



## **BRAS ADVANCED COURSE**

### **CTD module 3 - Quality section**

**8<sup>th</sup> edition November 28 - 29, 2019**

Venue: Novotel Brussels Airport - Leonardo Da Vinci Laan 25, 1831 Diegem

### **Program and speakers**

#### Day 1

- 08.30 Registration and coffee
- 09.00 Welcome & introduction to the course  
Marc Benijts (BRAS)
- 09.15 Overview CTD - Quality related issues  
Katrien Van Landuyt (FAMHP)
- 09.45 Stability in the Pharmaceutical World  
Kristof Loones (Janssen)
- 10.30 coffee break
- 11.00 Drug substance: general requirements  
Bernard Pirotte (Ulg)
- 11.45 Drug substance: synthesis and control during synthesis  
Michel Guillaume (Janssen)
- 12.30 Lunch
- 13.15 Relevant analytical techniques and method validation  
Bart De Spiegeleer (Ugent)
- 14.00 Drug substance: impurities  
Sonja Beken (FAMHP) - René Hanselaer (FAMHP)
- 15.00 coffee break
- 15.15 Drug products: General overview and practical tips  
Helene Van de Ven (FAMHP)
- 16.00 Parenteral dosage forms  
Roland Schots (Roval Pharma)
- 16.45 Solid oral dosage forms  
Valérie Vanhoorne (Ugent)
- 17.30 End of first day



## Day 2

- 09.00 Variations according to Regulation EC 1234/2008  
Roselien Poppe (FAMHP)
  
- 09.30 Handling of Variations to Module 3  
Angeline Lienart (FAMHP) - Liesbeth Bogaert (FAMHP)
  
- 10.15 Variations - Theoretical & practical application worked out through several case studies  
Introduction to the cases  
Mixed panel FAMHP & Industry: Kim Boue (Janssen Pharmaceutica) - Bart Denayer (FAMHP) -  
Guy Fonck (FAMHP) - Debbie Lettani (Janssen Pharmaceutica) - Ann Matton (Pfizer) - Rembert  
Van de Sande (Pfizer) - Helene Van de Ven (FAMHP) - Katrien Van Landuyt (FAMHP)
  
- 10.30 Coffee break
  
- 11.00 Work out of case studies in workshops (1)  
Mixed panel FAMHP & Industry
  
- 12.30 Lunch
  
- 13.30 Work out of case studies in workshops (2)  
Mixed panel FAMHP & Industry
  
- 15.00 Coffee break
  
- 15.15 Work out of case studies in workshops (3)  
Mixed panel FAMHP & Industry
  
- 16.45 Closing remarks  
Marc Benijts
  
- 17.00 End of course

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](mailto:bras@bras-org.be) or call her on 0472 97 35 74.

**Fees:** BRAS member **900€ (excl. VAT)** - Non-BRAS member **1.100€ (excl. VAT)**

It is understood, to be admitted to the session, that the fees have been pre-paid. **In case of cancellation after 15 November 2019 or no-show, the fees are due and will be invoiced.**