

Module 11: Quality and Regulatory Practice in the Pharmaceutical Industry

Module title			
Quality & Regulatory Practice in the Pharmaceutical Industry			
Module NFQ level	Module number / reference	ECTS Value	Duration
9	MSC-PBM-QRP	5	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
Certificate in Quality & Regulatory Practice in the Pharmaceutical Industry		Award	N/a
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)	None		
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	<p>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.</p> <p>Industry experience is beneficial but not a requirement.</p> <p>Ideally, they would also hold a third level teaching qualification (e.g. the Griffith College Certificate in Education, Learning and Development).</p>		0.25

Analysis of required learning effort		
*Effort while in contact with staff	Minimum ratio teacher / learner	Hours
Classroom and demonstrations	1:100	30
Mentoring and small-group teaching	1:20	6
Other (specify)		
Independent Learning		
Directed e-learning (hours)		-
Independent Learning (hours)		89
Other hours (specify)		-
Work-based learning hours of learning effort		-
Total Effort (hours)		125

Allocation of Marks					
	Continuous Assessment	Supervised Project	Proctored Practical Exam.	Proctored Written Exam	Total
Percentage Contribution	50%	-	-	50%	100%

1.1.1 Module aims and objectives

This module aims to introduce learners to the quality systems and the regulatory framework that assures the quality, safety, and efficacy of medicinal products. The importance of pharmaceutical quality systems as a comprehensively designed and correctly implemented management system incorporating Good Manufacturing Practice (GMP) and Quality Risk Management is a fundamental part of this module. The module includes a broad overview of pharmaceutical product life cycle management in a regulatory and legal environment – from discovery through development and commercialization to patent expiry and post-market exclusivity.

This module aims to demonstrate the importance of pharmaceutical quality, and provide key information pertaining to quality approaches that apply to the development, manufacture, and supply of medicines. To integrate the principles of quality systems with management to enable learners to understand how they apply within business, and the effects of GxP on the business. It also aims to enable learners to understand the regulatory framework that underpins pharmaceutical product development from discovery through pre-clinical research, clinical trials, registration and release, and give learners an insight into the costs to the organisation of poor quality, how they are handled and appropriate strategies to mitigate against the risks. Finally, the module aims to provide an overview of the evolution of product profile; pharmaceutical quality, quality improvement and risk management practices in manufacturing (GMP) and supply. To understand the framework for distribution of pharmaceutical products on an international level.

1.1.2 Minimum intended module learning outcomes

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

- MIMLO 11.1 Critique the processes involved in bringing drugs from the development stage through to market as registered pharmaceutical medicines.
- MIMLO 11.2 Critically analyse the concepts of quality and quality assurance in the development, manufacture, and supply of medicines.
- MIMLO 11.3 Evaluate the importance and impact of quality systems in the manufacture and supply of medicines.
- MIMLO 11.4 Critically assess the role and activities of different regulatory bodies and the necessity for such control in the development, manufacture, and supply of medicines.

- MIMLO 11.5 Relate the impact and consequences of poor quality, deviations, complaints and recalls on the organisation, and describe approaches to address and prevent them.
- MIMLO 11.6 Critically assess the latest trends in quality systems, management, process control, medicines and regulation.

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

This is a core module on the programme, in addition to being offered as a standalone micro-credential. It aims to introduce learners to the quality systems and the regulatory frameworks that assures the quality, safety, and efficacy of medicinal products. The module includes a broad overview of pharmaceutical product life cycle management in a regulatory and legal environment – from discovery through development and commercialization to patent expiry and post-market exclusivity. This industry specialisation is of key importance for all pharmaceutical business managers. This module supports the achievement of the following MIPLOs (per each award):

Programme Title	MIPLOs achieved
MSc in Pharmaceutical Business Management	(i), (ii), (iv), (v), (x)
PgDip in Science in Pharmaceutical Business Management	(i) to (iv), (viii)
Certificate in Pharmaceutical Business Management	(i) to (iv), (vii)
Certificate in Quality and Regulatory Practice in the Pharmaceutical Industry	All MIPLOs

1.1.4 Information provided to learners about the module

This module aims to introduce learners to the role of marketers and marketing in the pharmaceutical industry, and to improve learner knowledge and understanding of the various approaches used. 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

Stages of bringing medicinal products and devices to market

- Drug (pre)formulation
- Small molecule and biopharmaceutical products (Regulation of Biological Medicinal Products and Advanced Therapies)
- Biotechnology and biosimilars
- Medical devices
- Product traceability

Pharmaceutical quality systems

- Defining quality
- Quality systems concepts
- Quality assurance approaches

- Requirements for quality systems
- Quality managements systems
- Quality control versus quality assurance
- Pharmaceutical quality within the management structure

Quality systems in practice – from molecule to market

- Legal and legislative basis – EU, USA, Asia.
- Regulations, guidelines and standards - CFR, EU Directives, Eudralex, ISO, (EU-and-US-GMP-GDP-similarities-and-differences)
- Good manufacturing practice (GMP)
- Good laboratory practice (GLP)
- Good clinical practice (GCP)
- Good distribution practice GDP
- Good documentation practice GDocP

Workshop 1: Assignment Workshop

- Review activities introduced in Lectures 1-6
- Relate theoretical concepts to practice.

Validation

- Validation strategies
- Change-control / re-validation
- Validation loop – Qualification versus validation

Regulatory affairs

- Auditing
- Auditing types and observations
- Tools to identify Problems
- Corrective and preventive actions CAPA
- Continuous quality improvement

Complaints, Quality defects and product recall

- Pharmacovigilance (PV), EudroVigilance, & Adverse drug reaction
- Post Market Surveillance
- Complaints
- Quality Defect Investigations
- Batch Recalls

Quality improvement and Risk management

- ICH Q8 Quality by Design (QbD)
- The QbD Approaches to pharmaceutical development and life-cycle management
- Process Analytical Technology PAT
- Risk & Principles of risk management

- Risk Management Tools in Pharmaceutical industry
- Quality Risk management Process QRM

Workshop 2: Revision

- Revision of key concepts
- Exam preparation techniques
- Exam sitting techniques.

Indicative Teaching Plan

Weeks 1 & 2	Stages of bringing medicinal products and devices to market
Week 3	Pharmaceutical quality systems
Weeks 4, 5, & 6	Quality systems in practice – from molecule to market
Week 7	Workshop 1: Assignment workshop
Week 8	Validation
Week 9	Regulatory affairs
Week 10	Complaints, Quality defects and product recall
Week 11	Quality improvement and Risk management
Week 12	Workshop 2: Revision

1.1.6 Module teaching and learning (including formative assessment) strategy

Lectures 1-6 and Workshop 1 (session 7) deal with key concepts of product development, quality, and good practices governing manufacturing (GMP) and supply of medicines. The lectures provide information and background to help learners understand the key steps and quality processes involved in bringing drugs from development through to the market. The module includes a case study to underpin theoretical content enabling learners to explore individual aspects in more depth and in the context of their own work environment.

Workshop 1 helps to bring together the practical and the theoretical content of the module and, helps learners to complete the continuous assessment element of the module. This assessment is worth 50% of the overall mark.

Lectures 8-11 and Workshop 2 (session 12) examine the processes and personnel involved in quality management. They examine role of personnel both within and beyond the organisation who have a role in ensuring the quality and safety of medicines. They highlight the roles and responsibilities of regulatory bodies in different jurisdictions and legislative requirements.

The series of lectures also aims to provide learners with an overview of examples of poor quality and associated costs, in addition to approaches and tools to mitigate against these. The intention is to equip learners with a full understanding of the regulatory affairs and quality management systems that are relevant to batch release. This will be illustrated using a worked example, which marries all the key processes together and the decisions that are made prior to final sign-off of a batch. This is intended to widen the learner's scope of understanding and development later in their careers.

Workshop 2 is a revision and exam preparation workshop that takes place towards the end of the module. Typical assignment could include: Letter sent from HPRA detailing issues found with a finished product discovered at pharmacy level. The learner would be required to formulate a reply to the letter outlining a course of action appropriate to the circumstances and their seriousness, e.g. giving assurance that the product does not need to be recalled.

The assignment would also include the learner to propose further actions required, e.g. Investigate possible Root Causes and implement Corrective and Preventative Actions (CAPA's).

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

Lewis, R.J., Weintraub, S., Stiler, B., McHugh, J. and Zan, R. (2015) *RESULTS: The Future of Pharmaceutical and Healthcare Marketing*. Advantage Media Group

Additional Resources

Allport-Settle, M.J., (2019) *Current Good Manufacturing Practices: Pharmaceutical, Biologics, and Medical Device Regulations and Guidance Documents Concise Reference*, 2nd Ed.

Raleigh, NC: PharmaLogika Books.

Code of Federal Regulations CFR211, FDA

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm>

Cooper, B. (2017). *The GMP Handbook: A Guide to Quality and Compliance* (Paperback).

CreateSpace Independent Publishing Platform

Cunningham, A. (2010) 'Just in Time: An Approach for a cGMP Fill-Finish Facility', *Pharmaceutical Engineering* magazine, March/April 2010 (ISPE).

Sharp, J, (2011) *Quality in the Manufacture of Medicines and Other Healthcare Products* (2nd ed), Pharmaceutical Healthcare & Sciences Society.

Nally, J.D, (Ed), (2007) *Good Manufacturing Practices for Pharmaceuticals*, 6th Edition (Drugs and the Pharmaceutical Sciences). London, UK: Informa Healthcare.

Rodriguez-Perez, J. (2017) *Quality Risk Management in the FDA-Regulated Industry*, 2nd Ed. Milwaukee, WI: ASQ (American Society for Quality) Press.

Van Liedekerke, B. and Maes, I. (2007) *Pharmaceutical Manufacturing: Linking Vision and Decision Making to Achieve a Roadmap Toward cGMPs for the 21st Century*, *Pharmaceutical Engineering* magazine, Jul/Aug 2007 (ISPE).

X. Yu, L and Woodcock, J. (2015) FDA pharmaceutical quality oversight, *International Journal of Pharmaceutics* 491 (2015) 2–7.

Website resources:

Code of Federal Regulations CFR211, FDA

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm>

EPA (2019) Waste Regulations

http://www.epa.ie/pubs/advice/waste/wastepermitregulations/#.VF_excm00bE

Eudralex, Volume 4 Ed., EMA

http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

FDA, "FDA statement on FDA's modern approach to advanced pharmaceutical manufacturing,"

February 26, 2019, <https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-modern-approach-advanced-pharmaceutical-manufacturing>.

Hausner, PhD, D.B. and Moore, PhD, C.M.V. "Continuous Manufacturing Current Status",

Pharmaceutical Engineering, May/June 2018, <http://ispe.rog/pharmaceutical-engineering/many-june-2018/continuous-manufacturing-current-status>

Good manufacturing practice (GMP) resources

<http://www.ispe.org/gmp-resources>

ICH Quality guidelines (2014) Guidance for Industry: Q8, Q9 & Q10

<http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>

Pharmacovigilance

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000258.jsp&mid=WC0b01ac05800241de

Quality Assurance of Pharmaceuticals – A Compendium of Guidelines and Related Materials – Vol 1 & 2

http://www.who.int/medicines/areas/quality_safety/quality_assurance/resources/en/

Quality by design

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000162.jsp

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

Learners are required to work on a 50% weighted assignment. This is a Work Based Activity (WBA), which requires learners to identify areas of pharmaceutical quality systems, GMP, the application of regulatory frameworks and the role of regulatory bodies in their own workplace or a context in which they plan to work in the future; and develop a written plan to advance their application of the theoretical to the practical.

Learners sit an end of semester examination which contributes 50% towards their final mark for this module. The exam paper will cover content related to Pharmaceutical Product Lifecycle Management – From molecule to market and relevant global regulatory frameworks that apply. The exam paper will consist of two sections; with section A consisting of a case study and short answer style questions and section B requiring learners to answer essay style questions.

No.	Weighting	Type	Description	Learning outcomes assessed
1	50%	Written Report	This is a Work Based Activity (WBA) based on a case study.	1-3, 6
2	50%	Written Examination	End of Semester Exam The exam paper will consist of two sections; with section A consisting of a case study and short answer style questions and section B requiring learners to answer essay style questions.	1-6

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.