Course title <English>	医薬品・医療機器の開発計画、薬事と審査 Development strategy, plan, and regulatory affairs of drugs and medical devices	Affiliated department, Job title,Name	Graduate School of Medicine Professor,KAWAKAMI KOUJI

Grade alloted	Professional degree students	Number of credits	2	Course offered year/period	2015/Second semester

Day/period	Wed.3,4	Class style	Lecture	Language	Japanese and English

[Outline and Purpose of the Course]

Director and Instructors:
(Director) Koji Kawakami (Professor, Pharmacoepidemiology) Shiro Tanaka (Lecturer, Pharmacorpi.), Junko Komura (PMDA), Yasuhiro Fujiwara (National Cancer Center), Miyuki Niimi (Saku General Hospital), Christian Elze (Catenion), Haruko Yamamoto (National Cerebral and Cardiovascular Center), Hiromu Kutsumi (Kobe Univ.), Ikuo Horii (Cambridge Univ.), Yoko Uryuhara (Doshisya Univ.), Shigeyuki Wakitani (Mukogawa Women's Univ.), Hisashi Urushihara (Keio Univ.), Shinya Kimura (Japan Medical Data Center), Yoshie Onishi (CreativCeutical)

The development strategy, protocol design, project management, safety/efficacy assessment, and economic evaluation of drugs and medical devices will be lectured. The development of drug and medical device and the regulatory review in terms of manufacturing and control, nonclinical studies, clinical protocol, the new drug applications, and post-marketing will be discussed.

[Course Goals]

・The idea of drug/medical device development and regulatory review will be understood.
・To understand the strategy, protocol development, and project management of drug development and clinical trials.

[Course Schedule and Contents]

Lectures and discussions

※Lecture schedule
October 7 Drug Development strategy and translational research (Tanaka)
October 14 Industry R&D and regulatory reviewer training: nonclinical studies (Komura)
October 21 Industry R&D and regulatory reviewer training: protocol review of clinical trial (Fujiwara)
October 28 Industry R&D and regulatory reviewer training: CMC (Kawakami)
November 4 Project management of clinical trial (Niimi)
November 11 Global Development Strategy of New Drugs (Elze)
November 18 Industry R&D and regulatory reviewer training: medical devices (1) (Yamamoto)
November 25 Industry R&D and regulatory reviewer training: medical devices (2) (Kutsumi)
December 2 Data review and personalized medicine in drug development (Horii)
December 9 Life cycle management of drug (Uryuhara)
December 16 Industry R&D and regulatory reviewer training: regenerative medicine (Wakitani)
January 6 Industry R&D and regulatory reviewer training: postmarket (Urushihara)
January 13 Application of medical database in evaluation of health care (Kimura)
January 20 Health economy and outcomes research: Practice (Onishi)
January 27 Sight visiting of Kobe medical cluster (Kawakami, Tanaka)

Continue to 医薬品・医療機器の開発計画、薬事と審査(2)↓↓↓

医薬品・医療機器の開発計画、薬事と審査(2)

[Class requirement]

You must take this course along with the course H074 “Drug policy and regulations” and H079 “Drug development, evaluation and regulatory sciences” of Wednesday 2nd of the second semester for you to acquire fundamental understanding of the field.

[Method, Point of view, and Attainment levels of Evaluation]

Participation (50%) and report (50%)

[Textbook]

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).

[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

*Please visit KULASIS to find out about office hours.