

<b>Course title</b> <English>	医薬政策・行政 Drug Policy and Regulation		<b>Affiliated department, Job title,Name</b>	Graduate School of Medicine Professor,KAWAKAMI, KOJI	
<b>Target year</b>	Professional degree students	<b>Number of credits</b>	1	<b>Course offered year/period</b>	2017/The first half of second semester
<b>Day/period</b>	Wed.2	<b>Class style</b>	Lecture	<b>Language</b>	Japanese and English
<b>[Outline and Purpose of the Course]</b>					
<p>Director and Instructors: (Director) Koji Kawakami (Professor , Pharmacoepidemiology), Daisaku Sato (MHLW), Christian Elze (Catenion) , Yasuhiro Nishijima (MHLW), Masayoshi Murakami (Foundation for Biomedical Research and Innovation).</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> <p>[</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>					
<b>[Course Goals]</b>					
To understand the ideas of drug/medical device/food policy and regulations; medical industrialization and translational research policy.					
<b>[Course Schedule and Contents]</b>					
<p>Lecture schedule :</p> <p>October 4 Drug policy and regulations (Kawakami)</p> <p>October 11 Drug regulation in Japan (D.Sato)</p> <p>October 18 Drug regulation in the United States (Kawakami)</p> <p>October 25 Food safety regulations (Nishijima)</p> <p>November 8 Policy and development of medical devices (Kawakami)</p> <p>November 15 Healthcare Systems - Challenges and Reform(Elze)</p> <p>November 22 Translational research and industrialization (Murakami)</p>					
<b>[Class requirement]</b>					
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.					
<b>[Method, Point of view, and Attainment levels of Evaluation]</b>					
Participation (50%) and report (50%)					
<b>[Textbook]</b>					
<p>Suggested reading:</p> <p>Saeko Yasuo et al. Invitation to new drug development. Kyoritsu Press, 2006 (Japanese).</p> <p>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)

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**[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.