2016 Suite

OCR
Oxford Cambridge and RSA

Cambridge **TECHNICALS LEVEL 3**

APPLIED SCIENCE

Cambridge TECHNICALS 2016

Unit 11

Drug development

J/507/6158

Guided learning hours: 60

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LEVEL 3

UNIT 11: Drug development

F/507/6157

Guided learning hours: 60

Essential resources required for this unit: A functioning laboratory to carry out extraction techniques

This unit is internally assessed and externally moderated by OCR.

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.

TEACHING CONTENT

The teaching content in every unit states what has to be taught to ensure that learners are able to access the highest grades.

Anything which follows an i.e. details what must be taught as part of that area of content. Anything which follows an e.g. is illustrative, it should be noted that where e.g. is used, learners must know and be able to apply relevant examples in their work, although these do not need to be the same ones specified in the unit content.

For internally assessed units you need to ensure that any assignments you create, or any modifications you make to an assignment, do not expect the learner to do more than they have been taught, but must enable them to access the full range of grades as described in the grading criteria.

Learning outcomes The Learner will:	Teaching content Learners must be taught:
1 Understand drug discovery and development principles	1.1 Categories of drugs i.e.: • synthetic (small molecule) drugs • biological (biologics) (e.g. monoclonal antibodies as anti-cancer agents, blood clotting factors, therapeutic enzymes) 1.2 Research stages of drug discovery programme to identify i.e.: • consumer target (e.g. user groups) • effectiveness of existing products • legislative requirements • new and emerging technologies and materials • environmental pressures (e.g. ethical and socially responsible design) 1.3 Modelling techniques in drug development i.e.: • the role of quantitative structure-activity relationships (QSAR) • computational techniques. 1.4 Pharmacogenomics approach to drug development i.e.: • genomic profiling of different diseases and identification of targets • identification of sub-groups of patients that will benefit from targeted therapy
2 Understand the range of techniques used in drug production	2.1 Techniques used in drug production i.e.: • extraction • synthesis • purification 2.2 Analytical techniques in assessing the purity of products or intermediates i.e.: • Infra-red (IR) spectroscopy • low resolution and high resolution proton nuclear magnetic resonance spectroscopy(^{1}H-NMR) • biochemical and immunological screening • colorimetric methods • Enzyme-linked immunosorbent assay (ELISA)

Learning outcomes The Learner will:	Teaching content Learners must be taught:
3 Be able to carry out a basic extraction, synthesis, isolation and purification of a simple drug or pharmaceutical	3.1 Production processes of a simple drug or pharmaceutical, i.e.: • extraction process • chemical synthesis, isolation and purification procedure • preparation
4 Understand the importance of product formulation and dosage form	4.1 The basic principles of pharmaceutics i.e.: • route of administering • bioavailability (e.g. solubility, molecular size, hydrophobicity, resistance to proteolysis / other enzymatic degradation.) 4.2 Solubility and stability of pharmaceutical formulation i.e.: • expiration • shelf life • packaging, labelling and storage
5 Understand the importance of planning clinical trials when introducing new drugs	5.1 Planning the development of new drugs i.e.: • timescales • costs • clinical trials • safety • dosage • effectiveness • validity and reliability • statistical interpretation of the results

GRADING CRITERIA

LO	Pass	Merit	Distinction
	The assessment criteria are the Pass requirements for this unit.	To achieve a Merit the evidence must show that, in addition to the Pass criteria, the candidate is able to:	To achieve a Distinction the evidence must show that, in addition to the pass and merit criteria, the candidate is able to:
1. Understand drug discovery and development principles	*P1: Identify the initial stages of a drug development programme	M1: Describe modelling techniques used in drug development	D1: Evaluate pharmacogenomics approaches to drug development
2. Understand the range of techniques used in drug production	*P2: Outline techniques used in drug production		
	P3*: Describe analytical techniques in assessing the purity of products or intermediates	M2: Explain how analytical techniques are used in assessing the purity of products or intermediates	
3. Be able to carry out a basic extraction, synthesis, isolation and purification of a simple drug or pharmaceutical	*P4: Demonstrate the use of a procedure to extract a pharmaceutical from plant, animal or microbial source	M3: Describe the chemistry involved in the extraction of pharmaceutical from plant, animal or microbial source	
4. Understand the importance of product formulation and dosage form	*P5: Identify the basic principles of pharmaceutics		D2: Evaluate the formulations of named drugs for oral, subcutaneous and intravenous administration
	*P6: Identify methods used to increase stability of medicines		
5. Understand the importance of planning clinical trials when introducing new drugs	*P7: List the steps in developing a new drug including an appreciation of timescales, costs and clinical trials	M4: Interpret the results of clinical trial data	D3: Evaluate the validity and reliability of a clinical trial and justify their conclusions based on an understanding of data

ASSESSMENT GUIDANCE

This unit combines practical skills with the theoretical background needed, set in the context of the drug development process. A large part of the content could usefully be assessed through a project approach, so that learners choose an example (e.g. Ibuprofen – see The Ibuprofen Story, in resources – and / or a biological therapeutic) and research the ways in which different aspects of what they have learned can be applied to a real-life situation. This could be particularly useful in assessing LO1. Learners could also prepare posters or flowcharts summarising the drug development process, annotated with details of the roles of the people involved, the skills and techniques used and the importance of each step in contributing to a successful outcome.

LO2: practical skills should be assessed to the extent of the equipment available. Interpretation of spectra can be assessed using materials available on the Royal Society of Chemistry website, e.g. the Spectra School (see Resources).

LO5: this could be assessed through use of a published clinical trial and having learners interpret and critically assess the data and conclusions drawn.

Feedback to learners: you can discuss work-in-progress towards summative assessment with learners to make sure it's being done in a planned and timely manner. It also provides an opportunity for you to check the authenticity of the work. You must intervene if you feel there's a health and safety risk.

Learners should use their own words when producing evidence of their knowledge and understanding. When learners use their own words it reduces the possibility of learners' work being identified as plagiarised. If a learner does use someone else's words and ideas in their work, they must acknowledge it, and this is done through referencing. Just quoting and referencing someone else's work will not show that the learner knows or understands it. It has to be clear in the work how the learner is using the material they have referenced to inform their thoughts, ideas or conclusions.

For more information about internal assessment, including feedback, authentication and plagiarism, see the centre handbook. Information about how to reference is in the OCR Guide to Referencing available on our website: http://www.ocr.org.uk/i-want-to/skills-guides/.

SYNOPTIC LEARNING AND ASSESSMENT

It will be possible for learners to make connections between other units over and above the unit containing the key tasks for synoptic assessment. Please see Section 6 of the Qualification Handbook for more details. We have indicated in the unit where these links are with an asterisk.

Name of other unit and related LO	This unit:
Unit 1 Science fundamentals LO5 Understand the importance of inorganic chemistry in living systems LO6 Understand the structures, properties and uses of materials	LO1 Understand principle drug discovery and development processes 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

Name of other unit and related LO	This unit:
Unit 2 Laboratory techniques LO2 Be able to separate, identify and quantify the amount of substances present in a mixture LO3 Be able to determine the concentration of an acid or base using titration LO4 Be able to examine and record features of biological samples LO5 Be able to identify cations and anions in samples	LO1 Understand principle drug discovery and development processes 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
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	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
Unit 6 Control of hazards in the laboratory LO1 Understand the types of hazard that may be encountered in a laboratory LO2 Be able to use health and safety procedures to minimise the risk presented by hazards in a laboratory	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
Unit 10 Testing consumer products LO1 Understand the influence of regulatory bodies on development of consumer products LO2 Understand how product testing determines the development of 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 LO5 Be able to test the effectiveness of consumer product tests	LO1 Understand principle drug discovery and development processes 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. LO5 Understand the importance of planning clinical trials when introducing new drugs

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