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 KOUJI

Grade alloted	Professional degree students	Number of credits	1	Course offered year/period	2015/Intensive, Second semester

Day/period	Wed.2	Class style	Lecture	Language	Japanese and English

[Outline and Purpose of the Course]

Director and Instructors:
(Director) Koji Kawakami (Professor, Pharmacoepidemiology), Ikuo Horii (Cambridge Univ.), Hiromitsu Shirasawa (MSD, Japan), Hisashi Urushihara (Keio Univ.), Lu Chiafeng (Baker&McKenzie), Yoshie Onishi (CreativCeutical), Shiro Tanaka (Lecturer, Pharmacorpi.)

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.

[Course Goals]

To understand idea of the development, evaluation, cost/benefit of medicinal products.

[Course Schedule and Contents]

Lecture schedule：
December 2 Drug development and toxicity/safety (Horii)
December 9 Regulatory affairs in the globalwide pharmaceutical company (Shirasawa)
December 16 Drug development and evaluation: Strategy and the role of academia (Kawakami)
January 6 Postmarketing surveillance (Urushihara)
January 13 Drug licensing in pharmaceutical industry (Lu)
January 20 Pharmacoeconomics and value-based drug pricing (Onishi)
January 27 Sight visiting of Kobe medical cluster (Kawakami, Tanaka)

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

*Please visit KULASIS to find out about office hours.