

CEMDC Modul II

Module 2 of Cooperative European Medicines Development Course (CEMDC), an integral part of the IMI project Pharmaceutical Medicine Training Program was successfully organized between 26 - 29th September 2013. The CEMDC involves 10 participating European universities, including Faculty of Pharmacy, where activities are coordinated by Prof. Dr. Irena Mlinarič - Raščan, vice dean for research work. During an intensive 4-day program entitled Non-clinical and early clinical pharmaceutical development, 20 lectures were given by Slovenian and foreign professors and lecturers from Slovenian pharmaceutical industry and European regulatory agencies. There were 8 participants from Slovenia, 7 from Hungary and 1 participant from Lithuania.

A number of 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 on a selection and the predictive value of the non-clinical tests (pharmacology, toxicology studies– genotoxicity, carcinogenicity, reproduction toxicity) and their integration into overall drug development plan. A few lectures gave a critical view on these tests and pointed out the importance of the results of non-clinical testing for first-into-man studies and further exploratory development in man.

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/>

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