

UKR Regulatory Affairs Ltd.



*International
Regulatory Services
for Pharmaceutical
and Healthcare
Business*

Consultancy Management of National & International Drug Licensing Procedures specialising in European Mutual Recognition & Decentralised Procedures

Services

- Strategic Regulatory Advice & Project Management
- Clinical Trial Applications
- Liaison with the UK (MHRA) & Irish (IMB) Health Authorities
- Preparation & Management of Regulatory Submissions/Dossiers:
 - Common Technical Document (CTD/eCTD)
 - National Applications
 - Mutual Recognition Procedures (MRP)
 - Decentralised Procedures (DCP)
 - SPC, PIL, Labelling
 - Patient Leaflet User/Readability Testing
- Post-Licensing Support (e.g. Variations)
- Internal Auditing
- Advertising Material

National Support for International Projects

(UK & Irish representative of **regulanet**[®])

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