



Special—GMP and CTD Registration requirements for sterile medicinal products

- ⇒ Understand the essentials of sterile manufacturing and aseptic processing
- ⇒ Gain fundamentals on Quality Sterilisation, Validation and Qualification
- ⇒ Learn how to implement Quality Risk management
- ⇒ Get informed about Quality Control for sterile products
- ⇒ Get acquainted with GMP Inspection guidelines WHO Technical Report series for sterile products and frequent GMP deficiencies observed
- ⇒ Learn how to compile CTD Module 3 for sterile dosage forms
- ⇒ Understand the criticality of information given to the national regulatory authority

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

Venue: Conference hall

Trainers: experienced trainers from international pharma industry

Duration: 4-5 days or 2-3 days for GMP and 1-2 for CTD Registration

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

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