**Course title**
Drug Development, Evaluation and Regulatory Sciences

**Affiliated department**
Graduate School of Medicine

**Job title, Name**
Professor, KAWAKAMI, KOJI

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<tr>
<th>Target year</th>
<th>Professional degree students</th>
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| Number of credits | 1 |

| Course offered year/period | 2017/Intensive, Second semester |

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<th>Day/period</th>
<th>Intensive</th>
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<th>Class style</th>
<th>Lecture</th>
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| Language | Japanese and English |

**[Outline and Purpose of the Course]**

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.)

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]**

- November 29 Regulatory affairs in the global wide 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:
[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.