



BRAS COURSE

INTRODUCTION TO REGULATORY AFFAIRS

15th edition May 13-14, 2019

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 language of the course is English.

The program proposes an introduction to the legal, scientific, organizational and administrative aspects of medical products given by 12 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 Pharmacovigilance
Michèle Sangeleer

15.00 coffee break

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

17.00 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 Berthels (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 Isabel Tack at bras@bras-org.be or call her on 0472 97 35 74.

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 3 May 2019 or no-show, the fees are due and will be invoiced.**