

Why chose Acta Pharma Services?

Navigating a safe course through the stormy seas of European Regulatory Affairs needs skill, knowledge and perseverance. Filing a marketing application isn't just a question of performing studies in accordance with ICH guidelines and submitting the CTD modules. Some regulatory requirements in the European Union are specific to the region but on top particular national regulations may also apply.

Acta Pharma Services was set up in 2001 to provide a professional, efficient and flexible range of consultancy services in regulatory affairs to the pharmaceutical industry. Based in London, England the company specialises in the preparation, filing and maintenance of marketing applications for the UK and European Union. Using Acta will allow you to achieve your aims and meet deadlines whilst controlling your costs.

Services Offered

Acta Pharma Services can handle all the mainstream activities associated with submission and maintenance of marketing authorisations. Our services include:

Submission services

- Development of regulatory strategies for Europe
- Planning and management of National, Decentralised and Centralised Procedures
- Regulatory authority liaison, hearings and appeals
- Planning and handling of agency meetings (including preparation of briefing documents)
- Interpretation of regulatory guidelines and advice on strategy

Documentation services

- Preparation and maintenance of regulatory dossiers for APIs (DMFs and Certificates of Conformity) and finished products (Marketing Applications)
- Preparation of Quality Overall Summaries for Drug Substance and Drug Product
- Preparation and auditing of Manufacturers' Licences
- Maintenance of marketing approvals including preparation of applications for licence variations
- Conversion of dossiers to CTD format
- Scientific report writing
- Preparation of product labelling and artwork

Project management

- Critical review of scientific and technical data against regulatory requirements
- Due diligence for licensing projects
- Preparation and filing of responses to regulatory questions
- Follow up with customer's internal departments and with company's external partners
- Short-term replacement of staff and project support
- Training in Regulatory Affairs