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| Course | Critical Path Research Management |
| Course No. | |
| Credits | 2 Credits |
| Grade | 1 Year |
| Timetable | Fall AB Mon 6, 7 |
| Instructor | Koichi Hashimoto, Masafumi Muratani, Hideo Tsurushima, Takahiro Kojima |
| Course Overview | Scientific empirical studies on safety and effectiveness are indispensable in the development of medicine, therapeutic instruments, medical materials, and therapeutic/diagnostic equipment. These days, scientific empirical studies on safety and effective has also become indispensable in the development of functional foods, etc. from the viewpoint of preventive medicine. In addition, rapid development of technical seeds is strongly required in accordance with the needs of the medical care site. Under these circumstances, this course aims to equip students with importance to manage R&D strategically and to understand the existence of various jobs related to medical/pharmaceutical/health, not only from the scientific point of view, but also from the technical management point of view. |
| Remarks | Conducted in English. |
| Course Type | Lectures |
| Link between Course Objectives and Activities | To study how social needs related to Food and Health is connected to research and development in laboratories through the topic of critical path and translational research in medicine (especially, development of drugs and medical devices). |
| Academic Goal | <ol style="list-style-type: none"> 1. Students will be able to explain the process of medical drug and device development. 2. Students will be able to explain the importance of pre-clinical and clinical studies evaluating the safety and efficacy of medical drugs and devices. 3. Students will be able to explain the social situation of medical drug and device development, and the organization and authorized people concerning drug development. 4. Students will be able to explain the importance of technology for drug and device development and intellectual property. |
| Course Schedule | <ol style="list-style-type: none"> 1. Introduction to critical path research and translational research (Koichi Hashimoto) 2. Drug development I (Drug discovery) (Masafumi Muratani) 3. TBD 4. High-technology I (equipment, wet technology), High-technology II (data processing) (Masafumi Muratani) 5. High-technology (bio-informatics), Project management (Koichi Hashimoto) 6. Global drug development, and the role of Japan (Koichi Hashimoto) 7. Innovation of technology (Koichi Hashimoto) 8. TBD 9. An example of translational research I (Medical device) (Hideo Tsurushima) 10. An example of translational research II (Drugs) (Takahiro Kojima) |
| Course Prerequisites and Advisories | |
| Grading Philosophy (Percentage/ Criteria/ Methodology) | Class participation (40%) and reports (60%). Grading Criteria is A+ (Superior), A (Excellent), B (Good), C (Average) and D (Failure). |
| Self-Directed Learning Other Than Coursework | Read textbooks and activate discussion out of classes. |
| Textbooks, References and Supplementary Materials | Principles and Practice of Clinical Research, John I. Gallin, Frederic P. Oganibene, Academic Press |
| Office Hours | Name: Koichi Hashimoto E-mail: koichi.hashimoto@md.tsukuba.ac.jp By appointment only |
| Other (i.e. Expectations on Classroom, Conduct and Decorum etc.) | |

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| Related Courses | Entrepreneurship Training I Entrepreneurship Training II |
| Keywords | Critical Path Research, Translational Research, Drug development, Medial Device |