

PHARMED

Module 11

20 - 21 March 2019

For more information please contact :

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The courses take place in Brussels, at
IBIS BRUSSELS ERASMUS HOTEL
Route de Lennik 790 – 1070 Brussels
Phone : 32-02/523 62 82

Pharmacovigilance

- Pharmacoepidemiology and drug utilization studies
- European regulation of pharmacovigilance
- Pharmacovigilance in daily practice
- Recent trends in Pharmacovigilance

PHARMACOEPIDEMIOLOGY AND DRUG UTILIZATION STUDIES

Robert VANDER STICHELE

This course will summarise the basic concepts of the epidemiological method (case control studies, cohort studies, confounding ...) which must be well understood in order to perform adequate post-marketing surveillance.

EUROPEAN REGULATION OF PHARMACOVIGILANCE

Caroline DUMAS

The course will describe the pharmacovigilance requirements relating to medicinal products marketed in the EU. The legal provisions relating to pharmacovigilance, which are supported by a series of guidelines including those adopted in the EU under the ICH process, will be presented. The course will highlight the responsibilities of the Marketing Authorisation Holders, the Member States and the EMA.

PHARMACOVIGILANCE IN DAILY PRACTICE

Caroline DUMAS

C. Dumas will present her experience of "Product Surveillance for Industries" gained within the pharmaceutical industry, in various pharmacovigilance positions. The course will be illustrated by real life cases.

RECENT TRENDS IN PHARMACOVIGILANCE

Corinne JOUQUELET-ROYER

This course will present an overview of new concepts and tools in pharmacovigilance.



Robert VANDER STICHELE

M.D., RUG and VUB, Senior Researcher, Health Technology Assessment, Heymans Institute of Pharmacology and Belgian Health Care Council



Caroline DUMAS

M.D., MSc Former Senior Medical Regulatory / Pharmacovigilance positions in the pharmaceutical industry" - Pharmacovigilance Consultant.



Corinne JOUQUELET-ROYER

MD, former clinical pharmacologist at University of Nancy and University of Bordeaux, former specialist in pharmacovigilance at the French Centre de Pharmacovigilance and at GSK Biologicals, VP, Global Pharmacovigilance, Sanofi Pasteur, Lyon, France

WEDNESDAY
20 March 2019

Welcoming participants

9.30-10.00

Drug information to physicians and patients

Robert VANDER STICHELE

10.00-12.00

European regulation of pharmacovigilance

Caroline DUMAS

13.00-14.00

Pharmacovigilance in daily practice

Caroline DUMAS

14.00-15.45

Coffee break

15.45 - 16.15

Pharmacovigilance in daily practice

Caroline DUMAS

16.15-18.00

THURSDAY
21 March 2019

Basic concepts in pharmacoepidemiology

Robert VANDER STICHELE

09.00-10.50

Coffee break

10.50-11.10

Drug utilization studies

Robert VANDER STICHELE

11.10-13.00

Lunch

13.00-14.30

Recent trends in pharmacovigilance

Corinne JOUQUELET-ROYER

14.30-17.30