



Kompass Regulatory Services provides a extensive portfolio of regulatory and clinical affairs services

Quality, Confidentiality, Compliance and Value are the cornerstones of our service
We are integral to the successful development and global registration of medicines

We embrace a distinctively hands-on approach where confidentiality is paramount

We understand our client needs and maintain positive long-term partnerships

We are driven and dedicated to deliver strategies and solutions for success
We have strong track record for delivering excellent results to our clients
We strive to turn vision into reality in a timely and cost effective manner

Our personal dedication to quality service is our commitment

Our mission is to exceed our clients' expectations

Your Success is Our Success

Our Team is Your Team

REGULATORY & CLINICAL SERVICES:

- ✓ eCTD
 - Dossier preparation, publishing, compilation, review, validation and tracking
 - CTD & NTA migration, NeeS
- ✓ Licence registrations and maintenance
 - European & U.S.
 - National, MRP, DCP & Centralised
 - BCS- based Biowaiver applications
 - DMF preparation & submission
 - Human & Herbal licence maintenance
- ✓ Readability testing/PIL testing/mock-up creation
- ✓ Product Quality Review Reports/Annual Reports
- ✓ Clinical and non-clinical overviews & summaries
- ✓ SPC sourcing and harmonisation
- ✓ Clinical Trial Applications & IMPD
- ✓ Controlled Substances licensing & Management
- ✓ Due diligence, SOP preparation, Site Master File & Auditing
- ✓ PSUR compilation
 - Literature searching
 - Expert reports
 - Electronic reporting
- ✓ Detailed Description of Pharmacovigilance Systems
- ✓ QPPV and Deputy QPPV
- ✓ Medical Devices
 - CE mark
 - Technical File
 - PMA
 - 510(K)
 - CT applications

Contact:

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