



# **BMSC13014 *Biotherapeutics and Industry***

## **Term 1 - 2020**

Profile information current as at 11/05/2024 08:17 pm

All details in this unit profile for BMSC13014 have been officially approved by CQUUniversity and represent a learning partnership between the University and you (our student). The information will not be changed unless absolutely necessary and any change will be clearly indicated by an approved correction included in the profile.

### Corrections

#### **Unit Profile Correction added on 19-04-20**

The Residential School for this unit has been postponed and you will need to complete this at a later date. Further details about the residential school will be made available on Moodle in due course.

## 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 in the 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: 12

Student Contribution Band: 8

Fraction of Full-Time Student Load: 0.25

### Pre-requisites or Co-requisites

Pre-requisite: BIOL12106 Molecular Biology

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 - 2020

- 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 12-credit Undergraduate unit at CQUniversity requires an overall time commitment of an average of 25 hours of study per week, making a total of 300 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. **Practical Assessment**

Weighting: Pass/Fail

#### 2. **Learning logs / diaries / Journal / log books**

Weighting: Pass/Fail

#### 3. **Report**

Weighting: 60%

#### 4. **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 Verbal feedback from the student

##### Feedback

The residential school was engaging and provided an opportunity to use specialist equipment relevant to the medical research field.

##### Recommendation

Continue to provide a detailed 7-day residential school to facilitate training on specialist equipment.

## 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. Review and 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



### Alignment of Assessment Tasks to Learning Outcomes

Assessment Tasks	Learning Outcomes				
	1	2	3	4	5
1 - Practical Assessment - 0%	•	•			
2 - Learning logs / diaries / Journal / log books - 0%		•			
3 - Report - 60%			•	•	•
4 - Presentation - 40%			•	•	•

### Alignment of Graduate Attributes to Learning Outcomes

Graduate Attributes	Learning Outcomes				
	1	2	3	4	5
1 - Communication				•	•
2 - Problem Solving			•	•	

Graduate Attributes	Learning Outcomes				
	1	2	3	4	5
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 - Learning logs / diaries / Journal / log books - 0%	•			•	•		•	•		
3 - Report - 60%	•	•	•	•		•				
4 - 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 6th Edition \(APA 6th edition\)](#)
- [Harvard \(author-date\)](#)

For further information, see the Assessment Tasks.

## Teaching Contacts

**Jason Steel** Unit Coordinator  
[j.steel@cqu.edu.au](mailto:j.steel@cqu.edu.au)

## Schedule

### Week 1 - 09 Mar 2020

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

### Week 2 - 16 Mar 2020

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

### Week 3 - 23 Mar 2020

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

### Week 4 - 30 Mar 2020

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

### Week 5 - 06 Apr 2020

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

### Vacation Week - 13 Apr 2020

Module/Topic	Chapter	Events and Submissions/Topic
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### Week 6 - 20 Apr 2020

Module/Topic	Chapter	Events and Submissions/Topic
Topic 6: Clinical Phase II Trials - Informed Patient Consent and Pharmacovigilance		

### Week 7 - 27 Apr 2020

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

### Week 8 - 04 May 2020

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

**Week 9 - 11 May 2020**

Module/Topic	Chapter	Events and Submissions/Topic
Topic 9: Clinical Phase III trials - Protocols		<b>Therapeutic development proposal</b> Due: Week 9 Friday (15 May 2020) 5:00 pm AEST

**Week 10 - 18 May 2020**

Module/Topic	Chapter	Events and Submissions/Topic
Topic 10: Clinical Phase III trials (cont)- Clinical Project Management, Blinding and Global Trials		

**Week 11 - 25 May 2020**

Module/Topic	Chapter	Events and Submissions/Topic
Residential School. This is a compulsory laboratory session held at the Rockhampton campus.		

**Week 12 - 01 Jun 2020**

Module/Topic	Chapter	Events and Submissions/Topic
Topic 11: Clinical Phase III trials (cont) - Ethics, Consultants and Medical Advisory Boards		

**Review/Exam Week - 08 Jun 2020**

Module/Topic	Chapter	Events and Submissions/Topic
		<b>Laboratory Book</b> Due: Review/Exam Week Friday (12 June 2020) 5:00 pm AEST <b>Conference Presentation</b> Due: Review/Exam Week Friday (12 June 2020) 5:00 pm AEST

## Term Specific Information

The coordinator for this unit is Dr Jason Steel. Please feel free to contact me anytime on j.steel@cqu.edu.au or on 07 4930 6391.

### TEXTBOOK

There is no prescribed textbook for BMSC13014 Biotherapeutics and Industry. 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.

### RESIDENTIAL SCHOOL

There is a compulsory Residential School associated with this unit, which is held from Monday 25th May until Sunday 31st May 2020. 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, in this 12 credit unit. 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.

An online drop-in session will be provided in the week following the residential school to provide support for the analysis and interpretation of data gathered during the Residential School. Attendance at this online session is non-compulsory and times can be scheduled accordingly for individual or group discussions as required.

## Assessment Tasks

### 1 Assessment of 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
- Immunofluorescence 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

#### Return Date to Students

#### Weighting

Pass/Fail

#### Minimum mark or grade

70%

#### 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

Detailed marking rubrics will be available on the Moodle site for this unit. Each technique will be scored as per the rubric, and minimum of 70% of the total marks are required to pass this assessment.

#### Referencing Style

- [American Psychological Association 6th Edition \(APA 6th edition\)](#)
- [Harvard \(author-date\)](#)



**Submission**

Offline Online

**Submission Instructions**

Please submit your microscope slides, flow cytometry results and real-time PCR data and results through the Moodle Assessment Submission site. Competency in cell culture techniques will be assessed during the Residential School, whilst the data analysis and interpretation will be assessed as per your submission on the completion of 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**

- Communication
- Problem Solving
- Critical Thinking
- Information Literacy
- Team Work
- Cross Cultural Competence

## 2 Laboratory Book

**Assessment Type**

Learning logs / diaries / Journal / log books

**Task Description**

Biotechnology companies are required to provide adequate documentation of their laboratory activities. Laboratory records are the primary source of evidence provided when ownership of biotechnology companies intellectual property (IP) is contested in a court of law. Hence, you will be assessed on your competency to accurately record your experimental findings during the Residential School. You will undertake the cell-based techniques as outlined in the Laboratory Manual (available on the Moodle site for this unit). You will be tasked to record your daily activities, results, observations and conclusions in this manual. This will also include information relevant to preparation for the techniques, including calculations involved in the preparation of solutions or reagents. There will also be daily worksheets provided to you regarding compliance with Standard Laboratory Practices in a PC2 Laboratory (Physical Containment Level 2 Laboratory).

You will be required to complete the Laboratory Manual in conjunction with the discussions held during Residential School and the associated reading available on the Moodle site for this unit. Submission of the completed Laboratory Manual can be performed as hard copy at the completion of Residential School, or online through the Moodle Assessment Submission Site.

**Assessment Due Date**

Review/Exam Week Friday (12 June 2020) 5:00 pm AEST

**Return Date to Students****Weighting**

Pass/Fail

**Minimum mark or grade**

70%

**Assessment Criteria**

You will be assessed on the following criteria:

- Appropriate use of an introduction for each experiment
- Accuracy in laboratory recording, including the methodology used and documentation of results
- Quality and appropriate use of labeling and images or tables for presentation of results
- Correct spelling and appropriate use of technical terms
- Demonstrated knowledge of the regulatory laws, government guidelines or institutional committees that govern biosafety, animal and human ethics

Marks will be allocated within the Laboratory Manual for each section, and a detailed marking rubric will be available on the Moodle site for this unit.

**Referencing Style**

- [American Psychological Association 6th Edition \(APA 6th edition\)](#)

- [Harvard \(author-date\)](#)

### **Submission**

Offline Online

### **Learning Outcomes Assessed**

- Display professional behaviour consistent with the safety and ethical practices of the laboratory

### **Graduate Attributes**

- Communication
- Information Literacy
- Team Work
- Cross Cultural Competence
- Ethical practice

## **3 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 (3rd April 2020) 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.
- Specific referencing to scientific literature is essential. APA or Harvard style is acceptable, and the use of Endnote is highly encouraged.

### **Assessment Due Date**

Week 9 Friday (15 May 2020) 5:00 pm AEST

### **Return Date to Students**

Within 2 weeks of assessment date.

### **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 6th Edition \(APA 6th edition\)](#)
- [Harvard \(author-date\)](#)

## Submission

Online

## Submission Instructions

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

## Learning Outcomes Assessed

- Review and 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
- Information Literacy
- Information Technology Competence

# 4 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

Review/Exam Week Friday (12 June 2020) 5:00 pm AEST

## Return Date to Students

Exam Week Friday (19 June 2020)

## 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 6th Edition \(APA 6th edition\)](#)
- [Harvard \(author-date\)](#)

### **Submission**

Online

### **Learning Outcomes Assessed**

- Review and 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
- Information Literacy
- Information Technology Competence
- Cross Cultural Competence

## 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