Univerza *v Ljubljani* Fakulteta *za farmacijo*



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CEMDC Modul II

Postgraduate Cooperative European Medicines Development Course (CEMDC) is an integral part of the IMI project Pharmaceutical Medicine Training Program. It involves 10 participating European universities, including Faculty of Pharmacy, where activities are coordinated by Prof. Dr. Irena Mlinarič - Raščan, vice dean for research work.

CEMDC Module 2: »Non-clinical, pharmaceutical and early clinical development« was successfully completed at Faculty of Pharmacy in Ljubljana in November 19th-22nd, 2015 with 17 participants from Hungary, Italy, Lithuania and Slovenia. During intensive 4-day program 20 lectures were given by Slovenian and foreign lecturers from pharmaceutical industry and European regulatory agencies. The lectures were devoted to steps in the pharmaceutical development of a drug substance and to an efficient, safe and high quality synthetic or biological/biosimilar drug product. The main focus was given on selection and predictive value of the non-clinical tests (pharmacology, toxicology studies: genotoxicity, carcinogenicity, reproduction toxicity) and their integration into overall drug development plan. The lecturers pointed out the importance of the results of non-clinical testing for first-into-human studies and further exploratory development in human and gave a critical view on them.

We thank all the local and foreign lecturers for high-quality lectures and great atmosphere!

For more information go to: http://cemdc.eu/about-cemdc/

Link to the pictures: J:\Fotografije\2015_11_19 - CEMDC, Module 2, 19.-22. November 2015\Izbor slik CEMDC 2015