Module 10: Product Commercialisation

Module title			
Product Commercialisation			
Module NFQ level	**Module number / reference**	**ECTS Value**	**Duration**
9	MSC-PBM-CCIPI	10	12 Weeks
Parent programme(s)		**Stage of parent programme**	**Semester No.**
Master of Science in Pharmaceutical Business Management		1	1 or 2
Postgraduate Diploma in Science in Pharmaceutical Business Management		1	1 or 2
Certificate in Pharmaceutical Business Management		1	1 or 2
Teaching and Learning modes	**Proportion** (% of Total Directed Learning)		
Classroom / Face to Face	80%		
Workplace			
Online			
Other (Identify)	Blended: 20%		
Entry requirements (statement of knowledge, skill and competence)			
Learners should normally hold an honours (NFQ Level 8) degree in a cognate or non-cognate discipline or equivalent qualification, from an approved tertiary/or professional institution.			
Maximum number of learners per instance of the module	100		
Average (over the duration of the module) of the contact hours per week	3		
Pre-requisite module title(s) (if any)	N/A		
Co-requisite module title(s) (if any)	N/A		
Is this a capstone module? (Yes or No)	No		
Module-specific physical resources and support required per centre (or instance of the module)			
Lecture room with internet access, audio-visual equipment and white board. Moodle Area.			
Specification of the qualifications (academic, pedagogical and professional/occupational) and experience required of staff working in this module.			
Role e.g. Tutor, Mentor etc	**Qualifications & experience required:**		**# of Staff with this profile (WTEs)**
Lecturer	Lecturing staff are required to hold at least a master's degree in Business, Engineering, Management or Leadership, or a related discipline and/or an equivalent professional qualification. Industry experience is beneficial but not a requirement. Ideally, they would also hold a third level teaching qualification (e.g. the Griffith College Certificate in Education, Learning and Development).		0.4

Analysis of required learning effort		
***Effort while in contact with staff**	**Minimum ratio teacher / learner**	**Hours**
Classroom and demonstrations	1:100	60
Mentoring and small-group teaching	1:20	12
Other (specify)		
Independent Learning		
Directed e-learning (hours)		-
Independent Learning (hours)		178
Other hours (specify)		-
Work-based learning hours of learning effort		-
Total Effort (hours)		250

Allocation of Marks					
	Continuous Assessment	**Supervised Project**	**Proctored Practical Exam**	**Proctored Written Exam**	**Total**
Percentage Contribution	60%	-	-	40%	**100%**

1.1.1 Module aims and objectives

This module aims to introduce learners to the Regulatory, Financial and Commercialisation Frameworks in the Pharmaceutical and Biotechnology Industry. Success in the pharmaceutical and biotech industry requires a basic understanding of the R&D, financial and commercial launch paradigms. The main purpose of the module is to explore the phases of R&D through to regulatory approval; understanding the basic financial considerations and elements of global commercial launch. This module highlights the emergence of Biosimilars and Platform technology in a competitive and ever-changing global marketplace.

1.1.2 Minimum intended module learning outcomes

On successful completion of this module the learner will be able to:

MIMLO 10.1 Critically evaluate the Keys Phases in Pharmaceutical/Biotech Research and Development.
MIMLO 10.2 Analyse the role of Global Regulatory Affairs.
MIMLO 10.3 Evaluate the regulatory approval process in both the US and EU for new drug applications and changes to existing NDA.
MIMLO 10.4 Define a Biosimilar and discuss the challenges associated with the growth of the Biosimilar Market.
MIMLO 10.5 Evaluate basic financial investment metrics and demonstrate their associated advantages and disadvantages plus other selection methods.
MIMLO 10.6 Differentiate the elements of a commercial launch including phases, milestones and success factors.
MIMLO 10.7 Critically analyse the position of Platform technology as an emerging technology; co-developing new processes with vendors and/or other stakeholders.

1.1.3 Rationale for inclusion of the module in the programme and its contribution to the overall MIPLOs

The Pharmaceutical and Biotechnology Industry is a specialised, high-tech, industry subject to myriad regulations and represents a unique commercial operating environment. This module aims to introduce learners to the Regulatory, Financial and Commercial Frameworks in the Pharmaceutical and Biotechnology Industry. Success in the pharmaceutical and biotech industry requires an understanding of the phases of R&D through to regulatory approval; financial considerations and the elements of global commercial launch. This module aims to fulfil these needs and additionally address current trends in the global marketplace such as the emergence of Biosimilars and Platform technology.

This module supports the achievement of the following MIPLOs (per each award):

Programme Title	MIPLOs achieved
MSc in Pharmaceutical Business Management	(i), (ii), (v) to (viii)
PgDip in Science in Pharmaceutical Business Management	(i), (ii), (iv), (viii)
Certificate in Pharmaceutical Business Management	(i), (ii), (iv) to (x)

1.1.4 Information provided to learners about the module

This module aims to introduce learners to the industry specific subjects of Regulatory, Financial & Commercial Frameworks in the Pharmaceutical & Biotechnology Industry, and to improve learner knowledge and understanding of these subjects. It examines concepts, theories, and practices around these and the application of these to real 'life' situations which are relevant to learners now and in their future working lives.

The module draws on material from a variety of sources - academic works, case studies, documentaries, etc., to achieve a multi-layered scaffolded approach to developing an understanding of leading change projects in modern organisations.

The module is structured to help learners learn more about the topic through blended learning, including attending lectures, reading case studies and notes, completing short activities, watching video clips, and assessment activities.

1.1.5 Module content, organisation and structure

Module Curriculum

Week 1: Research & Development

- Study types, Phase 1, 2 and 3
- Centre selection
- Advisory board, Safety Board
- Regulatory clearance
- Ethics boards
- Use of contract organisations
- Data interpretation, audits
- Intellectual Property

Week 2: Global Regulatory Affairs

- CMC (Chemistry Manufacturing and Controls)
- Regulatory Agencies.
- Global Regulatory Framework, Overview

Week 3: US Approval Process

- Overview of the Drug Development and NDA (New Drug Approval) Process
- Phases from laboratory to NDA review
- Drug Master File
- Question Based Review (QbR)
- Changes to an approved NDA or ANDA
  - Prior Approval Supplement
  - Supplement - CBE
  - Annual Report
- Examples 1, 2

Week 4: EU Approval Process

- Voluntary Harmonisation Procedure (VHP)
- Phases & Timelines
- Clinical Trial Application CTA
- Active Substance Master File (ASMF)
- Scientific Advice
- Common Technical Document CTD
- Examples 1, 2

Week 5: Biosimilars

- Definition of a Biosimilar, WHO Guidelines
- Growth of the Biosimilars market
- Impact of LOE, Patent Expiration; Research in Biosimilars
- The current global regulatory landscape
- Major differences in regulations
- Automatic Substitution or Interchangeability
- Challenges for the development & approval of a Biosimilar (companies & regulators)
- Case Study

Week 6-7: Financial Investment Metrics

- Assumptions & Risk
- Basic Metrics (ROI, Payback); advantages & disadvantages of both
- Advanced Appraisal Tools (NPV, Discounted Payback, PI); advantages & disadvantages
- IRR
- Discuss:
- PI to prioritise investments
- IRR vs ROI
- Other Selection Methods
- Project Management Methodology and Information Systems
- Expert Judgment
- Project Selection Methods Summary

Week 8-9: Commercial Teams

- Role of the Commercial Launch Team & Launch Overview
- Business Proposition (marketplace feasibility)
- Commercial Strategy
- Commercial Planning
- Commercial Execution (Trade planning and retail activation)
- Commercial Evaluation
- Measure retail performance
- Core team & extended team
- Key Product Launch Milestones
- Manufacturing site selection
- Prototype development/approval
- Registration batches /formal stability
- FDA registration/approval
- Graphics /labelling approval
- Process /packaging validation
- Commercial launch build
- QA Testing /release
- Ship to trade
- Launch Work-streams & associated activities
- Key Success Factors for Development and Commercialization

Week 10-12: Platform Technology

- Definition of a Platform Technology
- Pros / Cons Platform Technology vs. Custom technology
- New technology co-development; Vendor partnering
- Process flow (using worked example)
- Proof of Concept (POC)
- Implementation Phase
- Key GO /NO Go steps
- Governance & Roles and Responsibilities & Communication
- Knowledge Management
- Vendor Interaction
- Return-on-Investment

Teaching Plan

Week 1	Research and Development
Week 2	Global Regulatory Affairs
Week 3	US Approval Process
Week 4	EU Approval Process
Week 5	Biosimilars
Weeks 6 & 7	Financial Investment Metrics
Weeks 8 & 9	Commercial Teams
Weeks 10, 11, & 12	Platform Technology

1.1.6 Module teaching and learning (including formative assessment) strategy

The overall strategy is very much a scaffolded, constructivist, approach to facilitating learners to develop industry knowledge basics, while developing a critical awareness of the "bigger picture" of how the industry as a whole.

Lectures 1 through 4 focus on developing an understanding of the pharmaceutical product development and approval processes. Lecture 5 explores the growth of Biosimilars. The next section of the module, lectures 6 through 9 explore financial and commercial considerations, and finally the module wraps up with an exploration of platform technology.

The module will be assessed through a mixture of continuous assignment and end of semester exam. This involves continuous assessment at 60% of the overall credits, and the examination a 40% of overall credits.

1.1.7 Work-based learning and practice-placement

There is no work based learning or practical placement in the module.

1.1.8 E-learning

Griffith College uses Moodle, a virtual learning environment, to support its delivery of e-learning activities in the form of peer-to-peer support based around activities where learners give and receive feedback, forums where learners must contribute, formative quizzes and video links.

1.1.9 Module physical resource requirements

A classroom setting is used for the onsite & virtual delivery of the module through a series of 10-12 lectures including assignment and assessment workshops. Supports for learners include course material, lecture notes, activities, short, self-administered questionnaires, case studies and related assessment tasks. These are supplemented with a module set book and online reading materials, PowerPoint presentations, and other activities using Moodle, the College's Virtual Learning Environment (VLE) provide additional support materials to help with self-study.

1.1.10 Reading lists and other information resources

Core Reference Materials

Abbott, F.M. and Dukes, G. (2011) *Global pharmaceutical policy: ensuring medicines for tomorrow's world*. Cheltenham: Edward Elgar.

Additional Resources

Sage (ed) (2008) *The SAGE Handbook of Healthcare: Global Policies, Business Opportunities, Scientific Developments*. London: SAGE.

Edwards, L.D., Fox, A.W. and Stonier, P.D. (eds) (2011) *Principles and Practice of Pharmaceutical Medicine*. Oxford, UK: Wiley-Blackwell.

Williams, D.R. (2013) *The Funding of Biopharmaceutical Research and Development* Sawston, UK: Woodhead Publishing.

Journal of Pharmacy & Pharmaceutical Sciences
Clinical Research and Regulatory Affairs Journal

1.1.11 Specifications for module staffing requirements

Lecturer and other personnel should hold a Masters Level (Level 9) qualification in Business, Engineering, Management or Leadership. Industry experience is beneficial but not a requirement.

Ideally, they would also hold a third level teaching qualification (e.g. the Griffith College Certificate in Education, Learning and Development).

1.1.12 Module summative assessment strategy

The overall strategy is very much a scaffolded, constructivist, approach to facilitating learners to develop a keen understanding of the industry with respect to the module topics covered in lecturers and tutorials, as outlined in earlier sections. The module will be assessed on a mixed basis, with an end of semester examination worth 40% of the credits available, and an assignment worth the remaining 60%. This can be presented as a single assignment or two assignments as appropriate, and these can be assigned as individual or group assignments.

A typical spread of assessment for this module could be as follows:

No.	Weighting	Type	Description	Learning outcomes assessed
1	60%	Group Assessment	**Assessment: Market Access** Develop a market access strategy, including a written report and presentation to the board of directors of the case study organisation.	1, 3, 4
2	40%	Written Examination	End of Semester Exam	1-7

Reassessment/Repeat assessment strategy: Griffith College regulations state that learners must pass all component elements of the module to be deemed to have passed the module.

- In the event of a learner failing components of / this module, they will be required to submit a new individual repeat assignment which will be made available on Moodle to learners, and which must be submitted as per faculty instructions.
- In the event of a learner failing a group assessment element of this module, a new individual repeat assignment will be made available on Moodle to learners which must be submitted as per faculty instructions.
- In the event of the learner failing the exam, learners will take the re-sit exam at the next available sitting, details of which will be made available to learners via Moodle.

1.1.13 Sample assessment materials

Please see sample assessment supplementary document.