COURSE DESCRIPTION

Academic year: 2022/2023

University: Comenius University Bratislava

Faculty: Faculty of Pharmacy

Course ID:	**Course title:**
FaF.KFT/22-Mgr/20	Basics of Regulatory Pharmacy

Educational activities:
Type of activities: lecture / seminar
Number of hours:
per week: 1 / 1 **per level/semester:** 14 / 14
Form of the course: on-site learning

Number of credits: 2

Recommended semester: 8.

Educational level: I.II.

Prerequisites:

Recommended prerequisites:
Phartmacology (1), Social Pharmacy and Pharmacoeconomics

Course requirements:
Mandatory 80% attendance at lectures and seminar work, in particular cases a written test.
Scale of assessment (preliminary/final): Ongoing 0 / final 100

Learning outcomes:
By passing this course, student is acquiring basic knowledge from field of regulation of medicinal products, mainly of evaluation of non-clinical and clinical documentation in the process of registration of medicinal products, regulation of safety of medicinal product, evaluation of efficacy of medicinal products and basic knowledge concerning regulatory aspects and procedures in medicines agencies (SIDC, EMA) and regulatory principles in non-clinical testing and clinical trials. During classes, one solves case studies with experts from practice.

Class syllabus:
- history of regulation of medicinal products in context of increased need for safety and efficacy demonstration - principles of regulation of medicinal products, basic characteristics of medicinal products – quality, efficacy, safety - need for good manufacturing practice, good clinical practice, good laboratory practice from regulatory point of view – effects on non-clinical and clinical testing -integration of regulatory pharmacy into pre- and post-marketing, planning and overview of product strategy, transfer of information to interested parties - regulatory and practical aspects of non-clinical and clinical testing - re-evaluation, referrals in the EU, issues concerning confidentiality and transparency in regulatory processes – consistence of decisions and application of state of the art knowledge - orphan medicinal products, paediatric data, advanced therapies, biosimilars, generics – non-clinical and clinical aspects - over-the-counter vs. prescription-only medicines, legal status of medicinal products, evaluation of legal status - regulation and evaluation of medical devices - regulatory aspects of medicinal product´s documentation - off-label use and misuse from the regulatory point of view - regulatory aspects of pharmacovigilance, evaluation of adverse events and safety of medicinal products - evaluation of risk-benefit ratio in medicinal product´s regulation

Recommended literature:

Klimas J a kol: Basics of Regulatory Pharmacy, Univerzita Komenského v Bratislave, 2014
Guidelines of European medicines agency, see http://www.ema.europa.eu/ema/

Languages necessary to complete the course:
Slovak, English

Notes:
maximum number of students: 20, in case of higher interest - selection will be made based on: grade average (years 1-3), average from subjects Pharmacology and Social pharmacy and pharmacoeconomics, motivation letter, certificate (exam) proving knowledge of english language

Past grade distribution
Total number of evaluated students: 40

A	ABS	B	C	D	E	FX
100,0	0,0	0,0	0,0	0,0	0,0	0,0

Lecturers: prof. PharmDr. Ján Klimas, PhD., MPH

Last change: 01.12.2021

Approved by: prof. PharmDr. Ján Klimas, PhD., MPH