POST-GRADUATE PROGRAMME IN
PHARMACEUTICAL MEDICINE &
MEDICINES DEVELOPMENT SCIENCES

MODULE 3
Preclinical safety

11-12 May 2016
DRUG SAFETY EVALUATION: GENERAL AND REPRODUCTIVE TOXICOLOGY
René VERLOES

This course will review the regulatory requirements for nonclinical safety testing of pharmaceuticals, prophylactic and therapeutic vaccines. Dr Verloes will discuss the design and interpretation of general toxicity studies, their phasing in the drug development process and the place of toxicokinetics and of immunological readouts. A second part will address the carcinogenicity testing and the reproduction and developmental toxicity evaluation.

Impact of genotoxicity and carcinogenicity studies on drug development
Frank ATIENZAR

Pharmaceutical compounds need to be tested in a battery of genotoxicity assays before first in man (except for cancer treatment). Such assays are used to predict carcinogenicity risk in Human. Current genotoxicity guidelines will be explained. Unfortunately, regulatory genotoxicity tests are not adapted for early screening because such tests require significant amount of compounds, are time consuming and expensive. In vitro genotoxicity assays which play a central role in the selection of the most promising compounds at early stage of drug development will be described. Predictivity data will be presented for a wide range of assays. Structure activity relationship is key to better understand what is driving genotoxicity to help the chemical design of safer drugs. Finally, the course will also focus on non-genotoxic carcinogens.
SAFETY EVALUATION OF BIOTECHNOLOGY PRODUCTS AND GENE THERAPY
Philippe DETILLEUX

This course will consider the specific issues involved in the safety evaluation of anticancer drugs, biotechnology products and gene therapy agents.

CARDIAC SAFETY ASSESSMENT IN DRUG DEVELOPMENT
Jean-Pierre VALENTIN

The course will review the scientific, regulatory and medical aspects of cardiac safety evaluation of new drug candidates. Preclinical and clinical studies to investigate prolongation of cardiac repolarization and related issues (ventricular arrhythmias) will be discussed and the applicable regulatory guidelines outlined. The importance of a scientifically sound integrated safety assessment will be illustrated.

Novel Approaches in Investigative Toxicology
Stéphane DHALLUIN

The course will address the technological revolution that is currently happening in toxicology. Nowadays, it has become even more crucial than before to decide early on the progression of compounds through the various drug development stages. Some novel techniques/technologies, methods and approaches can be used to complement conventional toxicology studies in order to exploit them at best and make the most of the limited tissues and fluids that can be collected. Others (in cerebro, in silico, in vitro) even try to bring very early elements facilitating decision-making prior to the first in vivo toxicology studies. This course does neither pretend to be exhaustive nor to provide a catalogue of new approaches but will cover specific examples of investigative toxicology techniques/technologies in use or in development.
Wednesday 11 May 2016

9.30 – 10.00 Welcoming participants

10.00 – 13.00 René VERLOES
Non-clinical safety evaluation

14.00 – 16.00 Franck ATIENZAR
Impact of genotoxicity and carcinogenicity studies on drug development Stéphane DHALLUIN
Novel approaches in investigative toxicology

16.00 – 16.15 Coffee break

16.15 – 17.15 Jean-Pierre VALENTIN
Cardiac safety evaluation in drug development

Thursday 12 May 2016

9.00 – 10.50 René VERLOES
Non-clinical safety evaluation

10.50 – 11.10 Coffee break

11.10 – 12.00 René VERLOES
Non-clinical safety evaluation

12.00 – 13.00 Lunch

13.00 – 15.00 Stéphane DHALLUIN
Novel approaches in investigative toxicology

15.00 – 15.15 Coffee break

15.15 – 16.15 Stéphane DHALLUIN
Novel approaches in investigative toxicology

16.15 – 18.15 Philippe DETILLEUX
Safety evaluation of anticancer drugs, biotechnology products and gene therapy agents
REGISTRATION FEES FOR THE COURSE AND EXAMINATION

- Attendance to the 16 modules, access to all course notes on the private domain of our web site and examination: 7,000 €
- Attendance to 4 selected modules, access to all course notes on the private domain of our web site and examination: 3,000 €
- Attendance to one individual module, with a copy of the course notes: 600 €
- Examination only, with access to all course notes on the private domain of our web site: 1,500 €
- Second or third attempt at the examination: 200 €

Registration can be done at any time during the year.

Registration to a module includes two lunches and beverage breaks. A discount can be offered to candidates who are neither employed nor sponsored by a biopharmaceutical company.

Register by e-mail, by sending the completed registration form to pharmed@ulb.ac.be.
Download the registration form on our website.
Payment should be made upon receipt of our invoice.
The courses take place in Brussels, in Brussels, at HOTEL ERASME:
Route de Lennik 790 – 1070 Brussels (Phone: 32-02/523 62 82)

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