

HANDS-ON-TRAINING: COMPILATION OF MODULES 2 (P&A) & 3 OF CTD

The dynamic pharmaceutical industry sees a rapid turnover in staff members and the day-to-day tasks require a multitude of fields of expertise. This course will provide real and hands-on focused training and mentorship for **younger regulatory personnel, or persons who have to start with the CTD compilation process**. The goal of the training is to empower the junior staff member and give him/her confidence in the task he/she was trained on.

Date: Thursday 30 May 2019

Venue: Glenhove Conference Centre, 52 Glenhove Rd, Melrose

Time: 0900 - 1600

Who should attend:

- Newly appointed regulatory staff

Presenter and facilitator:

Leneri du Toit and Esthi Beukes

Topics:

Requirements for data and how to compile Module 2

- What information is required in this module?
- Can I request exemption from certain sections/ modules?

Requirements for pharmaceutical and analytical data and how to compile Module 3

- What information is required in this module?
- Can I request exemption from certain sections/ modules?

Trouble shooting and questions

- Sharing of experiences between delegates.