

Quality Review- CTD dossier

October 6th to 8th – 2012

CTD Fundamentals (27th, 28th & 29th May 2012 – Cairo/Egypt)

- **Seminar themes:**

1. Introduction - CTD & Module 3 (product & substance)
2. GRP regarding (CTD, Module 3.2.S) leading to product quality
3. New opportunities for the implementation of ICH Q8, Q9, Q10 & Q11 in dossier review process
 1. Authorities point of view
 2. Industry point of view
4. Possibilities of Risk Based Review.
5. Quality Risk Management case study for regulators (incl. classwork in small groups and final presentation in plenary)
6. Good review practices (GRP) - assessment/list of questions/clock stop/assessment of responses
7. Plan a meeting between Authorities and Industry
8. Impurity and Stability requirements for product quality
9. Case study: Review of Stability and Impurity Data (incl. classwork in small groups and final presentation in plenary)

Speakers:

Dr. Christa Wirthumer-Hoche, Dr. Cornelia Nopitsch-Mai & Dr. Fritz Erni