

HEALIXIA / BRAS ADVANCED COURSE

CTD module 3 – Quality section

9th edition December 2 – 3, 2021

Venue: Park Inn by Radisson Brussels Airport, Grensstraat 3, 1831 Machelen

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 (HEALIXIA / 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
Tine Eelen (Janssen)

Section II: Drug substance

11.45 Drug substance: general requirements
Eddy Dolusic (FAMHP)

12.30 Lunch

13.15 Drug substance: synthesis and control during synthesis
Michel Guillaume (Janssen)

14.00 Drug substance: impurities

- Non-Clinical aspects : Sonja Beken (FAMHP) – Evelyne Pirotte (FAMHP)
- Quality aspects : Eddy Dolusic (FAMHP)

15.15 coffee break

Section III - Drug product

15.30 Drug products: General overview and practical tips
Helene Van de Ven (FAMHP)

16.15 Parenteral dosage forms
Roland Schots (Roval Pharma)

17.00 Solid oral dosage forms
Valérie Vanhoorne (UGent)

17.45 End of first day

Program and speakers 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
Eline Van der Biest (FAMHP) & Liesbeth Bogaert (FAMHP)
- 10.15 Variations – Theoretical & practical application worked out through several case studies
Introduction to the cases
Mixed panel FAMHP & Industry: Elke Debie (Janssen) - Isabelle Delneville (FAMHP) – Bart Denayer (FAMHP) – Guy Fonck (FAMHP) – Ann Matton (Pfizer) – Rembert Van de Sande (Pfizer) – Helene Van de Ven (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