# BS979-20 Drug Discovery and Biopharmaceutical Development

## 24/25

**Department** 

Life Sciences

Level

Taught Postgraduate Level

Module leader

Alexander Cameron

**Credit value** 

20

**Module duration** 

3 weeks

**Assessment** 

100% coursework

**Study location** 

University of Warwick main campus, Coventry

# **Description**

## Introductory description

Students will develop a detailed knowledge of the potential for drug discovery and exploitation by the pharmaceutical industry and a critical appreciation of some of the various techniques in use. Students will acquire an integrated understanding of the breadth and depth of medicinal drug design and productions.

Module web page

#### Module aims

To allow students the opportunity to study the fundamental principles of drug discovery and biotechnology.

The module also extends the knowledge base relevant to the development and exploitation of biopharmaceutical products by the pharmaceutical industry. Students will integrating of the information presented with the core ethos of the programme by addressing issues concerned with the regulation of pre-clinical and clinical trials, through the Regulatory Procedures of development of biopharmaceuticles into a commercial reality.

## **Outline syllabus**

This is an indicative module outline only to give an indication of the sort of topics that may be covered. Actual sessions held may differ.

- The fundamental principles of drug discovery for medicinal gain.
- The process of drug discovery using molecular biology and genetic engineering.
- Recent advances in drug discovery, rational drug design, biological principles and detailed consideration of the research and development.
- Examples with proven exploitation whilst also addressing the limitations (and dangers) of the drug technologies and their commercial potential.
- Biopharmaceutical products: proteins, viruses, gene and cell therapy, vaccines.
- · Commercial exploitation: markets, diseases, companies.
- · Cell substrates: Mammalian/bacterial/fungal/insect. Cell bank manufacture and testing
- Development of a biopharmaceutical: Stages in development from pre-clinical safety studies through Phase I – II – III – IV clinical studies.
- Regulatory Agencies; procedure, policies and guidelines.
- Chemistry, Manufacture and Control (CMC).
- Good Manufacturing Practice and Quality Assurance:
- Manufacture: Processes for extracting, purifying, formulating and filling. Process validation and qualification.
- Products: Vaccines, Advanced Therapy Medicinal Products, Biosimilars

## **Learning outcomes**

By the end of the module, students should be able to:

- Have a broad, integrated knowledge of drug discovery and biopharmaceuticals and respective industries.
- Be able to critically assess the commercial advantages and disadvantages when selecting a new drug target.
- Be able to critically assess the use of novel drug design techniques and their risk to the pharmaceutical industry
- Be able to demonstrate knowledge of drug and biopharmaceutical development for the treatment of common and rare diseases
- Have a good understanding of the manufacturing and regulation of biopharmaceuticals

## Indicative reading list

- Textbook of Drug Design and Discovery (4th Edition) Eds: P. Krogsgaard- Larsen, U. Madsen, and K. Stromgaard. 2009 CRC Press.
- 2. Biopharmaceuticals: Biochemistry and Biotechnology, (2nd Edition) G. Walsh 2003 Wiley

"Biology and Biotechnology" Kreuzer and Massey. Publ. ASM Press (2005). ISBN 1-55581-304-6

"Pharmacology" Rang and Dale's. Publ. Elsevier (2012).

#### ISBN 9780702034718

"Drug Design: Structure- and Ligand-Based Approaches". Merz, Ringe and Reynolds (2010).

ISBN-10: 0521887232

## Subject specific skills

Demonstrate a broad knowledge and understanding of small molecule drugs and biopharmaceutical development.

Recognise and analyse the problems associated with the development and use of biopharmaceuticals in a commercial process.

Recognise the underlying principles re clinical trials, manufacture and commercial implementation of drugs and biopharmaceuticals.

Understand the role of a multi-disciplinary approach in the commercialisation of drugs and biopharmaceuticals.

#### Transferable skills

Present both oral and written reports giving a well-argued critique of selected subject.

# Study

# Study time

Гуре	Required
Lectures	16 sessions of 1 hour (8%)
Seminars	8 sessions of 2 hours 30 minutes (10%)
Practical classes	(0%)
Other activity	50 hours (25%)
Private study	64 hours (32%)
Assessment	50 hours (25%)
Total	200 hours

## **Private study description**

Assessment preparation Self-directed study

## Other activity description

50 hours assessment preparation

## Costs

No further costs have been identified for this module.

### **Assessment**

You do not need to pass all assessment components to pass the module.

Students can register for this module without taking any assessment.

## **Assessment group AF**

Weighting Study time
Case Study Presentations 50% 25 hours

The course is arranged to include the presentations as part of the teaching component. Each group will be assigned a drug product that they need to research and present to the class over 4 presentations, looking at different aspects of the drug manufacturing regulation and development process. The drug products are chosen to highlight how these processes vary from drug to drug. External lecturers will be there to feedback on the talks and to make sure that the important points are conveyed to the whole class.

Poster 50% 25 hours

The students should prepare a poster in powerpoint on a topic related to small molecule drug design (they will be given a choice of 3 topics). This should be formatted typically as a poster would be for presentation at a conference. The poster should be accompanied by a narrative of approx 500 words.

#### Feedback on assessment

Verbal generic feedback on group presentation; written group feedback on presentation; written feedback on poster.

# **Availability**

## Courses

This module is Core for:

- Year 1 of TLFS-J7N2 Postgraduate Medical Biotechnology and Business Management
- Year 1 of TBSS-C5N2 Postgraduate Taught Biotechnology, Bioprocessing and Business Management