

BRAS COURSE

INTRODUCTION TO REGULATORY AFFAIRS

14th edition May 28-29, 2018

Venue: AFMPS / FAGG – Eurostation II – Place Victor Hortaplein 40, 1060 Brussels

The course is addressed to people new to regulatory affairs who want to acquire a comprehensive foundation; to regulatory professionals wishing to update their knowledge, and to all collaborators working in close relationship with regulatory affairs and wishing to understand the role of the department.

The program proposes an introduction to the legal, scientific, organisational and administrative aspects of medical products given by 13 experienced tutors from university, FAMHP and industry.

Program and speakers

Day 1

08.30 Registration and coffee

09.00 Welcome & introduction to the course
Marc Benijts (BRAS)

09.15 Pharmaceuticals – definitions – product life cycle
Lieve Lammens (Janssen Research and Development)

10.15 The European Union and its institutions – The Belgian bodies
Peter Bogaert (Covington & Burling LLP) – Charlotte Ryckman (Covington & Burling LLP)

11.15 Coffee break

11.45 The pharmaceutical legislation (EU – B)
Peter Bogaert (Covington & Burling LLP) – Charlotte Ryckman (Covington & Burling LLP)

12.45 Lunch

13.45 Mdeon – art 10
Stéphanie Brillon (Mdeon)

14.30 Coffee break

14.45 European Medicines Agency – EU procedures for Marketing Authorisations
Ingrid Theeuwes (PhaRa consulting)

16.15 Pharmacovigilance
Michèle Sangeleer (Eli Lilly)

17.30 End of first day

Day 2

09.00 Legislation for clinical trials
Anne Lenaers (FAMHP)

10.15 Coffee break

10.45 CTD module 3
Evelien Wynendaele (Ugent)

11.45 CTD module 4
Gaëlle De Meyer (FAMHP)

12.45 Lunch

13.45 CTD module 5
Nele Steens (FAMHP)

14.45 Variations – renewals – extensions
Ingrid Prieschl (Merck Sharp & Dohme Europe)

16.00 Coffee break

16.15 Marketing Authorisation – Legal basis – Practical aspects linked to module 1
Katelijne Van Keymeulen (FAMHP) & Machteld Verbruggen (FAMHP)

17.15 Closing remarks
Marc Benijts (BRAS)

17.30 End of course

Registrations through our website. (www.bras-org.be)

For registration you click on the line of the session in “Future courses and events” on the Home Page and then sign up. If you are not yet registered on the website you will be asked to do so. The system will send you a confirmation of registration with payment modalities by return mail.

If you need more assistance please contact Brigitte at bras@bras-org.be or call her on 02.757 06 29.

Fees: BRAS member **900€** - Non-BRAS member **1.100€**

It is understood, to be admitted to the session, that the fees have been pre-paid. **In case of cancellation after 18 May 2018 or no-show, the fees are due and will be invoiced.**