

BRAS ADVANCED COURSE

CTD module 3 – Quality section

7th edition November 16-17, 2017

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

Program and speakers

Day 1

Section I: General aspects (substance & product)

- 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 Relevant analytical techniques and method validation
Wynendaele Evelien (Ugent)
- 10.30 coffee break
- 11.00 Stability in the Pharmaceutical World
Ooms Christel (Janssen)

Section II: Drug substance

- 11.45 Drug substance: general requirements
Bernard Pirotte (Ulg)
- 12.30 Lunch
- 13.15 Drug substance: synthesis and control during synthesis
Michel Guillaume (Janssen)
- 14.00 Drug substance: impurities
Sonja Beken (FAMHP) – René Hanselaer (FAMHP)
- 15.00 coffee break

Section III - Drug product

- 15.15 Drug products: General overview and practical tips
Isabelle Delneuville (FAMHP)
- 16.00 Parenteral dosage forms
Roland Schots (Roval Pharma)
- 16.45 Solid oral dosage forms
Vanhoorne Valérie (Ugent)
- 17.30 End of first day

Day 2

Section IV: Variations

- 09.00 Variations according to Regulation EC 1234/2008
Roselien Poppe (FAMHP)
- 09.30 Handling of Variations to Module 3
Daan Debremaeker (FAMHP) & Davy Van der Linden (FAMHP)
- 10.15 Variations – Theoretical & practical application worked out through several case studies
Introduction to the cases
Mixed panel FAMHP & Industry: Daan Debremaeker (FAMHP) – Isabelle Delneuve (FAMHP) –
Bart Denayer (FAMHP) – Guy Fonck (FAMHP) – Debbie Lettani (Janssen Pharmaceutica) - Ann
Matton (Pfizer) – Inge Terryn (Janssen Pharmaceutica) - Rembert Van de Sande (Pfizer) - Katrien
Van Landuyt (FAMHP)
- 10.30 Coffee break
- 11.00 Work out of case studies in workshops (1)
- 12.00 Lunch
- 13.00 Work out of case studies in workshops (2-3)
- 15.00 Coffee break
- 15.15 Work out of case studies in workshops (4)
- 16.15 Closing discussion on results of workshops
Mixed panel FAMHP & Industry
- 16.35 Closing remarks
Marc Benijts
- 16.45 End of course

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

For registration you click on the line of the course 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 8 November 2017 or no-show, the fees are due and will be invoiced.**