BMSC13020 *Drug Discovery and Clinical Trials*
Term 1 - 2024

Profile information current as at 19/05/2024 08:24 am

General Information

Overview

The development of new therapeutic products for the medical biotechnology industry requires comprehensive knowledge of techniques used to investigate their effects on various biological pathways at a cellular level. This unit will provide you with an opportunity to apply theoretical and practical knowledge of medical biotechnology, drug development and pre-clinical testing of a new therapeutic product for industry commercialisation. You will develop new practical skills and gain experience in experimental models used to study human disease and apply these in a simulated industry environment. Your practical skills and demonstration of professional knowledge, attitude and compliance with relevant safety protocols will be assessed in a laboratory environment. Attendance at the practical activities at a compulsory residential school is a requirement of this unit. You will also develop the skills to communicate your findings to a broader audience in the medical biotechnology industry through both written reports and oral presentations.

Details

Career Level: *Undergraduate*
Unit Level: *Level 3*
Credit Points: *6*
Student Contribution Band: *8*
Fraction of Full-Time Student Load: *0.125*

Pre-requisites or Co-requisites

Pre-requisite: BMSC12010 Clinical Biochemistry
Important note: Students enrolled in a subsequent unit who failed their pre-requisite unit, should drop the subsequent unit before the census date or within 10 working days of Fail grade notification. Students who do not drop the unit in this timeframe cannot later drop the unit without academic and financial liability. See details in the Assessment Policy and Procedure (Higher Education Coursework).

Offerings For Term 1 - 2024

- Mixed Mode
- Rockhampton

Attendance Requirements

All on-campus students are expected to attend scheduled classes – in some units, these classes are identified as a mandatory (pass/fail) component and attendance is compulsory. International students, on a student visa, must maintain a full time study load and meet both attendance and academic progress requirements in each study period (satisfactory attendance for International students is defined as maintaining at least an 80% attendance record).

Residential Schools

This unit has a Compulsory Residential School for distance mode students and the details are:
Click here to see your Residential School Timetable.

Website

This unit has a website, within the Moodle system, which is available two weeks before the start of term. It is important that you visit your Moodle site throughout the term. Please visit Moodle for more information.

Class and Assessment Overview

Recommended Student Time Commitment

Each 6-credit Undergraduate unit at CQUniversity requires an overall time commitment of an average of 12.5 hours of study per week, making a total of 150 hours for the unit.

Class Timetable

Regional Campuses
Bundaberg, Cairns, Emerald, Gladstone, Mackay, Rockhampton, Townsville

Metropolitan Campuses
Adelaide, Brisbane, Melbourne, Perth, Sydney

Assessment Overview

1. **Report**
Weighting: 60%
2. **Practical Assessment**
Weighting: Pass/Fail
3. **Presentation**
Weighting: 40%

Assessment Grading

This is a graded unit: your overall grade will be calculated from the marks or grades for each assessment task, based on the relative weightings shown in the table above. You must obtain an overall mark for the unit of at least 50%, or an overall grade of 'pass' in order to pass the unit. If any 'pass/fail' tasks are shown in the table above they must also be completed successfully ('pass' grade). You must also meet any minimum mark requirements specified for a particular assessment task, as detailed in the 'assessment task' section (note that in some instances, the minimum mark for a task may be greater than 50%). Consult the University's Grades and Results Policy for more details of interim results and final grades.

CQUniversity Policies

All University policies are available on the CQUniversity Policy site.
You may wish to view these policies:

- Grades and Results Policy
- Assessment Policy and Procedure (Higher Education Coursework)
- Review of Grade Procedure
- Student Academic Integrity Policy and Procedure
- Monitoring Academic Progress (MAP) Policy and Procedure – Domestic Students
- Monitoring Academic Progress (MAP) Policy and Procedure – International Students
- Student Refund and Credit Balance Policy and Procedure
- Student Feedback – Compliments and Complaints Policy and Procedure
- Information and Communications Technology Acceptable Use Policy and Procedure

This list is not an exhaustive list of all University policies. The full list of University policies are available on the CQUniversity Policy site.

Previous Student Feedback

Feedback, Recommendations and Responses

Every unit is reviewed for enhancement each year. At the most recent review, the following staff and student feedback items were identified and recommendations were made.

Feedback from Student feedback

Feedback
Residential School was vital to learning.

Recommendation
Retain hands-on residential school to assist students with their learning.

Feedback from Student feedback and unit coordinator self reflection.

Feedback
Using topic focused experts to teach the unit helped to better inform students of expectations in the biotechnology industry.

Recommendation
Where possible, continue to use experts with real world experience in biotechnology to teach this unit.

Unit Learning Outcomes

On successful completion of this unit, you will be able to:

1. Conduct molecular or cell-based tests used to study human disease
2. Display professional behaviour consistent with the safety and ethical practices of the laboratory
3. Critically analyse current scientific literature
4. Think critically to solve problems during the development and testing of therapeutics
5. Effectively communicate experimental findings to industry professionals through written reports and oral presentations.

Alignment of Learning Outcomes, Assessment and Graduate Attributes

— N/A Level ◦ Introductory Level • Intermediate Level • Graduate Level ◦ Professional Level ◦ Advanced Level

Alignment of Assessment Tasks to Learning Outcomes

Assessment Tasks	Learning Outcomes				
	1	2	3	4	5
1 - Practical Assessment - 0%	•	•			
2 - Report - 60%			•	•	•
3 - Presentation - 40%			•	•	•

Alignment of Graduate Attributes to Learning Outcomes

Graduate Attributes	Learning Outcomes				
	1	2	3	4	5
1 - Communication					•
2 - Problem Solving			•	•	•
3 - Critical Thinking	•	•	•	•	•
4 - Information Literacy					
5 - Team Work					
6 - Information Technology Competence					
7 - Cross Cultural Competence					
8 - Ethical practice	•	•			
9 - Social Innovation					
10 - Aboriginal and Torres Strait Islander Cultures					

Alignment of Assessment Tasks to Graduate Attributes

Assessment Tasks	Graduate Attributes									
	1	2	3	4	5	6	7	8	9	10
1 - Practical Assessment - 0%			•					•		
2 - Report - 60%	•	•	•							
3 - Presentation - 40%	•	•	•							

Textbooks and Resources

Textbooks

There are no required textbooks.

IT Resources

You will need access to the following IT resources:

- CQUniversity Student Email
- Internet
- Unit Website (Moodle)

Referencing Style

All submissions for this unit must use the referencing styles below:

- American Psychological Association 7th Edition (APA 7th edition)
- Vancouver

For further information, see the Assessment Tasks.

Teaching Contacts

Jason Steel Unit Coordinator
j.steel@cqu.edu.au

Schedule

Week 1 - 04 Mar 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 1: Pharmaceutical Industry, Drivers and Stages of Drug Development		

Week 2 - 11 Mar 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 2: From Diseases to Drugs		

Week 3 - 18 Mar 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 3: Preclinical Toxicity		

Week 4 - 25 Mar 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 4: Clinical Phase I Trials		

Week 5 - 01 Apr 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 5: Regulatory Agencies and Quality Regulations		

Vacation Week - 08 Apr 2024

Module/Topic	Chapter	Events and Submissions/Topic

Week 6 - 15 Apr 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 6: Clinical Phase II Trials - Informed Patient Consent and Pharmacovigilance		Submit topic for Assessment 1

Week 7 - 22 Apr 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 7: Clinical Phase II Trials (cont) - Roles and Responsibilities		

Week 8 - 29 Apr 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 8: Drug Manufacturing		

Week 9 - 06 May 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 9: Clinical Phase III trials - Protocols		

Week 10 - 13 May 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 10: Clinical Phase III trials (cont)- Clinical Project Management, Blinding and Global Trials		Assessment 1 Due - Therapeutic Development Proposal (Monday 13th May) **Assessment 1: THERAPEUTIC DEVELOPMENT PROPOSAL** Due: Week 10 Monday (13 May 2024) 11:59 pm AEST

Week 11 - 20 May 2024

Module/Topic	Chapter	Events and Submissions/Topic
Residential School. This is a compulsory laboratory session held at the Rockhampton campus.		Assessment 2: Practical skills assessment

Week 12 - 27 May 2024

Module/Topic	Chapter	Events and Submissions/Topic
Topic 11: Clinical Phase III trials (cont) - Ethics, Consultants and Medical Advisory Boards		Assessment 3 Due - Conference Presentation (Friday 31 May) **Assessment 3: CONFERENCE PRESENTATION** Due: Week 12 Friday (31 May 2024) 11:59 pm AEST

Review/Exam Week - 03 Jun 2024

Module/Topic	Chapter	Events and Submissions/Topic

Exam Week - 10 Jun 2024

Module/Topic	Chapter	Events and Submissions/Topic

Term Specific Information

The unit coordinator is Dr Jason Steel. Please feel free to contact me on j.steel@cqu.edu.au or on 07 4930 6391.
TEXTBOOK
There is no prescribed textbook for BMSC13020 Drug Discovery and Clinical Trials. There will be selected reading materials provided to you on the Moodle site for this unit.
LECTURES
The lectures are delivered by Anthony Bishop, Chief Scientific Officer at Factor Therapeutics. Anthony is an industry expert, having spent his career in the pharmaceutical biotechnology industry. These lectures will be pre-recorded, and will integrate the fundamentals of pharmaceutical development with specific case studies from the biotechnology industry.
The tutorials are delivered by Dr Jason Steel and will re-enforce the information from the pre-recorded lectures, whilst relating the content to the assessment tasks. Tutorials are conducted adhoc as required by the students.
RESIDENTIAL SCHOOL
There is a compulsory Residential School associated with this unit, which is held from Tuesday 23rd May until Thursday 25th May 2023. The duration of this Residential School may be longer than those you have attended previously, however this is appropriate for the achievement of the practical skills, and demonstration of professional behaviour required. You will learn various new cell-based techniques during the Residential School that are highly relevant to the biotechnology and research industries. There are competency-based assessments associated with these techniques during this Residential School, so attendance is compulsory.

Assessment Tasks

1 Assessment 1: THERAPEUTIC DEVELOPMENT PROPOSAL

Assessment Type
Report

Task Description
The lecture content from Weeks 1 to 8 will provide you with knowledge regarding how potential therapeutics are developed and translated into clinical trials in the biotechnology industry. The lectures are integrated with specific case studies to support your learning with real-world examples. In this assessment, you will be tasked to use this knowledge, and survey the existing literature on similar case studies, to develop your own potential new therapeutic. Ideally, this will initially involve the selection of a specific disease which has a key "driver" that is targetable by pharmaceuticals. This may be a disease without current treatments available, or an existing disease where treatments are available, however there is scope for further therapeutic improvement. You will select this disease by Friday of Week 4 and confirm this selection with the Unit Coordinator. Upon approval to proceed, you will develop a written proposal that addresses the following sections:
Part A: Who is your target patient population? What are the key characteristics of the disease that this therapeutic is designed to target?
Part B: What pre-clinical models of the disease would you propose to use to test your therapeutic?
Part C: Describe the pre-clinical toxicity study that you may propose for your therapeutic?
Please note the following as a guide:
The entire written proposal should be from 1,500 to 2,000 words in length.
Accurately describe the disease that you are proposing, including the specific characteristics of the disease that your proposed drug is targeting. This may be a genetic abnormality (e.g. gene translocation or mutation), abnormality in the blood serum biochemistry (e.g. excessive protein or lipid in the blood) etc.
The text should be prepared using a standard word processing software (e.g. Microsoft Word) with the appropriate use of figures, diagrams or tables as required and saved as a PDF.
Specific referencing to scientific literature is essential. APA, Harvard or Vancouver style is acceptable, and the use of Endnote is highly encouraged.

Assessment Due Date
Week 10 Monday (13 May 2024) 11:59 pm AEST

Return Date to Students

2 weeks after submission

Weighting
60%

Minimum mark or grade
50%

Assessment Criteria
The assessment of this written report will be based on the demonstrated knowledge of disease mechanisms and therapeutic targets, rationalisation and justification of your arguments and ideas, support of these arguments and ideas using appropriate robust scientific literature and clarity of the proposal with accurate referencing.
A detailed marking rubric will be available on the Moodle site for this unit.

Referencing Style

- American Psychological Association 7th Edition (APA 7th edition)
- Vancouver

Submission
Online

Submission Instructions
Please submit as a pdf file using the Moodle Assessment Submission Site.

Learning Outcomes Assessed

- Critically analyse current scientific literature
- Think critically to solve problems during the development and testing of therapeutics
- Effectively communicate experimental findings to industry professionals through written reports and oral presentations.

Graduate Attributes

- Communication
- Problem Solving
- Critical Thinking

2 ASSESSMENT 2: PRACTICAL LABORATORY SKILLS

Assessment Type
Practical Assessment

Task Description
Laboratory-based (preclinical) testing of pharmaceuticals is essential to demonstrate the desired efficacy and biological activity in the treatment of various diseases. Employers within the biotechnology and medical research industries commonly use cell-based models of human disease, and will be looking for graduates with a sound knowledge and practical training in such techniques. Hence, you will be assessed in this unit regarding your performance in undertaking these cell-based techniques, as described below.
During the Residential School, you will be provided with a pharmaceutical agent that has been recently discovered to have activity against cervical cancers. The hypothetical biotechnology company you are employed in has recently identified this agent from a plant that is indigenous to Australia, and currently has little knowledge of how this drug works as an anti-cancer agent. Your task during the Residential School will be to undertake a series of experiments (as outlined in a Laboratory Manual provided on the Moodle site) to explore the anti-cancer properties and mechanism of action of this new potential treatment for cervical cancer. The below techniques will be used during the Residential School:

- Culturing of human cervical cancer cells
- Flow cytometry
- Immunofluroescence microscopy
- Quantitative real-time PCR

Sufficient training on both the practical and theoretical components of these procedures will be provided during the Residential School. You will complete each of these cell-based techniques (as outlined in the Laboratory Manual on the Moodle site for this unit) and will be assessed on the quality of the outcomes of these procedures. The assessment will be conducted as follows:

- The unit coordinator will undertake the cell-based techniques in parallel with you as a benchmark of quality of the experimental output.
- If your first attempt at the technique does not meet the minimum passing criteria, you will be allowed a subsequent maximum of (two) attempts at this technique.

Assessment Due Date

Assessment of practical skills will be completed during the residential school

Return Date to Students

Assessment of practical skills will be discussed during the residential school

Weighting
Pass/Fail

Assessment Criteria
You will be assessed on the following criteria:

- Aseptic culture techniques
- Quality and interpretation of scatterplots from flow cytometer
- Quality of microscopy images
- Quality of quantitative real-time PCR results
- Analysis and interpretation of real-time PCR data
- Adequate labeling of experimental samples

Referencing Style

- American Psychological Association 7th Edition (APA 7th edition)
- Vancouver

Submission
No submission method provided.

Submission Instructions
You will be assessed on your practical skills during the Residential School

Learning Outcomes Assessed

- Conduct molecular or cell-based tests used to study human disease
- Display professional behaviour consistent with the safety and ethical practices of the laboratory

Graduate Attributes

- Critical Thinking
- Ethical practice

3 Assessment 3: CONFERENCE PRESENTATION

Assessment Type
Presentation

Task Description
Presentation of your research findings at scientific meetings or conferences will ensure dissemination of your discoveries to the broader scientific community. In this assessment, your task is to present research findings on the specific anti-cancer drug that you were using during residential school. The oral presentation of your research findings will begin with your experimental results that you achieved during the residential school. You will then present a series of logical subsequent experiments and anticipated results to conclusively determine the mechanism of action of this relatively unknown anti-cancer drug. You will refer to recent scientific literature in this field to design these subsequent experiments in an effort to draw robust conclusions on the mechanism of action of this drug. It is expected that the volume of experimental findings presented (and proposed) during this presentation will be sufficient for publication in a scientific journal (approximately 6 to 8 figures).
Please note that the presentation can be between 10-15 minutes in duration. It can be recorded and uploaded into the Moodle Assessment Submission Site. It should follow the below sections:

- Introduction regarding the discovery of the drug and target patient population.
- Presentation of methods used at Residential School
- Experimental results achieved during Residential School
- Presentation of proposed subsequent experiments and anticipated results
- Conclusion drawn from existing results (from Residential School) and from proposed experiments

The presentation can be prepared using any standard presentation software (for example, Powerpoint or Keynote). Links to recording software and instructions for how to record the presentation will be available on the Moodle site.

Assessment Due Date
Week 12 Friday (31 May 2024) 11:59 pm AEST

Return Date to Students

2 weeks after submission

Weighting
40%

Minimum mark or grade
50%

Assessment Criteria
You will be assessed on the following criteria:

- Clearly introduce the background information regarding the drug and accurately identify and describe the characteristics of the target patient population.
- Accurate and clear presentation of methodology (both from existing protocols used at Residential School and subsequent proposed experiments).
- Coherent and logical presentation of results in tabular or graphical format.
- Clear presentation of microscopy images with accurate labeling.
- Logical discussion of results with accurate and definitive conclusion outlined.
- Appropriate use of referencing of scientific literature

A detailed marking rubric will be available on the Moodle site for this unit.

Referencing Style

- American Psychological Association 7th Edition (APA 7th edition)
- Vancouver

Submission
Online

Learning Outcomes Assessed

- Critically analyse current scientific literature
- Think critically to solve problems during the development and testing of therapeutics
- Effectively communicate experimental findings to industry professionals through written reports and oral presentations.

Graduate Attributes

- Communication
- Problem Solving
- Critical Thinking

Academic Integrity Statement

As a CQUniversity student you are expected to act honestly in all aspects of your academic work.

Any assessable work undertaken or submitted for review or assessment must be your own work. Assessable work is any type of work you do to meet the assessment requirements in the unit, including draft work submitted for review and feedback and final work to be assessed.

When you use the ideas, words or data of others in your assessment, you must thoroughly and clearly acknowledge the source of this information by using the correct referencing style for your unit. Using others' work without proper acknowledgement may be considered a form of intellectual dishonesty.

Participating honestly, respectfully, responsibly, and fairly in your university study ensures the CQUniversity qualification you earn will be valued as a true indication of your individual academic achievement and will continue to receive the respect and recognition it deserves.

As a student, you are responsible for reading and following CQUniversity's policies, including the **Student Academic Integrity Policy and Procedure**. This policy sets out CQUniversity's expectations of you to act with integrity, examples of academic integrity breaches to avoid, the processes used to address alleged breaches of academic integrity, and potential penalties.

What is a breach of academic integrity?
A breach of academic integrity includes but is not limited to plagiarism, self-plagiarism, collusion, cheating, contract cheating, and academic misconduct. The Student Academic Integrity Policy and Procedure defines what these terms mean and gives examples.

Why is academic integrity important?
A breach of academic integrity may result in one or more penalties, including suspension or even expulsion from the University. It can also have negative implications for student visas and future enrolment at CQUniversity or elsewhere. Students who engage in contract cheating also risk being blackmailed by contract cheating services.

Where can I get assistance?
For academic advice and guidance, the Academic Learning Centre (ALC) can support you in becoming confident in completing assessments with integrity and of high standard.

What can you do to act with integrity?

Be Honest
If your assessment task is done by someone else, it would be dishonest of you to claim it as your own

Seek Help
If you are not sure about how to cite or reference in essays, reports etc, then seek help from your lecturer, the library or the Academic Learning Centre (ALC)

Produce Original Work
Originality comes from your ability to read widely, think critically, and apply your gained knowledge to address a question or problem