

Course title <English>	医薬政策・行政 【領域4】 Drug Policy and Regulation		Affiliated department, Job title, Name	Graduate School of Medicine Professor, KAWAKAMI, KOJI	
Target year	Professional degree students	Number of credits	1	Course offered year/period	2018/The first half of second semester
Day/period	Wed.2	Class style	Lecture	Language	Japanese and English
[Outline and Purpose of the Course]					
<p>Director and Instructors: (Director) Koji Kawakami (Professor , Pharmacoepidemiology), Meguro Yoshiro(MHLW), Yasuhiro Nishijima(MHLW), Christian Elze(Catenion), Keisuke Matsubayashi(Assistant Professor, Pharmacoepidemiology.)</p> <p>The policy and regulatory systems in Japan, EU, and the US involving healthcare, safety, science, food safety, and industry will be discussed.</p>					
[Course Goals]					
To understand the ideas of drug/medical device/food policy and regulations; medical industrialization and translational research policy.					
[Course Schedule and Contents]					
<p>Lecture schedule :</p> <p>October 3 Drug policy and reguraton(Kawakami) October 10 Drug regulation in the United states(Kawakami) October 17 Drug regulation in Japan(Meguro) October 24 Food safety regulations (Nisijima) October 31 Policy and development of medical devices(Kawakami) November 7 Healthcare Systems - Challenges and Reform(Elze) November14 Development of advanced drugs(Matsubayashi)</p>					
[Class requirement]					
You must take this course along with the course H079 “ Drug Development, Evaluation and Regulatory Sciences ” otherwise the entire grasp of the drug research, development, and regulations will not be achieved.					
[Method, Point of view, and Attainment levels of Evaluation]					
Participation (50%) and report (50%)					
[Textbook]					
<p>Suggested reading: Saeko Yasuo et al. Invitation to new drug development. Kyoritsu Press, 2006 (Japanese). Koji Kawakami (ed.) The Beginner ’ s guidance to the clinical research and development. Medical Do, 2010 (Japanese).</p>					
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医薬政策・行政 【領域4】(2)

[Reference books, etc.]

(Reference books)

Introduced during class

[Regarding studies out of class (preparation and review)]

Preparation in advance and review after lecture

(Others (office hour, etc.))

Koji Kawakami (3F, Bldg G) appointment required by email.

e-mail: kawakami.koji.4e@kyoto-u.ac.jp

intermediate

*Please visit KULASIS to find out about office hours.