and safety procedures to minimise the risk presented by hazards in a laboratory
	Synthesis and purification of aspirin	Unit 1 Fundamentals of science	LO4 Understand the principles of carbon chemistry
		Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
		Unit 3 Scientific analysis and reporting	LO1 Be able to use mathematical techniques to analyse data LO5 Be able to draw justified conclusions from data LO6 Be able to use modified, extended or combined laboratory techniques in analytical procedures LO7 Be able to record, report on and review scientific analyses
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory LO2 Be able to use health and safety procedures to minimise the risk presented by hazards in a laboratory
		Unit 10 Testing consumer products	LO2 Understand how product testing determines the development of consumer products
	Extraction and purification of paracetamol from tablets	Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
		Unit 3 Scientific analysis and reporting	LO1 Be able to use mathematical techniques to analyse data
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory LO2 Be able to use health and safety procedures to minimise the risk presented by hazards in a laboratory
		Unit 10 Testing consumer products	LO3 Be able to use quantitative titration techniques on consumer products LO4 Be able to use extraction and separation techniques on consumer products
		Unit 11 Drug development	LO4 Understand the importance of product formulation and dosage form

This unit (Unit 11)	Title of suggested activity	Other units/LOs	
LO3	Effect of plant extracts on microbes	Unit 2 Laboratory techniques	LO4 Be able to examine and record features of biological samples LO6 Be able to use aseptic technique
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory LO2 Be able to use health and safety procedures to minimise the risk presented by hazards in a laboratory
LO4	Principles of pharmaceutics	Unit 1 Fundamentals of science	LO2 Understand reactions in chemical and biological systems LO4 Understand the principles of carbon chemistry
		Unit 3 Scientific analysis and reporting	LO4 Be able to analyse and evaluate the quality of data LO5 Be able to draw justified conclusions from data
	Pharmacokinetics	Unit 1 Fundamentals of science	LO3 Understand cell organisation and structures
		Unit 3 Scientific analysis and reporting	LO4 Be able to analyse and evaluate the quality of data
		Unit 8 Cell biology	LO1 Understand the functions of the plasma membrane and endomembrane systems
	Product formulation	Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory
		Unit 10 Testing consumer products	LO2 Understand how product testing determines the development of consumer products
	Product packaging	Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory
	Labelling of medicines	Unit 2 Laboratory techniques	LO2 Be able to separate, identify and quantify the amount of substances present in a mixture
		Unit 6 Control of hazards in the laboratory	LO1 Understand the types of hazard that may be encountered in the laboratory
LO5	Timeline of drug development	Unit 11 Drug development	LO1 Understand drug discovery and development principles LO2 Understand the range of techniques used in drug development LO3 Be able to carry out a basic extraction, synthesis, isolation and purification of a simple drug or pharmaceutical LO4 Understand the importance of product formulation and dosage form
	Participating in a clinical study	Unit 10 Testing consumer products	LO2 Understand how product testing determines the development of consumer products
	Regulation of clinical studies	Unit 10 Testing consumer products	LO1 Understand the influence of regulatory bodies on development of consumer products
	Validity of clinical trials	Unit 3 Scientific analysis and reporting	LO5 Be able to draw justified conclusions from data
		Unit 10 Testing consumer products	LO2 Understand how product testing determines the development of consumer products
	Approving a new drug	Unit 10 Testing consumer products	LO1 Understand the influence of regulatory bodies on development of consumer products LO5 Be able to test the effectiveness of consumer product tests

KEY TERMS

Explanations of the key terms used within this unit, in the context of this unit	
Key term	**Explanation**
Active pharmaceutical ingredient (API)	The active drug substance contained in a medicine.
Adsorption	Binding to a chromatography stationary phase.
Analogues	A series of compounds with similar chemical structures made to investigate the relationship between the structure and activity of a drug or to improve the activity of the drug.
Bioavailability	A measure of the rate and extent to which a drug reaches its site of action.
Biologic/biological	An enzyme, protein, peptide or antibody used as a drug. Note that although 'biological' is an adjective, it is often used as a noun in this context.
Capture antibody	An antibody used to capture an antigen in ELISA.
Clinical phase	The phase of testing a new drug on human subjects before the drug is approved for use as a medicine.
Clinical trial	See clinical phase.
Clinical study	Research involving human volunteers ('participants') that is intended to add to medical knowledge. A clinical trial is a type of clinical study, but the latter term is broader and applies to basic research into diseases undertaken by doctors and biomedical scientists as well as the testing of new drugs.
Detection antibody	An antibody that is specific for a target antigen. The detection antibody may generate a colour or fluorescent product or it may require a secondary antibody.
Drug	A chemical or biological compound which has a physical or psychological effect on the body. Drugs can be used to treat diseases or their symptoms or for recreational purposes. Most drugs are available only with a doctor's prescription and are strictly regulated.
Drug target	A protein (enzyme or receptor) involved in the disease process. Potential drugs modify the functioning of the drug target in a way that cures or treats the disease. The early stages of drug development require model systems using drug targets.
Efficacy	A measure of how well a drug works at its required dose.
ELISA	Enzyme linked immunosorbent assay; an immunological method used in analysis and screening.
Eluate	The fluid emerging from a chromatography column that may contain the substance being separated.
Eluent	The fluid medium used in chromatography to carry compounds through the chromatography column.
Enteric administration	Drug delivery route that involves absorption through the intestines. The drug will normally have its action throughout the body.
Excipient	A component in a formulation added to the active ingredient. Examples are bulking agents (for tablets) or diluents (for liquid medicines). Other substances may be added that assist in manufacture or delivery of the drug.
Fast protein liquid chromatography (FPLC)	A type of HPLC suitable for use with proteins.
Formulation	The process by which different chemical substances, including the active drug (API) are combined to produce a medicine. Formulation is a noun, e.g. you might refer to a 'sustained release formulation' but you will often see it used as a verb, as in 'to formulate a medicine'.
Good manufacturing practice (GMP)	Practices needed to conform to the guidelines set by the regulatory agencies.

Explanations of the key terms used within this unit, in the context of this unit	
Key term	**Explanation**
High performance liquid chromatography (HPLC)	Column chromatography method that uses very small particles and high pressures to achieve a very effective separation. It can be used for analysis or, on a larger scale, for purification.
Hit compound	A substance with characteristics or activity that make it worth further development; it is sometimes shortened to 'hit'.
Hydrophobic	A non-polar substance that is immiscible with water, e.g. oils and many organic solvents.
Hygrophobic	A compound that is intolerant of moisture; the term is usually used in the context of formulations. Not to be confused with the more widely-used 'hydrophobic'.
Hygroscopic	A substance that absorbs water molecules from its surroundings. This can lead to them dissolving in the water they absorb.
Ligand	A substance that binds to a molecule or ion such as a biological receptor. Ligands can be small molecules, such as drugs, or larger molecules such as peptides or proteins.
Medicinal chemistry	A branch of organic chemistry where the effectiveness of a hit compound can be improved by making analogues with similar structures in an attempt to produce compounds with more favourable characteristics.
Me-too drug	A drug that is very similar to existing drug(s) that treat the same disease.
Microtitre plate	A plastic plate with 96 wells arranged in an 8 x 12 layout used for ELISA and other types of assay.
Natural product	A drug substance from a biological source such as an animal, plant or microorganism.
Parenteral administration	A route for drug delivery by injection, inhalation or absorption through the skin. It is a route other than oral, where absorption is via the intestines.
Pharmacogenetics	The study of how individual genes affect an individual's response to drugs.
Pharmacogenomics	The study of how an individual's genome (genetic makeup) influences their response to drugs.
Pharmacokinetics	The study of how a drug is absorbed by the body, how it reaches the target tissues, how it is metabolised (broken down) and excreted.
Placebo	A medically inert substance used as a control in clinical trials. A placebo should represent the drug being tested as closely as possible, with the exception of the active ingredient.
Polymorphism	In the context of drug discovery and development, polymorphism generally refers to the existence of two or more forms of a drug target (usually a protein).
Potency	A measure of the activity of a drug. Compounds with high potency can be given in lower doses, helping to reduce side effects.
Primary antibody	An antibody specific for a particular antigen.
Process development	The scale up of new synthetic processes from the laboratory, through pilot plant to full-scale commercial manufacture. It brings together many disciplines such as synthetic organic chemistry, process technology and chemical engineering.
Reliability	In the context of drug development, reliability can be assessed as the proportion of all variation in a clinical trial that is not due to errors in measurement.
Secondary antibody	An antibody that binds to the detection antibody. The secondary antibody will be labelled with a coloured or fluorescent compound or an enzyme that can be used to generate a coloured or fluorescent product.

Explanations of the key terms used within this unit, in the context of this unit	
Key term	**Explanation**
Single nucleotide polymorphism (SNP)	A change in a single base in a DNA sequence, e.g. C replaces G. This means that the two variants are alleles.
Solid phase	The solid material (usually a gel, polymer, resin or inorganic matrix) used in chromatography. This can be the stationary phase or solid on which a liquid stationary phase is held in place.
Specificity	A measure of how much more a compound interacts with a drug target relative to how much it interacts with other enzymes or proteins. A drug with high specificity is likely to have fewer side effects.
Systemic	An action throughout the body, not just at the site of administration.
Unmet medical need	A medical condition for which there is currently no available treatment.

MISCONCEPTIONS

Some common misconceptions and guidance on how they could be overcome		
What is the misconception?	**How can this be overcome?**	**Resources which could help**
There is often confusion between drugs that are medicines or therapeutics and recreational drugs or drugs of abuse	Explain that the term drug can mean any substance that has a measurable physiological effect on the body. The difference between drugs as medicines and recreational drugs such as alcohol or drugs of abuse is the use to which the drug is put. In fact, many medicines can become drugs of abuse; opioids and prescription painkillers are examples.	What is a controlled medicine (drug)? NHS Choices http://www.nhs.uk/chq/Pages/1391.aspx This article explains how some medicinal drugs are controlled to prevent abuse. The page contains links to further pages on drug abuse.
A lead compound does not contain the element Pb	Explain that lead used in this context is not pronounced 'led', but as in 'dog lead'. It is sometimes used in the same sense as hit compound – a compound that has promising characteristics worthy of further development.	
The terms used to describe the instrumentation in chromatography can cause confusion	Provide learners with the opportunity to review different techniques of chromatography and apply terms such as 'stationary phase', 'mobile phase', 'elution', 'eluent' and 'eluate' to given separations. Stationary phases can be solid or liquids and mobile phases are 'fluid' and can be liquids or gases.	Modern chemical techniques: chromatography Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00001301/chromatography This extract from the Royal Society of Chemistry's Learn Chemistry website provides an overview of chromatographic techniques and exemplifies the terms used.

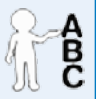
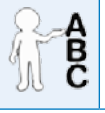
SUGGESTED ACTIVITIES

LO No:	1		
LO Title:	**Understand drug discovery and development principles**		
Title of suggested activity	**Suggested activities**	**Suggested timings**	**Also related to**
Categories of drugs	Drugs are broadly classified as being small molecules or biologics. Learners could learn about the different types by looking at how drugs have changed over time, from minerals or herbal remedies, to the earliest biologics to today's vaccines. Aspirin: A curriculum resource for post-16 chemistry and science courses Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/content/filerepository/CMP/00/000/045/Aspirin.pdf This is a resource published by the Royal Society of Chemistry (RSC) that includes a section on the history and development of aspirin and contains suggestions for activities. The History of Vaccines The College of Physicians of Philadelphia http://www.historyofvaccines.org/content/timelines/all This is a timeline detailing the history of vaccines. Smallpox Through Time Timelines.tv http://timelines.tv/index.php?t=3&e=1 This resource on smallpox includes material produced by the Wellcome Trust.  Learners could identify and present a chronology of drug developments throughout history. Learners could consider the advantages and disadvantages of small molecule drugs and biologics and prepare electronic or paper presentations on the subject.	1 hour	Unit 1 LO4, LO5, LO6 Unit 2 LO2

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Stages of drug discovery 	Development of a new drug starts before there is any laboratory work done. Target selection covers decisions such as the therapeutic area to address as well as scientific approaches to take. Making medicines The Association of the British Pharmaceutical Industry (ABPI) http://www.abpischools.org.uk/page/modules/makingmedicines/makingmedicines1.cfm?age=Age%20range%2016-19&subject=Chemistry The Association of the British Pharmaceutical Industry (ABPI) has a wide range of online resources that are applicable to various parts of this unit. The pages on creating medicines will be a useful place for learners to start; the first few pages make a good introduction, whereas the later pages are more relevant to later parts of the unit. The card sort activity could be downloaded by tutors to test learners' understanding of the timeline of drug discovery and the terms used to describe the stages. Lesson idea: Pharmaceutical company simulation Big Picture, Wellcome Trust http://bigpictureeducation.com/lesson-idea-pharmaceutical-company-simulation The Wellcome Trust has prepared a student activity based around a pharmaceutical company simulation. Aspects of this could be used in this activity, but there are also parts that would be appropriate later in the unit. Learners could use the resources to determine and evaluate the total financial cost of developing a new drug.	2 hours	Unit 10 LO1 Unit 11 LO2, LO4
Modelling techniques in drug development	Welcome to Alchemy? Royal Society of Chemistry (RSC) http://www.rsc.org/Education/teachers/resources/Alchemy/index2.htm The RSC Alchemy website covers a number of topics concentrating on a particular process in the chemical industry: The section on computation chemistry includes a video that illustrates the application of molecular modelling techniques in the design of a new drug. Tutors could use this as a whole class presentation, or individual learners could use it as a source of information to prepare a presentation on the subject.	30 minutes	Unit 1 LO4 Unit 11 LO2

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Pharmacogenomics approach to drug development	Learners may have covered genomics in Unit 5 Genetics. If not, the Wellcome Trust online articles will give a useful introduction. Genes, Genomes and Health Big Picture, Wellcome Trust http://bigpictureeducation.com/genes-genomes-and-health A useful introduction to genomics. Learners could work in groups, each group preparing a case study of a different application of pharmacogenomics; each group should then present their results to the class. How is pharmacogenomics being used? yourgenome http://www.yourgenome.org/stories/how-is-pharmacogenomics-being-used This resource has several examples of the application of pharmacogenomics. Tailoring medicines Big Picture, Wellcome Trust http://bigpictureeducation.com/tailoring-medicines This is another resource that learners could use to find pharmacogenomic applications.	1–2 hours (depending on level of prior knowledge)	Unit 5 LO4
Combinatorial chemistry	Welcome to Alchemy? Royal Society of Chemistry (RSC) http://www.rsc.org/Education/teachers/resources/Alchemy/index2.htm The RSC Alchemy website has a section covering combinatorial chemistry. Tutors could use this as a whole class presentation or individual learners could use it as a source of information to prepare a presentation on the subject. Tutors might consider extending this activity with a discussion on the reasons why combinatorial chemistry has not fulfilled its original promise.	30 minutes or 1 hour with extra discussion	Unit 1 LO4 Unit 11 LO2
Drug development timeline 	As learners progress through this unit they will cover different aspects of the drug discovery and development process. It would help them achieve a better understanding if they construct their own timeline as a poster or in electronic format which could be added to as they acquire more information about the different stages. Time to flourish – Inside innovation: the medicine development process The Association of the British Pharmaceutical Industry (ABPI) http://www.abpi.org.uk/our-work/library/industry/Pages/medicine-development-process.aspx A wallchart that can be downloaded from this link. Learners should be encouraged to produce their own version, rather than the one accessed via the link.	30 minutes	Unit 11 LO2, LO3, LO4, LO5

SUGGESTED ACTIVITIES

LO No:	2		
LO Title:	**Understand the range of techniques used in drug production**		
Title of suggested activity	**Suggested activities**	**Suggested timings**	**Also related to**
Techniques used in drug production: extraction 	New Drugs for Old – Context/problem-based learning Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00001040/new-drugs-for-old-pharmaceuticals-c-pbl This resource covers many areas that would be relevant to this unit. It is aimed at undergraduates so tutors will need to be selective in the parts they use with learners or adapt activities to match learner needs. The card sort, for example, will enable learners to develop their use of the key terms used to describe the stages in drug development.	1 hour	Unit 2 LO2 Unit 10 LO4
Techniques used in drug production: synthesis 	Learners could prepare a presentation on the different methods used in synthesis of APIs. Making medicines The Association of the British Pharmaceutical Industry (ABPI) http://www.abpischools.org.uk/page/modules/makingmedicines/makingmedicines1.cfm?coSiteNavigation_allTopic=1 The section on chemical manufacturing includes a virtual tour of a chemical pilot plant involved in producing APIs. Lesson idea: Pharmaceutical company simulation Big Picture, Wellcome Trust http://bigpictureeducation.com/lesson-idea-pharmaceutical-company-simulation Some parts of the pharmaceutical company role play/simulation would also be relevant here.	1 hour	Unit 1 LO4 Unit 6 LO1

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Techniques used in drug production: purification	Making medicines The Association of the British Pharmaceutical Industry (ABPI) http://www.abpischools.org.uk/page/modules/makingmedicines/makingmedicines1.cfm?coSiteNavigation_allTopic=1 Page 5 of this resource includes information about purification that learners could use in preparing a presentation on purification methods. The Interactive Lab Primer Royal Society of Chemistry (RSC) http://www.chem-ilp.net/index.htm Contains a range of video demonstrations, simulations and apparatus guides to illustrate a range of techniques used in the purification of compounds including pharmaceuticals. Learners are introduced to concepts of particle theory and chemical processes in the preparation and analysis of organic compounds. This interactive guide contains material relevant to many aspects of Learning Outcome 2.  Small groups of learners could each produce a short presentation or illustrated fact sheet on a particular technique using given key words. Alternatively, learners may develop a quiz to encourage the group to engage with the resources.	1 hour	Unit 2 LO2 Unit 6 LO1

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Analytical techniques 	Proton nuclear magnetic resonance (^{1}H-NMR) is an extremely powerful technique used in the analysis of organic chemicals at every stage in the drug development and production process. Laboratory and pilot plant tours The Association of the British Pharmaceutical Industry (ABPI) http://www.abpischools.org.uk/page/modules/labpilotplant/labpilotplant3.cfm?age=Age%20range%2016-19&subject=Chemistry This website includes a tour of an analytical chemistry laboratory and explains NMR as well as other widely used analytical techniques: gas chromatography (GC), mass spectrometry (MS) and high performance liquid chromatography (HPLC). The descriptions are very accessible and so learners could work through this tour themselves or tutors could use this as a class resource. Learners could summarise the usefulness of each method in a short, written paragraph. They should recognise that the most effective analyses use a combination of techniques. Learners have the opportunity to develop skills in NMR and HPLC-MS using the downloads. They could develop maths skills through identification of compounds by molecular mass of ion fragments in MS, identification of proton environments in NMR and analysis of retention times against database standards in HPLC in these or other activities. SpectraSchool Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/collections/spectroscopy Covers a range of spectroscopic techniques, including infra-red (IR) as well as NMR and MS. As well as covering the principles of the methods, there are various interactive resources for learners to practice their skills. New Drugs for Old – Context/problem-based learning Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00001040/new-drugs-for-old-pharmaceuticals-c-pbl Some of the resources relating to analysis in this resource might also be appropriate for some learners.	1 hour	Unit 2 LO2 Unit 3 LO1, LO2, LO4, LO5, LO6, LO7

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Biochemical and immunological screening	There is a wide range of biochemical and immunological methods used in drug development. Some of these are referred to in the videos on the RSC's Alchemy website that were listed as resources in suggested activities for Learning Outcome 1. Immunological techniques are particularly powerful and versatile. They can be used for analysis as well as screening. The 'bite-sized immunology' section on the British Society for Immunology website describes a number of experimental techniques that are used widely in development and analysis of drugs. Tutors may find the following sections provide useful information: the cytokine ELISPOT assay, ELISA, flow cytometry, laser confocal microscopy and the multiplex assay of cytokines. Experimental Techniques British Society for Immunology http://bitesized.immunology.org/experimental-techniques/ Learners could use these resources to research the techniques and make presentations to the class. Depending on the size of the class this might be better done by learners working in groups.	1 hour	Unit 4 LO6
Virtual lab tours 	The ABPI resource offers virtual tours of different laboratories and a chemistry pilot plant. Tutors could use these as the basis of a whole class activity, or learners could view them individually or in small groups. Learners could be invited to list the apparatus or facilities common to laboratories used for drug development. Laboratory and pilot plant tours The Association of the British Pharmaceutical Industry (ABPI) http://www.abpischools.org.uk/page/modules/labpilotplant/.cfm?age=Age%20range%2016-19&subject=Chemistry Virtual visits to chemistry laboratories and a pilot plant on a pharmaceutical company site.	30 mins	Unit 6 LO1, LO3

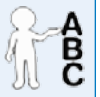
SUGGESTED ACTIVITIES

LO No:	3		
LO Title:	**Be able to carry out a basic extraction, synthesis, isolation and purification of a simple drug or pharmaceutical**		
Title of suggested activity	**Suggested activities**	**Suggested timings**	**Also related to**
Extraction of compounds from plants	Many of the earliest medicines were oils extracted from plants, sometimes called essential oils. This practical gives learners the opportunity to use a technique – steam distillation – that is used for the extraction of many plant oils. Extracting limonene from oranges Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00000692/extracting-limonene-from-oranges?cmpid=CMP00000770 In this case, limonene is extracted from orange peel. Learners could work in groups, or the tutor could carry out the extraction as a demonstration. Sugar is extracted from sugar beet on a large scale and the natural product is used in the manufacture of other important chemicals such as ethanol. Investigation of a familiar product could provide learners with an effective introduction to extraction from plants. Depending on the availability of the raw material, learners could carry out the extraction and purification of sugar from beet using this experiments pack by British Sugar: Education Resurces: Sugar production & processing British Sugar http://www.britishsugar.co.uk/Education-Resources.aspx The activities will enable learners to develop maths skills by taking and recording measurements. Learners could calculate the percentage yield of sugar obtained from a given mass of the raw material, for example.	1 hour	Unit 2 LO2 Unit 3 LO1 Unit 6 LO1, LO2 Unit 10 LO4
Synthesis of a simple medicine	The RSC has produced a resource covering production of simple medicines in the laboratory aimed at 14–18 year old learners. Preparation of all of these should be possible in most situations. Tutors could use one or more of these as an introduction to the subject: Challenging Medicines: Making Medicines - Practicals and PPT Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00000924/challenging-medicines-making-medicines-practicals-and-ppt Shows the extent to which everyday medicines can be made in the classroom.	1 hour	Unit 1 LO5, LO6 Unit 2 LO3, LO5 Unit 6 LO1, LO2

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Microscale synthesis of aspirin	Following on from 'The aspirin story' (a chapter within one of the resources listed in the first activity suggested for Learning Outcome 1), learners could synthesise aspirin themselves using a method published by the RSC. Microscale Chemistry – The microscale synthesis of aspirin Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00000556/the-microscale-synthesis-of-aspirin A microscale esterification reaction between 2-hydroxybenzoic acid (salicylic acid) and ethanoic anhydride using phosphoric acid as a catalyst.	30 minutes	Unit 1 LO4 Unit 6 LO1, LO2
Synthesis and purification of aspirin	Learners could carry out the extraction of the aspirin precursor salicin from the raw material, willow bark, and synthesise aspirin on a larger scale than that in the activity above. They could purify their product by recrystallization. Aspirin: A curriculum resource for post-16 chemistry and science courses Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/content/filerepository/CMP/00/000/045/Aspirin.pdf This resource details a challenging and engaging series of practical activities. Learners could undertake some or all of the practical activities, depending on the facilities and time available. They will need to carefully follow written instructions, including safety advice, to achieve a good yield from the extraction or synthesis. Learners could develop maths skills by calculating percentage yields and analysing chromatography data, for example.  RLC-lab homepage http://www.rlc-lab.com/  RLC-lab offers an analysis service with free registration for schools and colleges in which learners can have access to data from HPLC analyses of their own samples. They can interpret data and calculate the purity of their products. Useful resources are also provided upon registration.	1–3 hours	Unit 1 LO4 Unit 2 LO2 Unit 3 LO1, LO5, LO6, LO7 Unit 6 LO1, LO2 Unit 10 LO2

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Extraction and purification of paracetamol from tablets 	Although this activity does not involve extraction of a drug from a natural source it nevertheless enables learners to become familiar with the chemical processes of extraction involved in drug development. Learners could calculate the mass of the active ingredient extracted and compare with the data on the packaging in a quality control type scenario. Paracetamol Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00000058/paracetamol-book Consists of seven activities that can be used singly or as a package.	30 minutes	Unit 2 LO2 Unit 3 LO1 Unit 6 LO1, LO2 Unit 10 LO3, LO4 Unit 11 LO4
Effect of plant extracts on microbes	Investigating anti-microbial action Nuffield Foundation http://www.nuffieldfoundation.org/practical-biology/investigating-anti-microbial-action This microbiology practical activity investigates the anti-microbial activity of ethanolic extracts of plant tissues. The activity could be extended by learners investigating the antibacterial activity of a wider range of substances.	2 hours plus 2–3 days for incubation of bacterial cultures	Unit 2 LO4, LO6 Unit 6 LO1, LO2

SUGGESTED ACTIVITIES

LO No:	4		
LO Title:	**Understand the importance of product formulation and dosage form**		
Title of suggested activity	**Suggested activities**	**Suggested timings**	**Also related to**
Principles of pharmaceutics 	Tutors could use this as a starting point for an extended project on pharmaceutics, linking route of administration with topics such as product formulation and packaging. Tutors should select a range of medicines, including a range of different formulations as well as prescription only and over the counter medicines. Learners could then work in groups to research the factors that affect the bioavailability of the active ingredient and how these relate to the formulation of the medicine. This information can be incorporated into a presentation (electronic, poster, wallchart or visual display) featuring each group's chosen medicine. Chemistry in your cupboard: Nurofen Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00000012/nurofen This resource features Nurofen, with a section on its formulation.	1 hour	Unit 1 LO2, LO4 Unit 3 LO4, LO5
Pharmacokinetics 	Learners can add to their group's presentation using information about pharmacokinetics and how this might affect the formulation and/or dosage form of their chosen medicine. Learners could draw from and compare data on specific drugs to illustrate the factors that inform product formulations. Challenging Medicines: Physiochemical Properties Royal Society of Chemistry (RSC) http://www.rsc.org/learn-chemistry/resource/res00000926/challenging-medicines-physiochemical-properties#!cmpid=CMP00001230 This link takes you to a two-page handout which is available as a PDF, but there is a lot of further information available for learners who wish to investigate this subject in more detail.	1 hour	Unit 1 LO3 Unit 3 LO4 Unit 8 LO1
Product formulation	Learners should consider the factors that influence the formulation of their group's medicine. The following web page lists the different types of formulations: Different Formulations of Medicines Pharmacy-Xpress http://www.pharmacy-xpress.co.uk/manuals/training-handbook/2-different-formulations-medicines Other resources listed here include sections on product formulation that might be relevant to individual groups of learners.	30 minutes	Unit 6 LO1 Unit 10 LO2

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Product packaging	Product packaging is not just about presenting a drug in an attractive form – it has to meet regulatory requirements, keep the drug in a stable form until it is used and also be acceptable to the patient. Learners could use the ABPI resource on packaging pharmaceuticals to suggest appropriate packaging for their group's medicine. Tutors could also link this to work done in activities for Learning Outcome 1 and Learning Outcome 2. Making medicines: Packaging The Association of the British Pharmaceutical Industry (ABPI) http://www.abpischools.org.uk/page/modules/makingmedicines/makingmedicines7.cfm?age=Age%20range%2016-19&subject=Chemistry ABPI resource on packaging pharmaceuticals.	30 minutes	Unit 6 LO1
Labelling of medicines  	Learners could research the regulations that cover the labelling of medicines and add notes to their group's presentation to indicate how their particular medicine follows these regulations. In the UK this is governed by the Medicines and Healthcare products Regulatory Agency (MHRA) under UK and EU legislation. There is more information about this at: Best practice in the labelling and packaging of medicines Medicines and Healthcare products Regulatory Agency (MHRA) https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines Government guidance on UK requirements for labelling and packaging of medicines. Learners could construct an appropriately labelled 'mock' prototype package, including data on the identity and quantity of the active ingredient and formulation including units. Products could be peer assessed against guidance in the above document.	30 minutes	Unit 2 LO2 Unit 6 LO1
Bringing it all together – class activity  	Learners should make a presentation to the class about their group's medicine and summarise how the various factors they have studied have led to its formulation, packaging and labelling. The presentation could be made by a single member of each group, or the groups could choose to share it out between them. Individual learners could then prepare their own assessments of the different medicines and assess how well each formulation meets the needs of the drug company, pharmacist and patient. These activities could be delivered in an engaging scenario such as a sales pitch or conference to enable learners to develop their verbal and presentation skills.	1–2 hours, depending on class size	

SUGGESTED ACTIVITIES

LO No:	5		
LO Title:	**Understand the importance of planning clinical trials when introducing new drugs**		
Title of suggested activity	**Suggested activities**	**Suggested timings**	**Also related to**
Timeline of drug development	Having looked at the different aspects of drug production and development, this would be a good opportunity for learners to bring together the various pieces of work they have done relating to the timescales of developing new drugs. If learners have been updating their timeline (see the final activity suggested for Learning Outcome 1) they should be able to look at all the work they have done, think about how it all relates to the overall process of drug development and put together a package of information about the drug development process so that they can understand the clinical trials phase as a part of the overall drug development programme.	30 minutes	Unit 11 LO1, LO2, LO3, LO4
Participating in a clinical study 	The term clinical study is broader than just clinical trials – it includes basic medical research on human subjects as well as testing new medicines. Clinical trials NHS Choices http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx The NHS Choices website includes information about clinical studies from the participants' perspective. Learners could use links accessed via these web pages to identify a current or historical clinical trial of their choosing and summarise the key features of the trial. They could write a short, one-page overview of key points as outlined in the specification for Learning Outcome 5. They could include relevant statistics such as the number of volunteers, the duration of the study and the data used to evaluate efficacy. They could conclude by evaluating the validity and reliability of the trial. Healthy young volunteers are in great demand by organisations running clinical studies. Learners could prepare a list of questions that participants should ask before taking part in a clinical trial. Alternatively, learners could take part in a role play scenario where they are given a profile of relevant features and they are 'interviewed' by other learners for their suitability for a given clinical trial.	30 minutes	Unit 10 LO2

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Regulation of clinical studies 	In the UK, medical research is co-ordinated and partly regulated by the Health Research Authority (HRA): Study types Health Research Authority http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/study-types/ Sets out the different types of clinical studies and medical research. Approval of new medicines is the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA): Medicines & Healthcare products Regulatory Agency Gov.uk https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency Links to information about MHRA's activities and services. A short task should be sufficient for learners to become familiar with general aspects of regulation and where to find further information. Learners could be provided with a list of questions which can be answered by accessing and engaging with information by following these links. They could identify acronyms or describe the meaning of technical terms, for example.	30 mins	Unit 10 LO1
Validity of clinical trials	An entertaining and informative introduction to the whole area of evidence-based medicine, including clinical trials, is given by Dr Ben Goldacre in this TED talk: Battling bad science Ben Goldacre http://www.ted.com/talks/ben_goldacre_battling_bad_science.html Learners could view this TED talk to gain a different perspective on the pharmaceutical industry. They could be invited to constructively discuss their own views. Tutors could also provide learners with a more mainstream overview of the factors that affect the validity of clinical trials. The following article was published in the *Public Library of Science (PLoS) Clinical Trials*: Factors That Can Affect the External Validity of Randomised Controlled Trials Peter M Rothwell http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1488890/ Some learners may find the language used in this resource very technical, so tutors could use this as a source of material to adapt before presenting to the group.	1.5 hours	Unit 3 LO5 Unit 10 LO2

Title of suggested activity	Suggested activities	Suggested timings	Also related to
Cochrane Collaboration	Ben Goldacre mentions Cochrane in his talk. Learners could research Cochrane and its work on evidence-based medicine and analysis of clinical trials and prepare a report for the group. About us Cochrane http://www.cochrane.org/about-us A good place to start is the 'about us' section of the Cochrane website.	1–2 hours	
Approving a new drug	The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. About us Medicines & Healthcare products Regulatory Agency https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about This website covers many of the regulatory aspects of the approval process. The National Institute for Health and Care Excellence (NICE) is also part of the approval process in the UK, deciding which new medicines and treatments will be available on the NHS. Behind The Headlines: Does NICE take too long to approve drugs? National Institute for Health and Care Excellence (NICE) https://www.nice.org.uk/news/feature/behind-the-headlines-does-nice-take-too-long-to-approve-drugs This page on the NICE website will give learners an insight into the subject. These two resources might not be very engaging for learners, so they would be better suited to tutors finding appropriate background information. There are more accessible resources on the clinical trials and approval process for cancer drugs on the Cancer Research UK website: How long a new drug takes to go through clinical trials Cancer Research UK http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/how-clinical-trials-are-planned-and-organised/how-long-it-takes-for-a-new-drug-to-go-through-clinical-trials Learners could use these resources to prepare a report on either 'why does it take so long to develop a new drug?' or 'why does it cost so much to develop a new drug?'; information from other Learning Outcomes will be required here.	2 hours	Unit 10 LO1, LO5

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