

**Master of Science Program in  
Regulatory Science for Pharmaceutical and Health Products**

**Courses by group**

			credits
			Credits (lecture – practice – self-study)
<b>Plan A2</b>			
<b>1. Required courses</b>			<b>18 credits</b>
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)
<b>2. Elective courses</b>			<b>6 credits</b>
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)
<b>3. Thesis</b>			<b>12 credits</b>
PYRS	698	Thesis	12 (0-36-0)

Study plan (Plan A2)

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 506 Seminar in Regulatory Science I 1 (1-0-2) PYRS 503 Statistics in Regulatory Science for Pharmaceutical Products 3 (3-0-6) <b>Total credit 15 credits</b>	PYRS 502 Quality Management System and Quality Assurance 3 (3-0-6) <b>Elective course 6 credits</b> PYRS 698 Thesis 6 (0-18-0) <b>Total credit 15 credits</b>
2	PYRS 698 Thesis 3 (0-9-0) <b>Total credit 3 credits</b>	PYRS 698 Thesis 3 (0-9-0) <b>Total credit 3 credits</b>

**Master of Science Program in  
Regulatory Science for Pharmaceutical and Health Products**

**Courses by group**

**credits**

**Credits (lecture – practice – self-study)**

**Plan B**

**1. Required courses**

**18 credits**

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**

**12 credits**

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)

**3. Thematic Paper**

**6 credits**

PYRS	697	Thematic Paper	6 (0-18-0)
------	-----	----------------	------------

Study plan (Plan B)

Year	Semester 1	Semester
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 506 Seminar in Regulatory Science I 1 (1-0-2) PYRS 503 Statistics in Regulatory Science for Pharmaceutical Products 3 (3-0-6) <b>Total credit 15 credits</b>	PYRS 502 Quality Management System and Quality Assurance 3 (3-0-6) PYRS 508 Process of Drug Discovery and Pharmaceutical Product Development 3 (3-0-6) PYRS 507 Seminar in Regulatory Science II 1 (1-0-2) <b>Elective course 6 credits</b> PYRS 697 Thematic Paper 2 (0-2-0) <b>Total credit 15 credits</b>
2	PYRS 697 Thematic Paper 2 (0-2-0) <b>Total credit 2 credits</b>	PYRS 697 Thematic Paper 2 (0-2-0) <b>Total credit 2 credits</b>

ประธานหลักสูตร: ศาสตราจารย์ ลีณา สุนทรสุข (Leena.sun@mahidol.ac.th)