

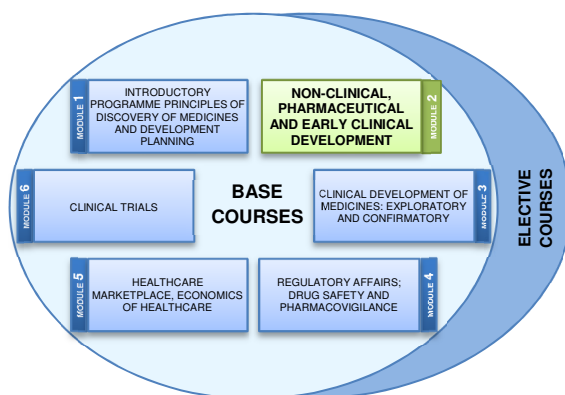
**BASE MODULE 2**  
**November 19<sup>th</sup>-22<sup>nd</sup>, 2015**  
**University of Ljubljana, Slovenia**

**Cooperative European Medicines Development Course**  
**PharmaTrain accredited**  
**Center of Excellence**

Learn medicines development closer to your working place at a PharmaTrain accredited international course organized jointly by universities teaching in the region.

## STRUCTURE OF THE EDUCATION PROGRAM

This multinational university program covers the entire process from drug discovery through all steps of medicines development up to the market. The target student population is professionals with medical, pharmaceutical or MSc (or equivalent) degrees in natural and life sciences.



## CERTIFICATES PROVIDED

The added-value of this course is that it results in a multinational certificate, which is scientifically accredited by the PhT organization, a guarantee of its broad international acceptance.

- **Module certificate (MC).** A stand-alone document certifying the successful completion of the module, including the examination. The module certificate will be issued by the respective Module-organizing University and will be accepted by the Coordinating University.
- **Diploma in Medicines Development (DMD) / Pharmaceutical Medicine.** This certificate, provided at the end of the Base Course, is based on an integrated assessment covering the entire syllabus following the completion of the 6 basic modules.
- **Master-Level Degree in Medicines Development (MLDMD) / Pharmaceutical Medicine.** This certificate is issued following completion of the entire master-level program containing both the Base and the Advanced Courses, and after a thesis has been submitted and successfully defended.

## LOCAL ORGANIZING COMMITTEE

prof. dr. Irena Mlinarič-Rašćan, assist. dr. Martina Gobec, assist. dr. Žiga Jakopin, assist. dr. Tijana Markovič, prof. dr. Iztok Grabnar, assist. prof. Tanja Gmeiner

## OUTCOME OF MODULE 2: NON-CLINICAL, PHARMACEUTICAL AND EARLY CLINICAL DEVELOPMENT

- Choice and predictive value of the non-clinical testing programme as part of the overall drug development plan for chemical and biological compounds.
- Integration of non-clinical tests into the overall drug development plan (including scheduling of toxicology tests with respect to clinical trials).
- Steps in the pharmaceutical development of a drug substance and final drug product (including chemical and biological compounds).
- Planning of clinical trial supplies for test substance and comparators (active and placebo).
- Overview of non-study requirements prior to First-into-Man studies.
- Molecular and cellular basis of toxic reactions.
- Principles and practical application of pharmacokinetics and toxicokinetics.
- Early exploratory development in man.
- Principles of clinical pharmacology and their application to clinical development.
- Influence of genetic factors in drug development and drug response.

## HOW TO APPLY

For admission, students must submit a copy of their degrees and a CV describing their professional experience to the CEMDC office OR local organizing committee. Tuition fee for the base module 2 is 800 €. For available scholarships, please contact the local organizing committee (CEMDC@ffa.uni-lj.si).

## CONTACTS

University of Ljubljana  
Faculty of Pharmacy



### BASE MODULE 2

University of Ljubljana, Faculty of pharmacy  
Askerceva 7, SI-1000 Ljubljana  
Phone: +386 (0)1 476 95 00  
Fax: +386 (0)1 425 80 31  
Email: [cemdc@ffa.uni-lj.si](mailto:cemdc@ffa.uni-lj.si)  
Website: <http://www.ffa.uni-lj.si/en.html>

### CEMDC Cooperative European Medicines Development Course

Semmelweis University, Semmelweis Tender Services and Innovation Centre Limited Liability Company  
Budapest, Hungary  
Fax: +36-1-459-1589  
Email: [office@cemdc.eu](mailto:office@cemdc.eu)  
Website: <http://www.cemdc.eu>

