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, KOJI

Target year	Professional degree students	Number of credits	2	Course offered year/period	2018/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 (Program-specific Professor, Clinical Biostatistics), Junko Komura (Setsunan Univ.),
Yasuhiro Fujiwara (National Cancer Center),Harue Tada(Kyoto Univ. Hospital) ,
Christian Elze (Catenion), Haruko Yamamoto (National Cerebral and Cardiovascular Center),
Yoshinaka(Shiga Univ. Of Medical Science), 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]

October 3 Drug Development strategy and translational research (Tanaka)
October 10 Industry R&D and regulatory reviewer training: nonclinical studies (Komura)
October 17 Industry R&D and regulatory reviewer training: CMC (Kawakami)
October 24 Industry R&D and regulatory reviewer training: protocol review of clinical trial (Fujiwara)
October 31 Project management of clinical trial (Tada)
November 7 The changing Dynamics of Bio-pharmaceutical Innovation (Elze)
November 14 Industry R&D and regulatory reviewer training: medical devices (1) (Yamamoto)
November 21 Industry R&D and regulatory reviewer training: medical devices (2) (Yoshinaka)
November 28 Data review and personalized medicine in drug development (Horii)
December 5 Industry R&D and regulatory reviewer training: regenerative medicine (Wakitani)
December 12 Life cycle management of drug (Uryuhara)
December 19 Industry R&D and regulatory reviewer training: postmarket (Urushihara)
December 26 Health economy and outcomes research: Practice (Onishi)
January 9 Application of medical database in evaluation of health care (Kimura)
January 16 Sight visiting of Kobe medical cluster

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 H109 “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.