

Course Detail

Master of Science Program in Regulatory Science for Pharmaceutical and Health Products (International Program)

Course Title:	Master of Science Program in Regulatory Science for Pharmaceutical and Health Products (International Program)
Master Degree:	Master of Science (Regulatory Science for Pharmaceutical and Health Products)
Academic Institution:	Faculty of Pharmacy, Departments of Microbiology, Pharmacy, Pharmaceutical Chemistry, Pharmacology and Manufacturing Pharmacy
Duration:	B.E. 2563-2565

Background and Rational:

Master of Science Program in Regulatory Science for Pharmaceutical and Health Products (International Program) is the first program in Thailand that offers body of knowledge as well as practical aspects in regulation of pharmaceutical and health products. The program is designed as integrated and multidisciplinary curriculum by collaborations of several departments including Pharmaceutical Chemistry, Pharmaceutical Manufacturing, Pharmacology, Microbiology and Pharmacy. The program involves both Thai and international regulations (EU, US, ASEAN and Japan) and complied with Thailand 4.0 policy. The program is driven by high caliber and high expertise faculty member. The learning process is designed as modules based on active learning, outcome based and problem based education. Lecture, laboratory, hand-on experiences as well as trainings in real sectors are provided for students. Students can get access to well-equipped laboratories, libraries and information technology facilities with necessary database. Research questions or thematic paper could be originated from students, which can be benefit to their future career and the graduates could pursue their careers in regulatory affairs in both governmental and private sectors. Upon the completion from the program, the graduates will be knowledgeable and skillful to work in the area of regulatory science in pharmaceutical and health products.

Objectives:

By the end of the study, students are able to

1. Possess moral, professional ethics and responsibility in the field of regulatory science for pharmaceutical and health products
2. Analyze and apply the knowledge in regulatory science for pharmaceutical and health products

3. Think critically, to analyze problems, to integrate and to synthesize knowledge in the field of regulatory science for pharmaceutical and health products

4. Have inter-personal skill with responsibility, management and leadership skills to effectively communicate and collaborate with intra- and inter-organizations in quality control of pharmaceutical and health products

5. Possess numerical and information technology skills required in regulatory science for pharmaceutical and health products

Course Synopsis & Methodology:

1. Study plan:

Plan B

Year	Semester 1	Semester 2
1	PYRS 500 Regulation of Drug and Health Products 3(3-0-6) PYRS 501 Management and Professional Skills in Regulatory Affairs 3(3-0-6) PYRS 504 International Approaches to Regulation 3(3-0-6) PYRS 505 Principles of Risk Management and Vigilance System for Health Products 2(2-0-4)	PYRS 502 Quality Management System and Quality Assurance 3(3-0-6) PYRS 507 Seminar in Regulatory Science II 1(1-0-2) PYRS 508 Process of Drug Discovery and Pharmaceutical Product Discovery and Pharmaceutical Product Development 3(3-0-6) Elective courses 6 credits PYRS 698 Thematic paper 2(0-18-0)
	PYRS 506 Seminar in Regulatory Science I 1(1-0-2) PYRS 503 Statistics in Regulatory Science for Pharmaceutical Products 3(3-0-6)	
	Total 15 credits	Total 15 credits
2	Elective courses 2 credits PYRS 698 Thematic paper 2(0-18-0) Total 4 credits	PYRS 698 Thematic paper 2(0-18-0) Total 2 credits

2. Course Content/Study Topic:**Courses in the curriculum**

(1) Required Courses	18 credits
(2) Elective Courses: Not less than	12 credits
(3) Thematic paper	6 credits

1) Required Courses 18 credits**Credits (Lecture-Practice-Self Study)**

PYRS 500	Regulation of Drug and Health Products	3(3-0-6)
PYRS 501	Management and Professional Skills in Regulatory Affairs	3(3-0-6)
PYRS 502	Quality Management System and Quality Assurance	3(3-0-6)
PYRS 503	Statistics in Regulatory Science for Pharmaceutical Products	3(3-0-6)
PYRS 504	International Approaches to Regulation	3(3-0-6)
PYRS 505	Principles of Risk Management and Vigilance System for Health Products	2(2-0-4)
PYRS 506	Seminar in Regulatory Science I	1(1-0-2)

2) Elective Courses: Not less than 12 credits**Credits (Lecture-Practice-Self Study)**

PYRS 507	Seminar in Regulatory Science II	1(1-0-2)
PYRS 508	Process of Drug Discovery and Pharmaceutical Product Development	3(3-0-6)
PYRS 509	Regulation of Biological Products	2(2-0-4)
PYRS 510	Risk Management Tools for Pharmaceutical Industry	2(2-0-4)
PYRS 511	Structure and Management of Clinical Trials	2(2-0-4)
PYRS 512	Intellectual Properties for Health Products	2(2-0-4)
PYRS 513	Pharmaceutical Commerce	2(2-0-4)
PYRS 514	Regulation of Food and Dietary Supplements	2(2-0-4)
PYRS 515	Regulatory of medical device	2(2-0-4)

In addition to elective courses mentioned above, a student may register other courses in international program offered by other faculties' equivalent to graduate studies, Mahidol University or the ones offered by other universities according to the student's interest with the approval of the curriculum committee or the advisor.

Thematic paper

	Credits (lecture – practice – self-study)
PYRS 697 Thematic paper	6(0-36-0)

Applicants Qualifications:

Plan B

1. Prospective students should hold a Bachelor's degree in the area of pharmacy or related health science from Institutions of Higher Education in Thailand or foreign countries accredited by the office of the Higher Education Commission with a minimum GPA of 2.50 or equivalent
2. Prospective students should have the English competency that meet the requirements of the Faculty of Graduate Studies, Mahidol University (e.g. TOEFL score of at least 400 or the total IELTS score of at least 3 or any other equivalent scores.
3. Prospective students should have experience in regulatory of health products at least one year.
4. Other exceptions may be considered by the Program Committee and the Dean of the Faculty of Graduate Studies, Mahidol University.

Document Required:

1. Transcript
2. CV with a statement of purpose
3. TOEFL or IELST score

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***The application procedure will complete when TICA has received the hard copy of the application form and other related documents through the Royal Thai Embassy/Permanent Mission of Thailand to the United Nations/Royal Thai Consulate – General accredited to eligible countries/territories.