Advanced course on FDA regulatory processes, 3 ECTS

Learning outcomes

After the course the student will understand:

1) What are the regulatory milestones in clinical drug development towards marketing authorization in the US.
2) What preclinical and clinical data are needed for an FDA submission packages across the development cycle
3) What are the prerequisites of clinical trials that support regulatory submissions

Content

The main processes, workflows and activities of US drug regulatory authority Food and Drug Administration (FDA). This is an advanced course on legal frameworks, guidelines, procedures used in the marketing authorization application for FDA

1. Approved assignments

2. Active and approved participation in seminar and team exercise (mandatory attendance)

3. Approved grade in the knowledge quiz

Implementation methods

1. Lectures (10 hours)
2. Seminar (8 hours)
3. Team exercise (6 hours)
4. Individual exercises on-line (6 hours)
5. Studies on own and assignments (approximately 46 hours)

Evaluation scale

Pass/fail

Evaluation criteria

Passes/failed in attendance, exercises, participation during exercises and discussions

Approved quiz

Learning material

Delivered during the course via Moodle site

Further information

Students should have passed the course DRUG0026 Drug Regulation or have similar basic knowledge on general drug regulatory process and especially FDA.

Max. 24 enrolled to the course

Course schedule

Date	Time	Location	Topic
22.11. 2021	10.00-16.00	Osmo Järvi hall, Medisiina C building	Course kick off IND: • Introduction to working with FDA • Pre-IND meeting • Investigator Brochure • IND Submission • First in Human study • Clinical Pharmacology Studies • Phase 2 study
23.11. 2021	10.00-16.00	Alhopuro hall, Medisiina D building	NDA: • End of Phase 2 Meeting • Investigator meetings • Phase 3 Trials • Toxicology Studies Continued • Clinical Pharmacology Package • Pre-NDA meeting • NDA Submission • Label negotiations • Full Prescribing Information
24.11. 2021	10.00-15.00	Pha2, PharmaCity	Example Review of naloxegol NDA (public data) and prescribing information
25.11. 2021	10.00-16.00	Pha2, PharmaCity	Mock FDA advisory board • Students are divided into teams representing the sponsor, FDA, consumer advocates, experts

Course leaders:

Jaakko Lappalainen, Chief, Addiction Psychiatry at Crozer-Keystone Health System, Wilmington, Delaware, United States;

Ullamari Pesonen, Professor, UTU

Registration is open until 14.11.2021: https://link.webropolsurveys.com/S/B1E75A9E183590EF