	中毒学 Toxicology				department.		me A	Graduate School of Medicine Associate Professor,HARADA KOUJI Graduate School of Medicine Professor,KOIZUMI AKIO	
Grade allot	ed Professional degree	students	Number	of cred	its	2		rse offered /period	2016/Second semester
Day/period	Fri.2	Cla	ss style	Lecture)			Language	Japanese and English

[Outline and Purpose of the Course]

I. Course Description

The understanding of GLP (Good Laboratory Practice) is essential for toxicology study. The course is aimed to provide the basis of modern toxicology research. In addition, advanced toxicology for toxicokinetics and chemical analysis will be given in the latter half of the course.

[Course Goals]

II. Course Goals and Objectives

Knowledge of GLP

Knowledge of toxicokinetics and mathematical models

Knowledge of chemical analysis

Skill to audit toxicological research

[Course Schedule and Contents]

Course Schedule

1 Oct 7 Orientation

2 Oct 14 GLP "General Provisions" and "Organization and Personnel"

3 Oct 21 GLP "Facilities" and "Equipment"

4 Oct 28 GLP "Testing Facilities Operation" and "Test and Control Articles"

5 Nov 4 GLP "Protocol for and Conduct of a Non-clinical Laboratory Study"

6 Nov 11 GLP "Records and Reports"

7 Nov 18 GLP "Disqualification of Testing Facilities"

8 Nov 25 GLP "Timing of Pre-clinical Studies in Relation to Clinical Trials"

9 Dec 2 GLP "Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals"

10 Dec 9 GLP "Safety Pharmacology Studies for Human Pharmaceuticals"

11 Dec 16 Toxicokinetics 1

12 Jan 6 Toxicokinetics 2

13 Jan 13 Research ethics

14 Jan 20 Chemical analysis 1

15 Jan 27 Chemical analysis 2

[Class requirement]

Elective.

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

III. Methods of Instruction

Lecture

Continue to 中毒学(2)↓↓↓

中毒学(2)
Small group teaching and discussion
[Textbook]
Instructed during class IV. Course Text and Readings 1. Code of Federal Regulations ICH Guideline 2. Lu's BASIC TOXICOLOGY 4th edition Frank C. Lu and Sam Kacew, Taylor and Francis, 2002
[Reference books, etc.]
(Reference books)
[Regarding studies out of class (preparation and review)]
V. Course Grade Attendance and active participation 50% Presentation 50%
(Others (office hour, etc.))
Credits of "Introduction to Toxicology" and "Occupational health and environmental health sciences" are required.
*Please visit KULASIS to find out about office hours.