

Course title <English>	医薬品の開発と評価 Drug Development, Evaluation and Regulatory Sciences		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	2017/Intensive, Second semester
Day/period	Intensive	Class style	Lecture	Language	Japanese and English
[Outline and Purpose of the Course]					
<p>Director and Instructors: (Director) Koji Kawakami (Professor , Pharmacoepidemiology), Takafumi Hasebe (MOF), Ikuo Horii (Cambridge Univ.), Hiromitsu Shirasawa (MSD, Japan), Hisashi Urushihara (Keio Univ.), Yoshie Onishi (CreativCeutical), Izumi Sato (Assistant Professor, Pharmacoepidemiology.)</p> <p>The efficacy and safety of the drug, biologics, and medical devices are evaluated through the drug development process involving preclinical and clinical studies, manufacturing, and post-marketing surveillance. Also, cost/benefit consideration through the comparative effective research is necessary. Fundamental considerations of these issues along with research examples will be discussed.</p>					
[Course Goals]					
To understand idea of the development, evaluation, cost/benefit of medicinal products.					
[Course Schedule and Contents]					
November 29 Regulatory affairs in the globalwide pharmaceutical company (Shirasawa) December 6 Drug development and evaluation: Strategy and the role of academia (Kawakami) December 13 Drug development and toxicity/safety (Horii) December 20 Postmarketing surveillance (Urushihara) December 27 Pharmacoeconomics and value-based drug pricing (Onishi) January 10 Finance of Japan and healthcare (Hasebe: provisional) January 17 Drug evaluation using pharmaco-epidemiological methods (I. Sato) January 24 Sight visiting of Kobe medical cluster					
[Class requirement]					
You must take this course along with the course H074 “ Drug policy and regulation ” 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]					
Suggested reading: Hartzema, A.C. et al., ed. Pharmacoepidemiology: An Introduction 3rd ed., Harvey Whitney. 1998. 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).					
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医薬品の開発と評価(2)

[Reference books, etc.]

(Reference books)

[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.