UNIVERSITI MALAYA

FAKULTI FARMASI
Faculty of Pharmacy

POSTGRADUATE HANDBOOK

ACADEMIC SESSION 2024/2025

Faculty of Pharmacy, Universiti Malaya reserves the right to make decisions and amendments to the information contained in this Handbook as it deems.

Faculty of Pharmacy
Universiti Malaya
50603 Kuala Lumpur
https://pharmacy.um.edu.my

Welcoming Message from Dean

Welcome to the Faculty of Pharmacy, Universiti Malaya!

We are excited to welcome you to our esteemed faculty, ranked among the top 60 in the QS World University Rankings. Congratulations on embarking on this vital step in your career through our postgraduate programs.

Whether you are enrolled in the Master of Science in Pharmacy (MScP), Master in Pharmaceutical Legislation and Regulatory Control, Master of Pharmaceutical Science in Drug Discovery and Development, or Doctor of Philosophy (PhD), you are entering a transformative journey that will shape your future in pharmacy.

Our programs are designed to equip you with advanced knowledge and skills, whether you focus on research, regulatory science, or drug development. Your work here will be critical to tackling pressing healthcare challenges and advancing pharmaceutical sciences globally.

We encourage you to strive for both academic excellence and personal growth. In today's evolving healthcare environment, the ability to innovate, lead, and collaborate is crucial. Our faculty is committed to supporting you with top-tier education and mentorship to ensure you are fully prepared for your future roles.

As you pursue your studies, stay motivated and aim high. Your journey with us will not only advance your career but will also contribute to the future of healthcare.

Thank you, and **Welcome on Board**!

PROFFESOR DR. HASNIZA ZAMAN HURI
Dean
Faculty of Pharmacy

Foreword from the Deputy Dean of Postgraduate, Research and Innovation

Dear Postgraduate Students,

Welcome to the Faculty of Pharmacy at Universiti Malaya!

As Deputy Dean of Postgraduate, Research, and Innovation, it is my pleasure to congratulate you on joining one of the most dynamic academic communities in the world.

Whether you are pursuing a postgraduate program by coursework or research, you are about to embark on an exciting academic journey that will challenge, inspire, and equip you to make impactful contributions to healthcare and pharmaceutical sciences.

Our faculty is committed to supporting your academic and research goals. We provide a vibrant, interdisciplinary environment where innovation is encouraged and excellence is nurtured. I encourage you to fully engage with your program and take advantage of the vast opportunities for research, collaboration, and personal growth that lie ahead.

I am confident that your time here will be transformative and fulfilling, and I look forward to seeing your achievements contribute to the global advancement of science and healthcare.

Once again, welcome, and best of luck on this exciting journey.

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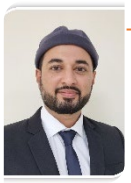

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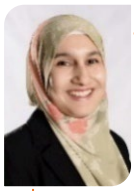

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VISSION, MISSION, OBJECTIVES AND MOTTO

VISION

To be a global eminent faculty in pharmacy education, research and innovation

MISSION

To produce high-quality graduates and research towards enhancement of nation's health and well-being

OBJECTIVES

- To nurture competitive, innovative and highly ethical graduates that effectively contribute to healthcare
- To foster innovative and cutting-edge research to impact human health nationally and globally
- To develop outstanding leaders in healthcare that inspire future tranformation of the society

MOTTO

- EPITOME OF EXCELLENCE

MASTERS OF PHARMACEUTICAL SCIENCE IN DRUG DISCOVERY AND DEVELOPMENT (COURSEWORK)

PROGRAMME TITLE, PHILOSOPHY, PRINCIPLES, PROGRAMME EDUCATIONAL OUTCOMES (PEO) AND PROGRAMME LEARNING OUTCOMES (PLO)

Programme Title

Title of the conferred degree: Masters of Pharmaceutical Science in Drug Discovery and Development

Programme Philosophy

The Masters of Pharmaceutical Science in Drug Discovery and Development programme offered by the Universiti Malaya is based on the following philosophy.

- *The programme offers a curriculum that equip graduates with a comprehensive understanding of drug discovery, technological advancements, ethical considerations and global perspective in innovative drug development.*

Programme Principles

Aligning to the programme philosophy, the programme revolves around the following key principles:

1. Integration of multidisciplinary knowledge in various disciplines such as bioinformatics, advanced medicinal chemistry and biology, pharmacology, clinical and regulatory affairs, and advanced pharmaceutics to provide a holistic approach in providing a well-rounded education that prepares graduates to tackle complex drug discovery and development issues.
2. Experiential learning through a guided research project that will instill research skills, extensive hands-on experience, critical thinking, problem solving abilities necessary for a successful drug discovery and development.
3. Encourages exploration of the latest research and technological advancement in drug discovery and development to produce innovative and technological driven approaches in advancing the field.
4. Cultivates professional ethics and integrity through awareness in ethical framework, regulatory guidelines and responsible conduct in drug discovery and development.
5. The programme instill passion for lifelong learning and continuous professional development so graduates will adapt to the rapidly evolving field of drug discovery and development throughout their career.

Programme Educational Objectives (PEO)

1. Graduates will establish themselves as professionals by applying in-depth knowledge and understanding critically and creatively to resolve complex drug discovery and development or related pharmaceutical problems.
2. Graduates will adapt proficiently a wide range of digital and analytical tools or technologies to conduct research or investigation in resolving complex issues and questions related to the areas of drug discovery and development independently while adhering to legal, ethical, professional and sustainable practice.
3. Graduates will communicate effectively and demonstrate good leadership quality in an organisation.
4. Graduates will continue to improve by engaging in lifelong interdisciplinary learning essential for industrial, research and academic careers.

Programme Learning Outcomes (PLO)

PLO1 – Demonstrate in-depth and accurate knowledge and understanding towards current and future needs in the areas of drug discovery and development.

PLO2 – Apply knowledge critically and creatively to resolve complex disciplinary and practical problems in the areas of drug discovery and development.

PLO3 – Conduct credible problem solving or investigation to resolve complex issues and questions in the areas of drug discovery and development.

PLO4 – Communicate and interact effectively with peers in the areas of drug discovery and development as well as general audience.

PLO5 – Select and use suitable digital and analytical tools or techniques to resolve drug discovery and development related problems.

PLO6 – Demonstrate leadership qualities through collaboration with peers and others.

PLO7 – Demonstrate commitment to lifelong learning and personal development.

PLO8 – Conduct research and investigation with minimal supervision adhering to legal, ethical, professional and sustainable practice in the areas of drug discovery and development.

ACADEMIC PROGRAMME

PROGRAMME STRUCTURE

NO.	COURSE		CREDIT
1.	Core Courses	OQB7001 Methods in Drug Discovery and Pre-Clinical Drug Development	4
		OQB7002 Clinical Research and Regulatory Affairs	4
		OQB7003 Advanced Pharmacology and Toxicology	4
		OQA7005 Pharmaceutical Product Development	4
		OMX7001 Research Methodology	3
		OQB7004 Research Project	12
2.	Choose **FOUR** Electives	OQB7005 Pharmaceutical Bioinformatics	12
		OQB7006 Advanced Medicinal Chemistry	
		OQB7007 Pharmacogenomics, Pharmacokinetics, and Pharmacodynamics in Precision Medicine	
		OQA7008 Design of Pharmaceutical Dosage Forms	
		OQA7009 Development of Novel Drug Delivery Systems	
		OQA7010 Pharmaceutical Engineering and Production Facilities	
Total Credit Value			43

COURSE STRUCTURE

FULL TIME STUDY PLAN

Year	Component	Semester I			Semester II			Special Semester		
		Code	Course	Credit	Code	Course	Credit	Code	Course	Credit
1	Core	OQB7001	Methods in Drug Discovery and Pre-Clinical Drug Development	4	OQB7002	Clinical Research and Regulatory Affairs	4	OQB7004	Research Project*	6
		OQA7005	Pharmaceutical Product Development	4	OQB7003	Advanced Pharmacology and Toxicology	4			
		OMX7001	Research Methodology	3	OQB7004	Research Project*	6			
	Elective		Elective Elective	3 3		Elective Elective	3 3			
	Total Credit			**17**			**20**			**6**
Grand Total Credits = 43										

* Continue to special semester

ELECTIVE COURSES LIST

Drug Discovery Path:

1. Pharmaceutical Bioinformatics
2. Advanced Medicinal Chemistry
3. Pharmacogenomics, Pharmacokinetics and Pharmacodynamics in Precision Medicine

Drug Development Path:

4. Pharmaceutical Engineering and Production Facilities
5. Design of Pharmaceutical Dosage Forms
6. Development of Novel Drug Delivery Systems

PART TIME STUDY PLAN

Year	Component	Semester I			Semester II			Special Semester		
		Code	Course	Credit	Code	Course	Credit	Code	Course	Credit
1	Core	OQB7001	Methods in Drug Discovery and Pre-clinical Drug Development	4	OQB7002	Clinical Research and Regulatory Affairs	4			
		OQA7005	Pharmaceutical Product Development	4	OQB7003	Advanced Pharmacology and Toxicology	4			
	Elective		Elective	3		Elective	3			
	Total Credit			**11**			**11**			

Year	Component	Semester I			Semester II			Special Semester		
		Code	Course	Credit	Code	Course	Credit	Code	Course	Credit
2	Core	OMX7001	Research Methodology	3	OQB7004	Research * Project	6	OQB7004	Research Project*	6
	Elective		Elective	3		Elective	3			
	Total Credit			**6**			**9**			**6**
Grand Total Credits = 43										

* Continue to special semester

ELECTIVE COURSES LIST

Drug Discovery Path:

1. Pharmaceutical Bioinformatics
2. Advanced Medicinal Chemistry
3. Pharmacogenomics, Pharmacokinetics and Pharmacodynamics in Precision Medicine

Drug Development Path:

4. Pharmaceutical Engineering and Production Facilities
5. Design of Pharmaceutical Dosage Forms
6. Development of Novel Drug Delivery Systems

COURSE SUMMARY

CORE COURSES

OQB7001 Methods in Drug Discovery and Pre-Clinical Drug Development (4 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Discuss the concepts and applications of drug discovery and development.
- Demonstrate practical and analytical skills on drug design and discovery methods.
- Relate the lead compound identification and characterisation using advanced analytical techniques.

Course Synopsis

This course aims to provide advanced concepts of both theoretical and practical aspects of drug design, drug development, plan, and undertake the data from lab-based examinations, investigations, trials by carrying out experiments and simulations to attain expertise in the areas of molecular docking, computational chemistry, medicinal chemistry, drug synthesis, drug discovery and bioassays.

Reference

1. Silverman R.B. and Holladay, M.W. The Organic Chemistry of Drug Design and Drug Action, 3rd edition, 2015, Academic Press, Waltham MA, USA
2. Patrick, G. L. An introduction to Medicinal Chemistry, International Edition, 2018, BIOS Scientific Publishers, Oxford, UK
3. Skoog, D.A., West, D.M., Holler F.J. (2021). Fundamentals of Analytical Chemistry, 10th Edition, Saunders, Philadelphia.
4. Watson. D.G. (2017). Pharmaceutical Analysis E-Book: A Textbook for Pharmacy Students and Pharmaceutical Chemists, 4th Edition, Churchill Livingstone: London.
5. Singh, D. B. (2020). Computer-Aided Drug Design. Springer. (e-Book)

Marking and Assessment Methods

Continuous Assessment 100%

OQB7002 Clinical Research and Regulatory Affairs (4 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Explain good clinical practice, clinical trials management, and monitoring.
- Analyse the local and global regulations governing clinical research.
- Evaluate clinical research procedures and methods in accordance with ethics and compliance with guidelines.

Course Synopsis

This course is designed to provide knowledge on clinical research which is an important field of medical science that deals with the evaluation of new drugs and novel therapies. This course also exposes the students to the domain of regulatory affairs which forms a network of standardised laws, regulations, and guidelines. The regulatory affairs thus facilitate new therapy innovation and safety of subjects enrolled in clinical research and trial management. This module will also cover the evaluation aspect of clinical research.

Reference

1. Chow & Liu. Design and Analysis of Clinical Trials: Concepts and Methodologies, Third Edition. 2013. Wiley.
2. Lawrence M et al. Fundamentals of Clinical Trials. Fifth Edition. 2015 Edition. Springer.
3. Stephen B Hulley et al. Designing Clinical Research. Fifth Edition. 2022. Wolters Kluer.
4. Malaysian Guideline for Good Clinical Practice. Fourth Edition. 2018, NPRA, MOH.
5. Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition, 2016, NPRA, MOH.
6. Malaysian Guideline for Safety Reporting of Investigational Products, First Edition, 2014, NPRA, MOH
7. Malaysian Guideline for Application of Clinical Trial Import License and Clinical Trial Exemption. 6.3 Edition, July 2016, NPRA, MOH.
8. Guidelines for Good Clinical Practice (GCP) Inspection, 2015, NPRA, MOH.

Marking and Assessment Methods

Continuous Assessment 100%

OQB7003 Advanced Pharmacology and Toxicology (4 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Relate the principles of pharmacology and toxicology in drug development and action.
- Implement studies involving molecular and experimental pharmacology to identify drug target interaction on signalling.
- Apply toxicology knowledge to the safety assessment of drugs in humans.

Course Synopsis

In this module, students will learn the principles of pharmacology and relate it to the development of medicines and the treatment of disease. In addition, students will learn the principles of toxicology and how toxicology is applied to assess the toxicity effects of drugs to humans.

Reference

1. Katzung, B.G. (2020) Basic and Clinical Pharmacology. 15th edition. McGraw Hill.
2. Rang, H.P., Dale, M.M., Ritter, J.M. & Moore, P.K. (2018) Pharmacology. 9th edition. Churchill Livingstone.
3. Goodman & Gilman's The Pharmacological Basis of Therapeutics (2018). 13th edition. McGraw-Hill.
4. Francesco C, Guido F. (2015). General and Molecular Pharmacology. 1st edition. Wiley.
5. 5) Klaassen, C. D. (2018) Toxicology: The basic science of poisons. Casarett & Doull's 9th edition. McGraw-Hill Medical.
6. 6) Williams, P.L., James, R. C., Roberts, S. M. (2022) Principles of toxicology: Environmental and Industrial Applications. 4th edition. John-Wiley.

Marking and Assessment Methods

Continuous Assessment 100%

OQB7004 Research Project (12 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Prepare a written research proposal.
- Integrate the principles of research in carrying out data collection.
- Interpret data correctly.
- Critique research findings in relation to published literature.
- Compose a written dissertation according to the requirements.
- Perform an oral presentation of the research findings.

Course Synopsis

Students will carry out their research project under the supervision and guidance of the respective lecturers in the Faculty of Pharmacy. They will collect data, analyse them and write-up their dissertations. Every student will also present their work orally.

Reference

1. Ecarnot, F., Seronde, M. F., Chopard, R., Schiele, F., & Meneveau, N. (2015). Writing a scientific article: A step-by-step guide for beginners. European Geriatric Medicine, 6(6), 573-579.
2. Paltridge B, Starfield S. Thesis and Dissertation Writing in a Second Language: A Handbook for Students and Their Supervisors. 2nd ed. Routledge; 2020. doi:10.4324/9781315170022.
3. John I. Gallin, Frederick P. Ognibene, and Laura Lee Johnson. 2017. Principles and Practice of Clinical Research, 4th Edition. Academic Press, Inc., USA.

Marking and Assessment Methods

Continuous Assessment 100%

OMX7001 Research Methodology (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Determine research questions or/and research hypothesis for a related research.
- Critically analyse literature reviews based on their respective areas of research.
- Appraise principles underlying responsible conduct of research.
- Relate ethics and professionalism in conducting research based on relevant case studies.

Course Synopsis

This course is designed to provide knowledge and skills to the candidate related to research and responsible conduct of research. The content of this course includes introduction to research methodologies, literature review, research design, research proposal writing, research ethics, data analysis, usage of research software and topics related to good research practices.

Reference

1. Stephen B. Heard. The scientist's guide to writing: how to write more easily and effectively throughout your scientific career, Princeton University Press, 2016
2. Chinna K, Choo WY, Krishnakumari K. Statistical analysis using SPSS, Pearson Malaysia Sdn Bhd, 2016.
3. C.R. Kothari. Research methodology: Methods and techniques, 4th Edition, New Age International Pvt Ltd Publishers, 2019.
4. David Robertson Gordon Williams. Clinical and translational science, 2nd Edition, Academic Press, 2016.
5. Rita Faria. Research misconduct as white-collar crime. Palgrave Macmillan, 2018.
6. Edward Zanders, Lindsay MacLeod. Presentation skills for scientists: A practical guide. 2nd edition, Cambridge University Press, 2018.
7. Raymond Boxman, Edith Boxman. Communicating science: A practical guide for engineers and physical scientists, WSPC, 2016.
8. Malaysian education module on responsible conduct of research. (2017). Akademi Sains Malaysia.
9. The Malaysian Code of Responsible Conduct in Research. (2017). National Science Council.

10. How to work with your Institutional Animal Care and Use Committee (IACUC) https://ori.hhs.gov/education/products/ncstate/index.htm - Click on 'IACUC' at the bottom of the menu on the left of screen.

Marking and Assessment Methods

Continuous Assessment 100%

ELECTIVE COURSES
(DRUG DISCOVERY PATH)

OQB7005 Pharmaceutical Bioinformatics (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Use bio- or chemoinformatics tools and databases within pharmaceutical research.
- Analyse and interpret output from various online tools relevant to pharmaceutical bioinformatics.
- Integrate the use of bio- and chemoinformatics tools in pharmaceutical research.

Course Synopsis

This course is designed to give students a basic theoretical background and a working knowledge of the bioinformatics techniques that are related to pharmaceutical sciences. Emphasis will be placed on the application of the free tools available rather than the underlying theories and the course covers topics such as databases and tools, representation of molecules, alignment, homology modelling, docking, and QSAR, that are useful in designing new drugs.

Reference

1. Jarl E. S. Wikberg. 2020. Introduction to Pharmaceutical Bioinformatics, 4th Edition, Oakleaf Academic.
2. Navneet Sharma, Himanshu Ojha, Pawan Raghav, and Ramesh Goyal. 2021. Chemoinformatics and Bioinformatics in the Pharmaceutical Sciences, Elsevier.
3. Chris Rostron. 2020. Drug Design and Development, Oxford University Press.
4. Graham Patrick. 2017. Introduction to Medicinal Chemistry, 6th edition, Oxford University Press.

Marking and Assessment Methods

Continuous Assessment 100%

OQB7006 Advanced Medicinal Chemistry (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Relate the biological activity of the major drug classes to the chemical structures.
- Review the development of important drugs in the major drug classes and their structure-activity relationships.
- Design new chemical structures with potential biological activities.

Course Synopsis

This course deepens the understanding of the physicochemical concepts which underlie drug design and action.

Reference

1. Graham Patrick. Introduction to Medicinal Chemistry, 6th edition, Oxford University Press, 2017, ISBN: 9780198749691
2. Langer, Thierry & Bryant, Sharon. (2019). Successful Drug Discovery, Volume 4. Edited by János Fischer, Christian Klein, and Wayne E. Childers. ChemMedChem. 15. 10.1002/cmdc.201900599

Marking and Assessment Methods

Continuous Assessment 100%

OQB7007 Pharmacogenomics, Pharmacokinetics, and Pharmacodynamics in Precision Medicine (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Analyse the challenges and limitations of pharmacogenetic studies.
- Explain how genetic variation can affect the pharmacokinetics or pharmacodynamics of drugs.
- Appraise the strategies and analytical approaches for stratifying patients for optimal drug response or adverse drug reactions.
- Explain the different types of current and emerging biomarkers used in personalised medicine.

Course Synopsis

Pharmacogenomics and individualised therapy are exciting areas of medicine and scientific research. It has been known for many years that genetic variation can affect the efficacy of some drugs which may also result in adverse side effects. Recently, there have been developments in the treatment of diseases such as cancer and cystic fibrosis on the basis of patients' genetic information and are having a real impact on their survival and quality of life. In this module you will cover the basic concepts of pharmacogenomics and relate these to current clinical practice where appropriate. Additionally, you will have the opportunity to study in depth examples of individualised therapy in diseases such as cancer, cystic fibrosis and diabetes. You will also consider the introduction of genetic testing for new pharmacogenomic discoveries taking into account analytical and clinical validity, clinical utility and ethical aspects.

Reference

1. Martin M. Zdanowicz. (2017) Concepts in Pharmacogenomics, American Society of Health-System Pharmacists.
2. Wu, Alan H. B., Yeo, Kiang-Teck J. (2011) Pharmacogenomic Testing in Current Clinical Practice: Implementation in the Clinical Laboratory. Molecular and Translational Medicine, Springer.
3. Bertino, Joseph S., Koshuba, Angela, Ma, Joseph D., Fuhr, Uwe, De Vane, C. Lindsay. (2012) Pharmacogenomics: An Introduction and Clinical Perspectives, 1 st Edition, McGraw Hill.
4. Y.W. Francis Lam, Stuart A. Scott. (2019) Pharmacogenomics: challenges and opportunities in therapeutic implementation.
5. John E. Murphy (2017) Clinical pharmacokinetics. American Society of Health-System Pharmacists, 6th Edition.

6. Hartmut Derendorf, Stephan Schmidt (2019) Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications.LWW, 5th Edition.

Marking and Assessment Methods

Continuous Assessment 100%

ELECTIVE COURSES
(DRUG DEVELOPMENT PATH)

OQA7008 Design of Pharmaceutical Dosage Forms (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Examine various concepts of pharmaceutical formulation development and their packaging methods.
- Perform experiments and quality testing of the prepared pharmaceutical formulations.
- Measure the sequence of steps and factors affecting the design of formulation using a software.

Course Synopsis

Students will be introduced to the formulation aspects such as excipients. Students will get a detailed description of the formulation process of the solid, liquid and semisolid dosage forms. In addition, the students will also learn the experimental knowledge of dosage formulation.

Reference

1. Aulton's Pharmaceutics (2017): The Design and Manufacture of Medicines, 5th edition, Churchill livingstone, UK.
2. Remington: The Science and Practice of Pharmacy (2020), 23nd edition. Adeboye Adejare, Acedemic press. USA.
3. Handbook of Pharmaceutical Manufacturing Formulations, Third Edition (3rd ed.) (2019), 3 rd edition, Volume Six, Sterile Products. Sarfaraz K. Niazi, CRC Press, Florida, USA.
4. The Theory and Practice of Industrial pharmacy (2017), by Lachman and Lieberman, 4th edition, CBS publisher & Distributors.India.
5. United States Pharmacopoeia 43-NF 38, 2020.
6. British Pharmacopoeia 2018.

Marking and Assessment Methods

Continuous Assessment 60%

Final Examination 40%

OQA7009 Development of Novel Drug Delivery Systems (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Integrate the concepts of different novel drug delivery approaches in the literature and at the development stage.
- Explain the significance of nanotechnology and nanocarriers to ascertain the clinical intentions via diverse drug routes of administration.
- Integrate the awareness and skills necessary in the manufacturing of novel drug delivery systems.

Course Synopsis

Students will be introduced to overall concept of drug delivery and mechanisms of novel innovative drug delivery methods. Students will also be introduced to the principles of manufacturing of novel drug delivery products for various route of administration. Latest developments in the medical devices, biomolecular and biotechnology products will also be discussed that are in the market or those which are still in the research pipeline.

Reference

1. Aulton (2018) Aulton's Pharmaceutics: The design and manufacture of medicines, 4e, Churchill Livingstone.
2. Lyod Allen (2017) Ansel’s pharmaceutical dosage forms and drug delivery systems, Lippincott Williams & Wilkins, Philadelphia, USA.
3. Sarfaraz K. Niazi (2019) Handbook of Preformulation, Second edition, CRC Press, Tayler & Francis Group, UK.
4. Remington (2017) Essentials of Pharmaceutics, Edi. Linda Felton, Pharmaceutical Press, UK.
5. Sarfaraz K. Niazi (2019) Handbook of Pharmaceutical Manufacturing formulations, Third edition, CRC Press, Tayler & Francis Group, UK.
6. British Pharmacopoeia (2020) BP commission, UK.
7. United States Pharmacopoeia 42-NF 37 (2019) USP commission, Rockville, USA.
8. Remington (2020) The science and practice of pharmacy, 23 rd Edition, Edi.Adeboye Adejare, Academic press, Massachusetts, USA.

Marking and Assessment Methods

Continuous Assessment 100%

OQA7010 Pharmaceutical Engineering and Production Facilities (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Analyse the various facilities required in manufacturing of pharmaceutical products.
- Differentiate the pharmaceutical engineering concept and manufacturing production facilities.
- Plan the facilities required for the pharmaceutical industries.

Course Synopsis

Students will be introduced to the pharmaceutical engineering and technology, industrial design, production facilities and layout for tablet, capsule, liquid and semisolid dosage forms. Students will learn about the types of equipment and their function used in pharmaceutical dosage formulation including solid, liquid and sterile. They will also obtain detailed knowledge about the automated system used in industries and the process flow involved in production.

Reference

1. Cole, G. (1998). Pharmaceutical Production Facilities: Design and Applications. CRC Press. USA
2. Carlton and J. Agalloco, Validation of Pharmaceutical Processes, Marcel Dekker, Inc., 3rd Edition, 2003
3. Marlin TE. 2000. Process Control. Glandt ED, Klein MT, Edgar TF, editors. Singapore: Mc Graw Hill.
4. Seider WD, Seader JD, Lewin DR. 2003. Product and Process Design Principles. India: John Wiley and Sons Inc.
5. Sharp J. 2005. Good Pharmaceutical Manufacturing Practice. United States: CRC Press

Marking and Assessment Methods

Continuous Assessment 60%

Final Examination 40%

MASTERS IN PHARMACEUTICAL LEGISLATION AND REGULATORY CONTROL

(COURSEWORK)

PROGRAMME TITLE, OBJECTIVE, PROGRAMME EDUCATIONAL OUTCOMES (PEO) AND PROGRAMME LEARNING OUTCOMES (PLO)

Programme Title

Title of the conferred degree: Masters in Pharmaceutical Legislation and Regulatory Control

Programme Objective

The Masters in Pharmaceutical Legislation and Regulatory Control (PLRC) is a mode course one (1) year program with the aim of producing knowledgeable graduates in pharmaceutical legislation and regulatory affairs to meet the demand by government health related regulatory bodies and health related industries, such as pharmaceutical, cosmeceutical and nutraceutical.

Programme Educational Objectives (PEO)

1. Graduates will establish themselves as professionals in organisations related to pharmaceutical legislation and regulatory control (Professionalism).
2. Graduates will continue to improve skills engaging in lifelong learning in interdisciplinary fields (Personal continuous improvement).
3. Graduates will effectively communicate and demonstrate good leadership quality in an organisation (interpersonal and communication skills).
4. Graduates will contribute to the well-being of society (Social engagement).

Programme Learning Outcomes (PLO)

PLO1 – Acquire an in-depth and accurate knowledge towards current and future needs in the areas of legislation and regulatory control of pharmacy industry.

PLO2 – Apply knowledge critically to resolve complex problems in the area of legislation and regulatory control of pharmacy industry.

PLO3 – Demonstrate competency at work and undertake challenges positively related to the field of study.

PLO4 – Convey ideas and scientific knowledge to a diversity of audiences and work along collaboratively with people from different professions and communities.

PLO5 – Competently use a wide range of digital technologies and media to enhance study and research.

PLO6 – Demonstrate leadership, accountability, professionalism, and decision-making capability by working towards pre-determined goals and outcome.

PLO7 – Recognize the need to engage in life-long learning and entrepreneurial skills for continuous professional development.

PLO8 – Contribute professionally in improving legislation and regulatory control of pharmacy industry locally and globally.

ACADEMIC PROGRAMME

PROGRAMME STRUCTURE

NO.	COURSE		CREDIT
1.	Core Courses	OQA7001 Pharmaceutical Legislation	4
		OQA7002 Introduction to Legislation Writing and Auditing	3
		OQA7003 Quality Assurance	3
		OQA7004 Pharmaceutical Regulatory Affair	4
		OQA7005 Pharmaceutical Product Development	4
		OQA7006 Research Project	8
		OQA7007 Pharmaceutical Analysis and Testing	4
		OMX7001 Research Methodology	3
2.	Choose **THREE** Electives	OQB7005 Pharmaceutical Bioinformatics	3
		OQB7006 Advanced Medicinal Chemistry	3
		OQB7007 Pharmacogenomics, Pharmacokinetics, and Pharmacodynamics in Precision Medicine	3
		OQA7008 Design of Pharmaceutical Dosage Forms	3
		OQA7009 Development of Novel Drug Delivery Systems	3
		OQA7010 Pharmaceutical Engineering and Production Facilities	3
Total Credit Value			**42**

COURSE STRUCTURE

FULL TIME STUDY PLAN

YEAR 1									
Components	**Semester I**			**Semester II**			**Special Semester**		
	Code	**Course**	**Credit**	**Code**	**Course**	**Credit**	**Code**	**Course**	**Credit**
Core courses	OQA7001	Pharmaceutical Legislation	4	OQA7002	Introduction to Legislation Writing and Auditing	3			
	OQA7003	Quality Assurance	3	OQA7004	Pharmaceutical Regulatory Affair	4			
	OQA7005	Pharmaceutical Product Development	4	OQA7006	Research Project*	4	OQA7006	Research Project*	4
	OQA7007	Pharmaceutical Analysis and Testing	4					Elective	3
	OMX7001	Research Methodology	3						
Elective courses					Elective	3			
					Elective	3			
Total credits			**18**			**17**			**7**
Total Programme credits = **42**									

*Continue to special semester

ELECTIVE COURSES LIST

OQA7008 Design of Pharmaceutical Dosage Forms
OQA7009 Development of Novel Drug Delivery Systems
OQA7010 Pharmaceutical Engineering and Production Facilities
OQB7005 Pharmaceutical Bioinformatics
OQB7006 Advanced Medicinal Chemistry
OQB7007 Pharmacogenomics, Pharmacokinetics and Pharmacodynamics in Precision Medicine

PART TIME STUDY PLAN

YEAR 1									
Components	Semester I			Semester II			Special Semester		
	Code	Course	Credits	Code	Course	Credits	Code	Course	Credits
Core courses	OQA7001	Pharmaceutical Legislation	4	OQA7002	Introduction to Legislation Writing and Auditing	3			
	OQA7003	Quality Assurance	3	OQA7004	Pharmaceutical Regulatory Affair	4			
	OQA7005	Pharmaceutical Product Development	4						
Elective courses								Elective	3
Total credits			**11**			**7**			**3**

YEAR 2									
Components	Semester I			Semester II			Special Semester		
	Code	Course	Credits	Code	Course	Credits	Code	Course	Credits
Core courses	OQA7007	Pharmaceutical Analysis and Testing	4	OQA7006	Research Project*	4	OQA7006	Research Project*	4
	OMX7001	Research Methodology	3						
Elective courses					Elective	3			
					Elective	3			
Total creditss			**7**			**10**			**4**
Total Programme credits = **42**									

* Continue to special semester

ELECTIVE COURSES LIST

OQA7008 Design of Pharmaceutical Dosage Forms
OQA7009 Development of Novel Drug Delivery Systems
OQA7010 Pharmaceutical Engineering and Production Facilities
OQB7005 Pharmaceutical Bioinformatics
OQB7006 Advanced Medicinal Chemistry
OQB7007 Pharmacogenomics, Pharmacokinetics and Pharmacodynamics in Precision Medicine

COURSE SUMMARY

CORE COURSES

OQA7001 Pharmaceutical Legislation (4 Credits)

Learning Outcomes

At the end of the course, the students will be able to:

- Apply the concept of basic laws and related to the Pharmaceutical Legislation.
- Perform investigation and prosecution relating to the Pharmaceutical Law.
- Demonstrate ability to prosecute in mock courts presentation relating to cases of the pharmaceutical law.

Course Synopsis

Students will be introduced to concept of basic laws and legislation followed by the understanding of the five Malaysian Pharmaceutical Legislations. These legislations govern the control on chemical and pharmaceutical material, medicine, advertisement of medicine and medical matters as well as the professional ethics of pharmacist. Students will be exposed to the techniques of investigation and prosecution relating to the pharmaceutical laws. Student will have also been trained to hands-on mock trials relating to cases of the pharmaceutical laws.

Reference

1. Poisons act 1952 and its regulations.
2. Poisons act (advertisements and sales) 1956 and its regulations.
3. Drug sales act 1952 and its regulations.
4. Pharmacist registration act 1951 and its regulations.
5. Dangerous drug acts 1952 and its regulations.
6. Code of Ethics for Pharmacists 2018.
7. Malaysian National Medicine Policy 2012
8. Good Governance for Medicine (www.pharmacy.gov.my).
9. Malaysian Patent Act 1983 and its regulations.
10. Drug Supply Chain Security Act 2013.
11. Criminal Procedure Code Act 593 2016.
12. Evidence Act 1950 and its revision.
13. Trade Act 2010

Marking and Assessment Methods

Continuous Assessment 100%

OQA7002 Introduction to Legislation Writing and Auditing (3 Credits)

Learning Outcomes

At the end of the course, the students will be able to:

- Amend existing pharmaceutical law related.
- Draft the pharmaceutical law related and an intellectual property right (IPR) application.
- Conduct quality audit on the pharmaceutical premises according to pharmaceutical law.

Course Synopsis

Students will be exposed to the concept and techniques of amending the existing and drafting a new law related to the pharmaceutical as well as drafting for patent application. Student will also be trained to hands-on Quality Audit to develop skill in auditing pharmaceutical premises.

Reference

1. Poisons act 1952 and its regulations.
2. Poisons act (advertisements and sales) 1956 and its regulations.
3. Drug sales act 1952 and its regulations.
4. Pharmacist registration act 1951 and its regulations.
5. Dangerous drug acts 1952 and its regulations.
6. Code of Ethics for Pharmacists 2018.
7. Pharmaceutical Inspection Co-operation Scheme (IPCS) GMP guidelines 2021.
8. Malaysian Patent Act 1983 and its regulations.
9. Drug Supply Chain Security Act 2013.
10. Criminal Procedure Code Act 593 2016.
11. Evidence Act 1950 and its revision.
12. Trade Act 2010

Marking and Assessment Methods

Continuous Assessment 100%

OQA7003 Quality Assurance (3 Credits)

Learning Outcomes

At the end of the course, the students will be able to:

- apply the concept of various Good Regulatory Practices in pharmaceutical industry and other health care related industries.
- illustrate the regulatory requirements in drug development process.
- prepare various type of required Good Manufacturing Practice (GMP) documents in pharmaceutical industry and other health care related industries.

Course Synopsis

Students will be explored to the pharmaceutical industry and other health care industries worldwide. Students will also learn the overall concept of Quality Management system, Good Regulatory Practices such as GMP, GDP and GLP. Topics pertaining to the drug development and regulatory requirements will also include in this module. Students will be given project-based learning (PBL) workshop covering preparation of documents related to pharmaceutical industry and other related healthcare industries, such as preparation of site master file, drug master file, product development report, validation report, various standard operating procedures in production and quality control.

Reference

1. Aulton's Pharmaceutics (2021): The Design and Manufacture of Medicines, 6th edition, Churchill livingstone, UK.
2. Remington: The Science and Practice of Pharmacy (2020), 23rd edition. Mack Publishing Co. USA.
3. Sale of Drugs Act 1952.
4. Rules of Drugs and Cosmetics act 1984.
5. The GMP Handbook: A Guide to Quality and Compliance, Brendan Cooper,2017.
6. Pharmaceutical Inspection Co-operation Scheme GMP guidelines, 2021.
7. WHO GMP Guideline 2020.

Marking and Assessment Methods

Continuous Assessment 100%

OQA7004 Pharmaceutical Regulatory Affair (4 Credits)

Learning Outcomes

At the end of the course, the students will be able to:

1. Differentiate various regulatory agencies governing pharmaceutical industry and other health care related industries.
2. Compare various regulatory requirements for approval of new drugs and drug products as well related health care products.
3. Prepare submission a dossier required for new drugs, drug products and health care related products to the relevant regulatory agencies for registration.

Course Synopsis

Students will be introduced to the existing regulatory agencies governing pharmaceutical industry and other health care related industries worldwide to understand their role and functions. Students will be exposed to the regulatory affair of new drug, drug product and other health related products such as herbal, nutraceutical, cosmetical and biologics. Students will also learn about post marketing surveillance and pharmacovigilance. Global harmonization of pharmaceutical standards is also covered in this module. Student will be given various project-based learning (PBL) on the preparation of submission documents related to the registration of new drugs, drug products and other related healthcare products: herbal, cosmetical nutraceutical, biological products and health devices to the relevant regulatory body, such as FDA, NPRA, MHRA and PMDA.

Reference

1. Aulton's Pharmaceutics (2021): The Design and Manufacture of Medicines, 6th edition, Churchill livingstone, UK.
2. Remington: The Science and Practice of Pharmacy (2020), 23nd edition. Mack Publishing Co. USA.
3. Sale of Drugs Act 1952.
4. Rules of Drugs and Cosmetics act 1984.
5. Fundamental of Regulatory Affairs, RAPS, 3rd edition, 2020.
6. Pharmaceutical Inspection Co-operation Scheme GMP guidelines, 2021.
7. Drug Registration Guidance Document-NPRA, 2021.

Marking and Assessment Methods

Continuous Assessment 100%

OQA7005 Pharmaceutical Product Development (4 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Distinguish various stages of pharmaceutical product development from early stages until final product manufacturing.
- Relate the concept of preformulation and stability studies required for the pharmaceutical product development.
- Appraise the clinical trials, its data analysis and legislation in the pharmaceutical product development.

Course Synopsis

Students will be introduced to the concepts of drug development and its challenges. Formulation factors, pharmacokinetics to be considered while formulation design. The purpose of clinical trials in drug development will also be exposed to the students. Students will learn about drug and biological drug manufacturing as well as “scaling-up” techniques. The students will also be introduced to the concept of bioavailability, methods to enhance bioavailability and bioequivalence studies.

Reference

1. Aulton (2018) Aulton's Pharmaceutics: The design and manufacture of medicines, 4e, Churchill Livingstone.
2. Lyod Allen (2017) Ansel’s pharmaceutical dosage forms and drug delivery systems, Lippincott Williams & Wilkins, Philadelphia, USA.
3. Simon Gaisfod & Mark Saunders (2013) Essentials of pharmaceutical preformulation, Wiley – Blackwell, UK.
4. Remington (2017) Essentials of Pharmaceutics, Edi. Linda Felton, Pharmaceutical Press, UK.
5. Sarfaraz K. Niazi (2019) Hand Book of Pharmaceutical Manufacturing formulations, Third edition, CRC Press, Tayler & Francis Group, UK.
6. Remington (2020) The science and practice of pharmacy, 23rd Edition, Edi.Adeboye Adejare, Academic press, Massachusetts, USA.

Marking and Assessment Methods

Continuous Assessment 40%

Final Examination 60%

OQA7006 Research Project (8 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Assess the research hypothesis by carrying out relevant procedures for data collection.
- Analyse research findings precisely and with full integrity.
- Compose research findings.
- Explain research findings using published literature as one of the main sources of reference.
- Generate a written dissertation and an oral presentation from the research findings based on established guidelines and appropriate aid tools.

Course Synopsis

Students will carry out their research project under the supervision and guidance of the respective lecturers in the Faculty of Pharmacy. They will collect data, analyse them and write-up their dissertations. Every student will also present their work orally.

Reference

1. Zaheer-Ud-Din Babar (2020) Pharmacy Practice Research Methods. Springer Singapore.
2. Ibrahim et al. Research Designs and Methodologies Related to Pharmacy Practice. Encyclopedia of Pharmacy Practice and Clinical Pharmacy. 2019, 7–21.
3. Gorvin et al. (2017) Research Methods: From Theory to Practice. Oxford University Press Inc.

Marking and Assessment Methods

Continuous Assessment 100%

OQA7007 Pharmaceutical Analysis and Testing (4 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Differentiate different types of analytical instruments for pharmaceutical testing.
- Analyse the concept of quality control in pharmaceutical analysis and testing.
- Evaluate counterfeit pharmaceutical products using suitable analytical instruments and testing.

Course Synopsis

Students will learn the overall concept of pharmaceutical analysis and testing, including the quality control aspect as well as all basic equipment/instrumentations involved in pharmaceutical analysis and testing. This course covers both fundamental theory and the application of analytical methods commonly used in pharmaceutical analysis and testing. Students will be trained to validate counterfeit products using appropriate analytical instruments and testing.

Reference

1. Watson, D. (2020) Pharmaceutical Analysis: A Textbook for Pharmacy Students and Chemists. 5th ed. Churchill Livingston, UK
2. Meek, T.L. (2017) An Introduction to Spectroscopy, Atomic Structure and Chemical Bonding. Canoe Press, USA
3. Akitt, J.W and Mann, B.E. (2017) NMR and Chemistry: An Introduction to Modern NMR Spectroscopy. 4th ed. CRC Press, UK.

Marking and Assessment Methods

Continuous Assessment 60%

Final examination: 40%

OMX7001 Research Methodology (3 Credits)

Learning Outcomes

At the end of the course, students are able to**:**

1. Determine research questions or/and research hypothesis for related research.
2. Critically analyze literature reviews based on their respective areas of research.
3. Appraise principles underlying responsible conduct of research.
4. Relate ethics and professionalism in conducting research based on relevant case studies.

Course Synopsis

This course is designed to provide knowledge and skills to the candidate related to research and responsible conduct of research. The content of this course includes introduction to research methodologies, literature review, research design, research proposal writing, research ethics, data analysis, usage of research software and topics related to good research practices.

Reference

1. Stephen B. Heard. The Scientist's Guide to Writing: How to Write More Easily and Effectively throughout Your Scientific Career, Princeton University Press, 2016
2. Chinna K, Choo WY, Krishnakumari K. Statistical Analysis Using SPSS, Pearson Malaysia Sdn Bhd, 2012.
3. C.R. Kothari. Research Methodology: Methods and Techniques, 2nd Edition, New Age International Pvt Ltd Publishers, 2012.
4. David Robertson Gordon Williams. Clinical and Translational Science, 2nd Edition, Academic Press, 2016.
5. Rita Faria. Research Misconduct as White-Collar Crime. Palgrave Macmillan, 2018.
6. Edward Zanders, Lindsay MacLeod. Presentation Skills for Scientists: A Practical Guide 2nd Edition, Cambridge University Press, 2018.
7. Raymond Boxman, Edith Boxman. Communicating Science: A Practical Guide for Engineers and Physical Scientists, WSPC, 2016.
8. Malaysian Education Module on Responsible Conduct of Research. (2017). Akademi Sains Malaysia.
9. The Malaysian Code of Responsible Conduct in Research. (2017). National Science Council.
10. How to Work with Your Institutional Animal Care and Use Committee (IACUC)

Marking and Assessment Methods

Continuous Assessment 100%

ELECTIVE COURSES

OQA7008 Design of Pharmaceutical Dosage Forms (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Examine various concepts of pharmaceutical formulation development and their packaging methods.
- Perform experiments and quality testing of the prepared pharmaceutical formulations.
- Measure the sequence of steps and factors affecting the design of formulation using software.

Course Synopsis

Students will be introduced to the formulation aspects such as excipients. Students will get a detailed description of the formulation process of the solid, liquid and semisolid dosage forms. In addition, the students will also learn the experimental knowledge of dosage formulation.

Reference

1. Aulton's Pharmaceutics (2017): The Design and Manufacture of Medicines, 5th edition, Churchill livingstone, UK.
2. Remington: The Science and Practice of Pharmacy (2020), 23nd edition. Adeboye Adejare, Acedemic press. USA.
3. Handbook of Pharmaceutical Manufacturing Formulations, Third Edition (3rd ed.) (2019), 3rd edition, Volume Six, Sterile Products. Sarfaraz K. Niazi, CRC Press, Florida, USA.
4. The Theory and Practice of Industrial pharmacy (2017), by Lachman and Lieberman, 4th edition, CBS publisher & Distributors.India.
5. United States Pharmacopoeia 43-NF 38, 2020.
6. British Pharmacopoeia 2018.

Marking and Assessment Methods

Continuous Assessment 60%

Final Examination 40%

OQA7009 Development of Novel Drug Delivery Systems (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Integrate the concepts of different novel drug delivery approaches in literature and at the development stage.
- Explain the significance of nanotechnology and nanocarriers to ascertain the clinical intentions via diverse drug routes of administration.
- Integrate the awareness and skills necessary in the manufacturing of novel drug delivery systems.

Course Synopsis

Students will be introduced to the overall concept of drug delivery and mechanisms of novel innovative drug delivery methods. Students will also be introduced to the principles of manufacturing of novel drug delivery products for various route of administration. Latest developments in the medical devices, biomolecular and biotechnology products will also be discussed that are in the market or those which are still in the research pipeline.

Reference

1. Aulton (2018) Aulton's Pharmaceutics: The design and manufacture of medicines, 4e, Churchill Livingstone.
2. Lyod Allen (2017) Ansel’s pharmaceutical dosage forms and drug delivery systems, Lippincott Williams & Wilkins, Philadelphia, USA.
3. Sarfaraz K. Niazi (2019) Handbook of Preformulation, Second edition, CRC Press, Tayler & Francis Group, UK.
4. Remington (2017) Essentials of Pharmaceutics, Edi. Linda Felton, Pharmaceutical Press, UK.
5. Sarfaraz K. Niazi (2019) Handbook of Pharmaceutical Manufacturing formulations, Third edition, CRC Press, Tayler & Francis Group, UK.
6. British Pharmacopoeia (2020) BP commission, UK.
7. United States Pharmacopoeia 42-NF 37 (2019) USP commission, Rockville, USA.
8. Remington (2020) The science and practice of pharmacy, 23rd Edition, Edi.Adeboye Adejare, Academic press, Massachusetts, USA.

Marking and Assessment Methods

Continuous Assessment 100%

OQA7010 Pharmaceutical Engineering and Manufacturing Facilities (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Analyse the various facilities required in manufacturing of pharmaceutical products.
- Differentiate the pharmaceutical engineering concept and manufacturing production facilities.
- Plan the facilities required for the pharmaceutical industries.

Course Synopsis

Students will be introduced to the pharmaceutical engineering and technology, industrial design, production facilities and layout for tablet, capsule, liquid and semisolid dosage forms. Students will learn about the types of equipment and their function used in pharmaceutical dosage formulation including solid, liquid and sterile. They will also obtain detailed knowledge about the automated system used in industries and the process flow involved in production.

Reference

1. Cole, G. (1998). Pharmaceutical Production Facilities: Design and Applications. CRC Press. USA
2. Carlton and J. Agalloco, Validation of Pharmaceutical Processes, Marcel Dekker, Inc., 3rd Edition, 2003
3. Marlin TE. 2000. Process Control. Glandt ED, Klein MT, Edgar TF, editors. Singapore: Mc Graw Hill.
4. Seider WD, Seader JD, Lewin DR. 2003. Product and Process Design Principles. India: John Wiley and Sons Inc.
5. Sharp J. 2005. Good Pharmaceutical Manufacturing Practice. United States: CRC Press

Marking and Assessment Methods

Continuous Assessment 60%

Final Examination 40%

OQB7005 Pharmaceutical Bioinformatics (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Use bio- or chemoinformatics tools and databases within pharmaceutical research.
- Analyse and interpret output from various online tools relevant to pharmaceutical bioinformatics.
- Integrate the use of bio- and cheminformatics tools in pharmaceutical research.

Course Synopsis

This course is designed to give students a basic theoretical background and a working knowledge of the bioinformatics techniques that are related to pharmaceutical sciences. Emphasis will be placed on the application of the free tools available rather than the underlying theories and the course covers topics such as databases and tools, representation of molecules, alignment, homology modelling, docking, and QSAR, that are useful in designing new drugs.

Reference

1. Jarl E. S. Wikberg. 2020. Introduction to Pharmaceutical Bioinformatics, 4th Edition, Oakleaf Academic.
2. Navneet Sharma, Himanshu Ojha, Pawan Raghav, and Ramesh Goyal. 2021. Cheminformatics and Bioinformatics in the Pharmaceutical Sciences, Elsevier.
3. Chris Rostron. 2020. Drug Design and Development, Oxford University Press.
4. Graham Patrick. 2017. Introduction to Medicinal Chemistry, 6th edition, Oxford University Press.

Marking and Assessment Methods

Continuous Assessment 100%

OQB7006 Advanced Medicinal Chemistry (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Relate the biological activity of the major drug classes to the chemical structures.
- Review the development of important drugs in the major drug classes and their structure-activity relationships.
- Design new chemical structures with potential biological activities.

Course Synopsis

This course deepens the understanding of the physicochemical concepts which underlie drug design and action.

Reference

1. Graham Patrick. Introduction to Medicinal Chemistry, 6th edition, Oxford University Press, 2017, ISBN: 9780198749691
2. Langer, Thierry & Bryant, Sharon. (2019). Successful Drug Discovery, Volume 4. Edited by János Fischer, Christian Klein, and Wayne E. Childers. ChemMedChem. 15. 10.1002/cmdc.201900599

Marking and Assessment Methods

Continuous Assessment 100%

OQB7007 Pharmacogenomics, Pharmacokinetics, and Pharmacodynamics in Precision Medicine (3 Credits)

Learning Outcomes

At the end of the course, students are able to:

- Analyse the challenges and limitations of pharmacogenetic studies.
- Explain how genetic variation can affect the pharmacokinetics or pharmacodynamics of drugs.
- Appraise the strategies and analytical approaches for stratifying patients for optimal drug response or adverse drug reactions.
- Explain the different types of current and emerging biomarkers used in personalised medicine.

Course Synopsis

Pharmacogenomics and individualised therapy are exciting areas of medicine and scientific research. It has been known for many years that genetic variation can affect the efficacy of some drugs which may also result in adverse side effects. Recently, there have been developments in the treatment of diseases such as cancer and cystic fibrosis on the basis of patients' genetic information and are having a real impact on their survival and quality of life. In this module you will cover the basic concepts of pharmacogenomics and relate these to current clinical practice where appropriate. Additionally, you will have the opportunity to study in depth examples of individualised therapy in diseases such as cancer, cystic fibrosis and diabetes. You will also consider the introduction of genetic testing for new pharmacogenomic discoveries taking into account analytical and clinical validity, clinical utility and ethical aspects.

Reference

1. Martin M. Zdanowicz. (2017) Concepts in Pharmacogenomics, American Society of Health-System Pharmacists.
2. Wu, Alan H. B., Yeo, Kiang-Teck J. (2011) Pharmacogenomic Testing in Current Clinical Practice: Implementation in the Clinical Laboratory. Molecular and Translational Medicine, Springer.
3. Bertino, Joseph S., Koshuba, Angela, Ma, Joseph D., Fuhr, Uwe, De Vane, C. Lindsay. (2012) Pharmacogenomics: An Introduction and Clinical Perspectives, 1st Edition, McGraw Hill.
4. Y.W. Francis Lam, Stuart A. Scott. (2019) Pharmacogenomics: challenges and opportunities in therapeutic implementation.
5. John E. Murphy (2017) Clinical pharmacokinetics. American Society of Health-System Pharmacists, 6th Edition.

6. Hartmut Derendorf, Stephan Schmidt (2019) Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications.LWW, 5th Edition.

Marking and Assessment Methods

Continuous Assessment 100%

MASTER OF SCIENCE IN PHARMACY (RESEARCH)

Programme

The Master of Science in Pharmacy (MScP) is a full research programme leading to the submission of a dissertation.

Programme Structure and Module Registration

(1) This programme consists of 100% research work leading to the submission of a dissertation which format shall be stipulated as in Part VII, University of Malaya Regulations (Master's Degree) 2019.

(2) Candidates are required to enroll and register in the following modules during their candidature period:

OMX7001 – Research Methodology (on the first or second semester only)

OMA7002 – Dissertation (every semester until the submission of dissertation for examination)

Programme Educational Objectives (PEO)

PEO 1 – Graduates will establish themselves as professionals in related pharmaceutical fields.

PEO 2 – Graduates will continue to improve by engaging in lifelong interdisciplinary learning essential for industrial and academic careers.

PEO 3 – Graduates will effectively communicate and demonstrate good leadership quality in an organization.

PEO 4 – Graduates will contribute to the well-being of society.

Programme Learning Outcomes (PLO)

PLO1 – Master advanced theories, concepts and relevant scientific methods of pharmaceutical sciences.

PLO2 – Demonstrate proficiency in using cognitive skills to critically analyse and solve pharmaceutical sciences issues.

PLO3 – Demonstrate relevant practical skills in the area of pharmaceutical sciences to meet the current and future needs.

PLO4 – Able to communicate ideas efficiently and effectively as an active and progressive team member undertaking various team roles using oral and written forms.

PLO5 – Utilise a wide range of digital technologies and numerical skills to enhance the area of research and foster professional development.

PLO6 – Demonstrate strong leadership, accountability, work autonomously and responsibly within a broad organization.

PLO7 – Ability to practice lifelong learning and professional development in various areas of pharmaceutical profession.

PLO8 – Act professionally with high integrity in accordance to the existing laws and code of conducts in the context of their profession and obligations to society

Duration Of Study

Minimum period of candidature: 2 semesters

Maximum period of candidature: 8 semesters

Candidature Requirements

(1) Fulfil the minimum candidature duration of 2 semesters.

(2) Fulfil the university language requirement (Bahasa Malaysia) no later than the second (2nd) semester of candidature for international candidates.

(3) Attend and pass at least 3 credits of Research Methodology Course not later than the second (2nd) semester of candidature.

(4) Present and pass your research proposal at Proposal Defence not later than the second (2nd) semester of candidature.

(5) Present and pass your research progress at Candidature Defence not later than the third (3rd) semester of candidature.

(6) Show proof of acceptance for publication of at least one (1) article in journals indexed by Web of Science (WoS) (according to the criteria set in the publication guidelines), prior to graduation.

COURSE SUMMARY

OMX7001 Research Methodology (3 Credit)

Learning Outcomes

At the end of the course, students are able to:

(1) Determine research question or/and research hypothesis for related research.
(2) Critically analyze literature reviews based on their respective areas of research.
(3) Appraise principles underlying responsible conduct of research.
(4) Relate ethics and professionalism in conducting research based on relevant case studies.

Synopsis of Course Content

This course is designed to provide knowledge and skills to the candidate related to research and responsible conduct of research. The content of this course includes introduction to research methodologies, literature review, research design, research proposal writing, research ethics, data analysis, usage of research software and topics related to good research practices.

Assessment Weightage

Continuous assessment: 100%

OMA7002 Dissertation

Learning Outcomes

At the end of the course, students are able to:

(1) Interpret knowledge in theories, concepts, frameworks, research highlights and issues in selected research topics.
(2) Decide research methods and analytical techniques appropriate to the chosen research topic.
(3) Master relevant experimental skills to achieve the proposed research aim.
(4) Explain the research finding through written and oral presentations.
(5) Compose a dissertation in appropriate academic format.
(6) Defend or justify to the comments from the supervisor/reviewer/assessors.
(7) Value knowledge, information, and skills learnt from various sources for research and future personal/ career development.
(8) Complete research work that adheres to the ethical principles and responsible conduct of research practices.

Synopsis of Course Content

Registered students will carry out their research under the supervision of the respective lecturers in the Faculty of Pharmacy. They must register for the Research Methodology course and present/communicate their progress and findings in postgraduate seminars/publications. Students are also required to fill in progress reports in MAYA every semester. Every postgraduate student in the faculty will be a member of the Postgraduate Society, Faculty of Pharmacy.

Assessment Weightage

Not Applicable.

DOCTOR OF PHILOSOPHY

RESEARCH

Programme Title

The Doctor of Philosophy programme by research is a programme that consists of one hundred percent (100%) research leading to the submission of a thesis.

Programme Structure and Module Registration

(1) This programme shall consist of one hundred percent (100%) research work leading to the submission of a thesis of which the format shall be as stipulated as in Part VII, University of Malaya Regulations (Degree of Doctor of Philosophy) 2019.

(2) Candidates are required to enroll in the following modules during the registration period:

OVA8001 - Research Methodology (during the first or second semester)

OVA8002 – Thesis (every semester of candidature until the submission of Thesis for Examination)

Programme Educational Objectives (PEO)

PEO 1 – Advance innovation in research and work practices

PEO 2 – Lead research as researcher and/or practitioners with national and/or international expertise

PEO 3 – Disseminate research results and/or provide expert advice in ethical and professional conduct.

Programme Learning Outcomes (PLO)

PLO1 – Demonstrate a critical and in-depth understanding of frontier knowledge by generating substantial and original contributions to the field of study.

PLO2 – Synthesise and integrate existing and new knowledge in one or more discipline areas to address challenges and concerns in the field of study.

PLO3 – Design and implement advanced methodologies to resolve complex and emerging problems.

PLO4 – Communicate information, insights, ideas, problems and solutions cogently with experts in the field and general audience.

PLO5 – Build rapport to work effectively as part of a team to achieve decided outcomes.

PLO6 – Use suitable digital and analytical techniques to research problems.

PLO7 – Demonstrate intellectual leadership qualities and management skills to effectively collaborate with diverse partners.

PLO8 – Demonstrate commitment to lifelong learning and professional development with an entrepreneurial mindset.

PLO9 – Perform research adhering to legal, ethical, professional and sustainable practices.

Duration of Study

Minimum period of candidature: 4 semesters

Maximum period of candidature: 12 semesters

Candidature Requirements

(1) Fulfil the minimum candidature duration of four (4) semesters.
(2) Fulfil the University language requirement (Bahasa Malaysia) not later than the second (2^{nd}) semester of candidature for international candidates.
(3) Attend and pass Research Methodology Course not later than the second (2^{nd}) semester of candidature.
(4) Present and pass research proposal at Proposal Defence not later than the second (2^{nd}) semester of candidature.
(5) Present research progress at Confirmation Defence not later than the third (3^{rd}) semester of candidature (**ONLY** applicable to admission through Fast Track candidates)
(6) Present and Pass research progress at Candidature Defence not later than the fifth (5^{th}) semester of candidature
(7) Present your research progress at the Thesis Seminar before the submission of thesis for examination.
(8) Show proof of acceptance for publication of at least two (2) articles in journals indexed by Web of Science (WoS) (according to the criteria set in the publication guidelines), prior to graduation.

COURSE SUMMARY

OVA8001 Research Methodology (3 Credit)

Learning Outcomes

At the end of the course, students are able to:

(1) formulate research questions and hypothesis for related research.
(2) critically literature reviews based on their respective areas of research.
(3) Interpret principles underlying responsible conduct of research.
(4) Relate ethics and professionalism in conducting research based on relevant case studies.

Synopsis

This course is designed to provide knowledge and skills to the candidate related to research and responsible conduct of research. The content of this course includes an introduction to research methodologies, literature review, research design, research proposal writing, research ethics, data analysis, usage of research software and topics related to good research practices.

Assessment Weightage

Continuous assessment: 100%

OVA8002 Thesis

Learning Outcomes

At the end of the course, students are able to:

(1) Develop intensive and comprehensive knowledge in theories, concepts, frameworks, research highlights and issues in selected research topics.
(2) Design research methods and analytical techniques appropriate to the chosen research topic.
(3) Propose solutions or justification to the comments from the supervisor/reviewer/assessors.
(4) Manage research work that adheres to the ethical principles and responsible conduct of research practices.
(5) Explain the research findings through written and oral presentations.
(6) Compose a thesis in appropriate academic format.
(7) Integrate knowledge, information, and skills learnt from various sources for research and future personal/ career development.

Synopsis

Registered PhD students will carry out their research under the supervision of the respective lecturers in the Faculty of Pharmacy. They must register for the Research Methodology course and present/communicate their progress and findings in postgraduate seminar/publication. Students are also required to fill in progress reports in MAYA every semester. Every postgraduate student in the faculty will be a member of the Postgraduate Society, Faculty of Pharmacy.

Assessment Weightage

Not Applicable.

GRADING SCHEME

1. The assessment of examinations for programme by coursework shall be based on the following grading scheme:

Marks	Grade	Grade Point	Meaning
90.00 - 100.00	A+	4.00	High Distinction
80.00 - 89.99	A	4.00	Distinction
75.00 - 79.99	A-	3.70	Distinction
70.00 - 74.99	B+	3.30	Pass
65.00 - 69.99	B	3.00	Pass
60.00 - 64.99	B-	2.70	Fail
55.00 - 59.99	C+	2.30	Fail
50.00 - 54.99	C	2.00	Fail
45.00 - 49.99	C-	1.70	Fail
40.00 - 44.99	D+	1.30	Fail
35.00 – 39.99	D	1.00	Fail
00.00 - 34.99	F	0.00	Fail

2. All courses shall be assessed using grades A+ to F.
3. The passing grade for all courses is grade B.

APPEAL

1. APPEAL AGAINST EXAMINATION RESULTS

(1) A candidate who is not satisfied with his examination results including the continuous assessment component and/or final examination of the course may appeal for a review of his examination results.

(2) The appeal shall be made within seven (7) days from the official date of announcement of his examination results.

(3) A payment based on the prescribed rate shall be made to process the application for the final examination results to be reviewed. The payment made is nonrefundable regardless of whether the appeal is successful or otherwise.

(4) The appeal shall be made in a form prescribed by the University. The completed form shall be submitted to the Dean of the Faculty together with a copy of the receipt of the payment for the appeal made.

(5) The form for an appeal will not be accepted if it is:

(i) submitted after the period stipulated in sub regulation (1);

(ii) incomplete

(iii) submitted without the payment receipt.

(6) When an appeal is received, the Dean of the Faculty shall appoint a second examiner for the course concerned. The original Examiner and the appointed second Examiner shall review the answer script and/or any assessment component for the said course and report the results of the review to the Faculty Appeals Committee.

(7) The Faculty Appeals Committee will decide whether the mark and/or grade of the said candidate is retained or amended. The original examiner and the second examiner concerned may attend the Faculty Appeals Committee's meeting if needed.

(8) The Faculty Appeals Committee shall make recommendations of any amendments of marks and/or grades of the candidate to the Committee of Examiners for their approval.

2. APPEAL TO REVIEW EXAMINATION RESULTS OF DISSERTATION

(1) A candidate who is not satisfied with the examination results of the dissertation may appeal in writing to the Director of Academic Administration and Services Centre within one (1) month from the date of notification of examination results.

(2) The candidate's appeal will be considered by the Deputy Vice-Chancellor concerned. If the candidate's appeal does not merit consideration, the candidate will be informed that his appeal was rejected. If the candidate's appeal merits consideration, the appeal will be brought to the Special Senate Committee to review the examination results of the dissertation and submit its recommendation to the Senate.

(3) The Special Senate Committee shall comprise of the Deputy Vice-Chancellor concerned as Chairman and two (2) members of the Senate from the Science and Arts field.

3. APPEAL TO CONTINUE WITH STUDIES

(1) A candidate who has failed and exited from a course examination may appeal in writing to continue his studies to the Dean of the Faculty concerned within one (1) semester from the date of notification of his examination results. The candidate's appeal will not be considered if the candidate exceeds the specified period.

(2) The candidate's appeal will be reviewed and considered by the Faculty Appeals Committee before recommended to the University Appeals Committee.

(3) Subject to sub regulation above, the following appeals will not be reconsidered:

(i) a candidate whose appeal has been approved, and failed and exited in the semester in which the candidate was re-admitted; or

(ii) the candidate's appeal was rejected by the University Appeals Committee.

4. APPEAL TO ACTIVATE CANDIDATURE

(1) A candidate whose candidature has lapsed due to failure to renew his candidature, may submit an appeal to the Dean of the Faculty to continue his studies. The appeal shall be made in accordance with the procedure as prescribed by the University.

(2) Approval to activate the candidature may only be given if the lapsed candidature does not exceed two (2) semesters at any one time, subject to the remaining duration of candidature. A candidate whose appeal is approved has to pay a fine at the rate prescribed by the University.

5. APPEAL TO EXTEND MAXIMUM DURATION OF CANDIDATURE

(1) A candidate whose maximum candidature duration is about to expire but still requires time to complete the dissertation and other graduation requirements, may submit an appeal to extend the maximum duration of his candidature to the Dean of the Faculty. The appeal shall be made in the last semester before his candidature lapses and shall be made in accordance with the procedure as prescribed by the University.

(2) Extension of the maximum duration of candidature may be given for one (1) semester only at a time. Notwithstanding the provisions of this sub regulation, the maximum extension duration that may be approved for a candidate shall not exceed three (3) semesters. The candidate's status after the expiry of maximum extension duration is "Failed and Exit".

GRADUATION

1. PROGRAMME OF STUDY BY COURSEWORK

A candidate shall fulfil the following requirements that has been stipulated for a programme of study by Coursework:

(1) Fulfil the requirements of the course component, that is:

(a) achieves a final CGPA of 3.00 and above;

(b) completes the number of credits as prescribed for his Master's degree;

(c) fulfils the Faculty requirements, if any, where he is registered for his Master's programme;

(d) fulfils the language requirements as prescribed; and (e) fulfils the other requirements approved by the Senate from time to time.

(2) For a programme of study by coursework, the number of credits required for the purpose of graduation is at least 2/3 of the total number of credits for his programme of study and shall be obtained from courses carried out by this University except for University collaborative programmes and professional programmes governed by the respective professional body concerned.

2. PROGRAMME OF STUDY BY RESEARCH

A candidate shall fulfil the following requirements for the purpose of graduation for a programme of study by Research:

(a) has achieved sufficient academic merit and has passed in the examination of his dissertation and viva voce (if any) and/or other designated test;

(b) has fulfilled other requirements determined by the Faculty where the candidate is pursuing his programme of study;

(c) has fulfilled the language requirements as prescribed; and

(d) has fulfilled the other requirements approved by the Senate from time to time.