

## Regulatory Affairs Workshop on the Common Technical Document (CTD)

- ⇒ Understand the essentials of marketing authorization procedures
- ⇒ Get acquainted with the Common Technical Document and its use world wide
- ⇒ Gain fundamentals of compilation of CTD Modules for Generics
- ⇒ Learn how to get information and documents from different sources within and outside the company
- $\Rightarrow$  Define the most essential parts in the CTD
- ⇒ Understand the impact of CTD implementation on the product (pharmaceutical development, improvement of the products) as well as on the market (potentially new markets abroad)
- ⇒ Understand the criticality of information given to the national regulatory authority

## Join us for practical sessions, theoretical background and professional exchange!

Venue: Conference hall + practical sessions on site

Trainers: experienced trainers from international pharma industry

Duration: 2-3 days

Target group: professionals of pharmaceutical manufacturers (regulatory affairs managers, heads of Quality Assurance or heads of production), NMRA assessors

Can be combined with our training on Bioavailability and Bioequivalence.



E-Mail: irmgard.buchkremer@medeor.de