

Course title <English>	医薬政策・行政 Drug Policy and Regulation		Affiliated department, Job title, Name	Graduate School of Medicine Professor, KAWAKAMI KOUJI	
Grade allotted	Professional degree students	Number of credits	1	Course offered year/period	2015/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), Hirotaka Unami (MOF), Daisaku Sato (MHLW), Christian Elze (Catenion), Yasuhiro Nishijima (MHLW), Masayoshi Murakami (Kobe Biomedical Cluster).</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 7 Finance of Japan and healthcare (Unami) October 14 Drug policy and regulations (Kawakami) October 21 Drug regulation in Japan (Sato) October 28 Drug regulation in the United States (Kawakami) November 4 Food safety regulations (Nishijima) November 11 Healthcare systems in European countries (Elze) November 18 Policy and development of medical devices (Kawakami) November 25 Translational research and industrialization (Murakami)</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(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.

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intermediate

*Please visit KULASIS to find out about office hours.