[Outline and Purpose of the Course]

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).

The policy and regulatory systems in Japan, EU, and the US involving healthcare, safety, science, food safety, and industry will be discussed.

[Course Goals]

To understand the ideas of drug/medical device/food policy and regulations; medical industrialization and translational research policy.

[Course Schedule and Contents]

Lecture schedule:
October 4 Drug policy and regulations (Kawakami)
October 11 Drug regulation in Japan (D. Sato)
October 18 Drug regulation in the United States (Kawakami)
October 25 Food safety regulations (Nishijima)
November 8 Policy and development of medical devices (Kawakami)
November 15 Healthcare Systems - Challenges and Reform (Elze)
November 22 Translational research and industrialization (Murakami)

[Class requirement]

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.

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

Participation (50%) and report (50%)

[Textbook]

Suggested reading:
**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
intermediate

*Please visit KULASIS to find out about office hours.*