Drug Regulatory Affairs (18 months / 90 ECTS, Master of Science, E- Learning)

TABLE 2: COURSE DISTRIBUTION PER SEMESTER

A/A	Course type	Course title	Course code	Periods per week	Period duration	Number of weeks/ Semester	Total periods/ Semester	Number of ECTS
A' Semester								
1.	Compulsory	Drug development and ethical considerations in Pharma industry	**PHAR-615**	3	50	12	36	10
2.	Compulsory	The EU Regulatory Affairs System	**PHAR-616**	3	50	12	36	10
3.	Compulsory	Regulatory Strategy and Marketing Applications for new Medicinal products	**PHAR-617**	3	50	12	36	10
B' Semester								
4	Compulsory	Quality Assurance and compliance	**PHAR-618**	3	50	12	36	10
5	Compulsory	Clinical trials, Preclinical & Clinical Development and Documentation	**PHAR-619**	3	50	12	36	10
6	Compulsory	Pharmacovigilance and Pharmacoepidemiology	**PHAR-620**	3	50	12	36	10

C' Semester (Option Thesis+ Research methodology)								
7	Compulsory	Research Methodology	**PHAR-621**	3	50	12	36	10
8	Compulsory	Master Thesis	**PHAR- 622**	3	50	12	36	20
C' Semester (Option Courses instead of Thesis) **(1 compulsory Research Methodology and choose 2 from the 5 electives)**								
9	Compulsory	Research Methodology	**PHAR-621**	3	50	12	36	10
10	Elective	Regulation of Medical Devices	**PHAR-623**	3	50	12	36	10
11	Elective	Market Pricing and Reimbursement	**PHAR-624**	3	50	12	36	10
12	Elective	Health Technology Assessment	**PHAR-625**	3	50	12	36	10
13	Elective	Product's Life Cycle Activities	**PHAR-626**	3	50	12	36	10
14	Elective	International Regulatory harmonization	**PHAR-627**	3	50	12	36	10