

醫藥品法規科學博士學位學程

115 學年度(適用於在學學生)

最低修業年限	限修業期限以二至七年為限。
應修學分數	1. 至少應修畢十八學分，其中包含本學程訂定之必修學分。 2. 相關研究所碩士班畢業之研究生得免修已修畢及格之本學程之必修相同科目，可免修學分依學校規定辦理並由學程會議認定。
逕博應修學分數	逕修讀博士學位研究生至少應修畢三十學分，其中包含本學程所訂定之必修科目學分。
應修(應選)課程及符合畢業資格之修課相關規定	1. 必修科目：專題討論(四學分)、醫藥品產業概論(二學分)、生醫科技法律(三學分)、醫藥品政策與管理(二學分)、論文研究與寫作(一學分)、學術研究倫理(零學分)、性別平等教育線上課程(零學分)。 2. 選修科目三選一：藥品上市法規實務(二學分)、食品法律(二學分)、醫療器材上市法規實務(三學分)。 3. (a)法規科學組 選修科目多選一：藥事法規(一學分)、藥品與醫療器材之重大事件與法規管理專題研究(一學分)、醫藥品專利與技轉實務(二學分)、衛生行政與健康保險(二學分)、健康科技與經濟評估(二學分)、藥物流行病學(二學分)、醫療器材管理法規與實務(一學分)、生物製藥產業創業財務管理實務(一學分)、公共衛生學(二學分)。 (b)實證科學組 選修科目多選一：生物藥學通論(二學分)、生物藥學特論(二學分)。 4. 選修科目多選一：憲法與醫藥法規：實例分析(一學分)、美國憲法(二學分)、行政法(三學分)、民法總則(三學分)。

Ph.D. Program in Regulatory Science and Policy

Academic Year 2025 (Applicable to currently enrolled students)

Minimum Term of Study	The period of study is limited to two to seven years.
Minimum Credits	1. At least 18 credits shall be taken, including all required credits. 2. Students enter with a MS degree from relevant graduate schools are exempted from taking the same required courses, which they have taken and passed, while credits of exemption are administered in accordance with school regulations and affirmed via the PI meetings
Minimum Credits for Direct-Entrance Ph.D.	Students who enter directly from master programs shall complete at least 30 credits, including required credits.
Curriculum and Regulations	1. Required courses: seminar (4 credits), Introduction to the Pharmaceutical and Medical Device Industry (2 credits), Biomedical Technology and Law (3 credits), Pharmaceutical Policy and Management (2 credits), Thesis' Research and Writing (1 credit), Academic research ethics (0 credit), Gender Equity Education Online Course (0 credit). 2. Select one of the elective courses: Regulatory Practice of Drug (2 credits), Food Law (2 credits), Practical Skills of the Regulatory Requirements of Medical Devices (3 credits). 3. (a)Regulatory Science Group Select one of the elective courses: Pharmaceutical Law (1 credit), Special Research on Major Events and Regulatory Management of Pharmaceuticals and Medical Devices (1 credit), Pharmaceutical Patents and Technology Transfer Practice (2 credits), Health Policy and Health Insurance (2 credits), Health Technology Assessment (2 credits), Pharmacoepidemiology (2 credits), Medical Devices

	Regulation and Practice (1 credit), Financial Management Practices for Biopharmaceutical Startups (1 credit), Introduction to Public Health (2 credits). (b)Experimentation science Group Select one of the elective courses: Fundamentals in Biopharmaceutical Sciences (2 credits), Advanced Biopharmaceutical Sciences (2 credits). Select one of the elective courses: Constitutional Law, Medical Law, and Pharmaceutical Law: Case Study (1 credit), U.S. Constitutional Law (2 credits), Administrative Law (3 credits), Civil Law: General Principles (3 credits).
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