Regulatory Affairs Workshop on Bioequivalence Testing and Biowaiver

⇒ Understand the essentials of Bioavailabilty

⇒ Get acquainted with the ways of proofing Bioavailabitilty for new products and bioequivalence for generic drugs

⇒ Gain fundamentals on biowaivers and biopharmaceutics Classification System

⇒ Learn how to set up bioequivalence studies (e.g. duration, clinical study planning, reference product)

⇒ Learn from lessons of other countries on establishment of a BE center

⇒ Learn what international inspectors want to know on the clinical, pharmaceutical and analytical part of the study report

⇒ 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: 2 days

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

Can be combined with our training on CTD

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