Bridging Module B: An Introduction to the Pharmaceutical Industry

This module is intended to prepare learners from non-STEM/general business backgrounds for the in-depth pharmaceutical and regulatory learning outcomes required of learners to achieve on modules in semester two of this proposed programme.

Module title			
Introduction to the Pharmaceutical Industry			
Module NFQ level	**Module number / reference**	**ECTS Value**	**Duration**
9	MSC-PBM-IPI	5	6 weeks
Parent programme(s)		**Stage of parent programme**	**Semester No.**
N/a		Pre-programme	Pre Semester 1
Teaching and Learning modes	**Proportion** (% of Total Directed Learning)		
Classroom / Face to Face	**40%**		
Workplace			
Online	**40%**		
Other (Identify)	**Blended: 20%**		
Entry requirements (statement of knowledge, skill and competence)			
Learners undertaking this bridging module should normally hold an honours (NFQ Level 8) degree in a business or related 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	6 Note: This bridging course will be completed in advance of learners commencing semester 1 (online, in one to three weeks). Assessment will be submitted early in semester 1.		
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 in Business, Engineering, Management or Leadership 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).		0.2

Analysis of required learning effort		
*Effort while in contact with staff	Minimum ratio teacher / learner	Hours
Classroom and demonstrations	1:100	12
Mentoring and small-group teaching	1:20	12
Other (specify)		
Independent Learning		
Directed e-learning (hours)		24
Independent Learning (hours)		79
Other hours (specify)		0
Work-based learning hours of learning effort		0
Total Effort (hours)		125

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

B.1   Module aims and objectives

This module is a bridging module for learners with qualifications or work experience unrelated to the pharmaceutical industry. It aims to introduce learners to the pharmaceutical industry to enable them to form a strong understanding of it on which to build their knowledge throughout the programme. This is necessary to allow learners to "bridge the knowledge gap" existing between the different learner groups, and to provide a strong foundation for the understanding, contextualisation, and application of the programme as a whole. The module includes a broad overview of the industry itself, its key stakeholders and business types, the key functions within large pharmaceutical companies, the pharmaceutical value chain, key trends and processes in the industry, and of the external environment in which it operates.

This module aims to help learners to develop an understanding of the pharmaceutical industry, its motivators, value chain, internal and external operations, and internal and external environments. The module also aims to enable learners to critically analyse the internal and external environments, and to critically evaluate the role and responsibilities of the pharmaceutical industry nationally and internationally. Finally, the module aims to facilitate learners in developing a strong foundation for the programme, and future employment, focusing on the current state of the art and future trends in the industry.

B.2   Minimum intended module learning outcomes

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

MIMLO B.1   Demonstrate a strong understanding of the pharmaceutical industry and its major stakeholders.

MIMLO B.2   Evaluate the Pharmaceutical Value Chain from multiple business area perspectives.

MIMLO B.3   Demonstrate a strong understanding of the key business functions and processes within various pharmaceutical industries, including pharmaceutical development, manufacturing, distribution, and dispensing.

MIMLO B.4   Critically assess the latest trends in the pharmaceutical industry, including but not limited to aspects such digitalisation, industry 5.0, biopharmaceuticals, and gene-therapy innovations, quality, lean and good manufacturing practice.

MIMLO B.5   Critically Assess the Pharmaceutical Industry in the national and international context, considering political, economic, social, technological, environmental and legal factors.

MIMLO B.6   Understand the relationship between the internal environment, external environments and value chain of a typical pharmaceutical organisation, and the interconnectedness and interdependencies of these upon each other and various business functions.

B.3   Rationale for inclusion of the module in the programme and its contribution to the overall MIPLOs

This module has been included in the programme as a bridging module. It has been designed for learners who wish to undertake the programme but who do not have a background in the pharmaceutical industry, through education or work experience. The programme as a whole has been designed to help learners develop the skills needed to meet identified skills gaps in a very unique, high-tech, industry. It is of critical importance that learners have the specialist industry knowledge need to understand, contextualise, and apply the programme content as a whole, and to support their transition into a career in this area. This module aims to help learners to develop an understanding of the pharmaceutical industry, its motivators, value chain, internal and external operations, and internal and external environments.

B.4   Information provided to learners about the module

This module aims to introduce learners to the general subjects of business transformation and continuous improvement, 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.

B.5   Module content, organisation and structure

Module Curriculum
What is the Pharmaceutical Industry?
- Industry Overview
- Product Types
- The Irish Pharmaceutical Landscape
- The International Pharmaceutical Landscape
- Patents, Generics, Risk and Competition
- PESTEL Analysis

The role of the Pharmaceutical Industry in Society
- Corporate Social Responsibility
- Health Systems
- Employment
- Contribution to the Exchequer
- Communities

Stakeholder Analysis
- Major Stakeholders within the industry
- Role of non-regulatory stakeholders
- Role of regulatory stakeholders

- Impact of different Stakeholder Groups
- The Stakeholder Power-Interest Matrix

Pharmaceutical Value Chain
- Manufacturing
- Distributing
- Dispensing
- Activities, Costs, Value Adds
- Value Chain Analysis
- The Impact of this value chain from the PESTEL perspectives

Business Functions
- Common pharmaceutical organisations and their structures
- Business and Management Functions within organisational types
- Employee types and skillsets needed in different functional areas

Key Industry Trends
- Current News
- Current Trends
- Industry 5.0
- Digitalisation
- Biopharmaceuticals
- Gene-therapies
- Innovation
- Patents

Manufacturing and Business Management Concepts
- Broad Overview Quality Management in the pharmaceutical industry
- Broad Overview of Lean in the pharmaceutical industry
- Broad Overview of Good Manufacturing Practice in the pharmaceutical industry

Understanding the External Environment
- The political context
- The economic context
- The social context
- The technological context
- The environmental context
- The legal context
- PESTEL Analysis

Sustainability in the Pharmaceutical Industry
- Supply Chains
- Value Chain
- Environmental Concerns
- Mitigation
- Progress to Date

Teaching Plan

Lesson 1	Understanding the Industry, the players within it, and its role in society, Workshop 1: Stakeholder Analysis Online Topic Assessment 1
Lesson 2	Key Trends Online Topic Assessment 2
Lesson 3	Organisations, Business Functions and the Pharmaceutical Value Chain. Understanding the External Environment Online Topic Assessment 3
Lesson 4	Group Assignment Preparation Session
Lesson 5	Key Manufacturing and Business Management Concepts Online Topic Assessment 4
Lesson 6	Sustainability Online Topic Assessment 5

B.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 internal environment, external environment, stakeholders, trends, value chains impact each other and our society. The module learning materials and online topic quiz assessments (worth 50% of the total grade at 10% per quiz) must be completed in advance of commencing week 1, semester 1, with the group assignment due in week 3 of semester 1 (also worth 50% of the total grade). The rationale for this assessment approach and schedule is to scaffold the reaching of learning outcomes in the most effective way to support other modules learners will be due to begin in semester 1.

Each Lesson has multiple components covering different aspects of the curriculum, and will consist of approximately 2 teaching hours and 2 tutorial hours, plus 4 hours of additional directed e-learning.

Each lesson (apart from lesson 4) includes an open book online micro-assessment which will test the learners understanding of the key concepts of the lesson. Together these micro-assessments will ensure learners have a strong understanding of the industry upon commencing the principal programme.

Lesson 1 focuses on developing an understanding of the pharmaceutical industry landscape, what it is, what it does, who is involved, its impact on society. It also uses analytical frameworks to explore the power relationships between stakeholders.

Lesson 2 includes understanding current industry trends and their implications for the industry.

Lesson 3 explores the industry value chain, and the internal and external environments that pharmaceutical organisations operate in. An assignment preparation lesson set will follow then follow.

The final lessons (5 and 6), explore business and manufacturing approaches that are common in the industry, and introduce the issue of sustainability into the future.

The module will be assessed on 100% continuous assignment. The assessment strategy may be varied as needed, but an indicative strategy is outlined within the Module Summative Assessment Strategy below.

B.7   Work-based learning and practice-placement
There is no work based learning or practical placement in the module.

B.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.

B.9   Module physical resource requirements
A classroom setting is used for the onsite & virtual delivery of the module through a series of lessons lectures including lessons, tutorials 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.

B.10   Reading lists and other information resources

Core Reference Materials

McGavock, H. (2017) *How Drugs Work: Basic Pharmacology for Healthcare Professionals*. CRC Press, Taylor & Francis.

Roy, J. (2011) *An Introduction to Pharmaceutical Sciences: Production, Chemistry, Techniques and Technology*. Elsevier.

Additional Resources

Aitken, M. (2016) 'Understanding the Pharmaceutical Value Chain'. *Pharmaceuticals Policy and Law*, *18*(1-4), pp.55-66.

Gorecki, P.K. (2018) 'State/industry medicine pricing agreements, cost savings and counterfactuals: the case of Ireland.' *The Economic and Social Review*, *49*(1, Spring), pp.111-126.

Harrison C F (2017) Starting out in the pharma industry: Essential knowledge for life scientists: Volume 1 (Life After Life Science) CreateSpace Independent Publishing Platform

Kumar, A., Zavadskas, E.K., Mangla, S.K., Agrawal, V., Sharma, K. and Gupta, D. (2019) 'When risks need attention: adoption of green supply chain initiatives in the pharmaceutical industry'. *International Journal of Production Research*, *57*(11), pp.3554-3576.

Mulinari, S., Martinon, L., Jachiet, P.A. and Ozieranski, P. (2021) 'Pharmaceutical industry self-regulation and non-transparency: country and company level analysis of payments to healthcare professionals in seven European countries'. *Health Policy*, *125*(7), pp.915-922.

Biopharma 2020, Ireland, Conference Summary report: https://2hmcriw3psofj2qo3f8w6f17-wpengine.netdna-ssl.com/wp-content/uploads/2020/05/BPA-Report-Final.pdf

Irish Pharmaceutical Healthcare Association: https://www.ipha.ie/about-the-industry/

Pharmacy Regulator: https://www.thepsi.ie/

ICH Quality guidelines, ICH 8, 9 & 10
http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

Good manufacturing practice (GMP) resources: http://www.ispe.org/gmp-resources

B.11   Specifications for module staffing requirements
Lecturer and other personnel should hold a Masters Level (Level 9) qualification in Business, Engineering, Management or Leadership 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).

B.12 Module summative 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 internal environment, external environment, stakeholders, trends, value chains impact each other and our society. These will be covered in lecturers and tutorials as outlined in earlier sections. The module will be assessed on 100% continuous assignment. 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	50%	Individual online micro-assessments	**A series of online micro-assessments:** Each lesson set comprises one online assessment which must be completed as learners work through the module online. These are open book and based on the principle of assessment as learning.	All MIMLOs
2	50%	Group Assessment	**Assessment: Industry Analysis** Learners are required to work together to develop and present an in-depth 20-minute presentation on an assigned Industry Trend, or to develop a written industry newsletter on key trends. This is very much an assessment as learning approach.	1, 3, 4

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.

B.13 Sample assessment materials

Please see sample assessment supplementary document.