

# PHARMACEUTICAL SERVICES

## EUROPE

### Regulatory Services—Europe

A well planned regulatory strategy is essential to ensuring the best outcome for your product in the European market. Each product is unique and has its own strategic path to get from the manufacturer to market. Factors such as when and how to approach regulatory agencies, questions to ask, and proper interpretation of the answers can avoid excess time and expense. **toXcel** International will work with your company to provide a seamless progression for drug registration. We have experience working with both small and large pharmaceutical companies. **toXcel** can assist your company in the following areas:

- Non-Clinical Study Program Development
  - CRO selection and liaison
  - Protocol design and review
  - Study Monitoring
  - Good Laboratory Practice (GLP) Audit
  - Report review
- Prepare non-clinical section of Investigational Medicinal Product Dossier (IMPD) and Investigators Brochure (IB)
- Clinical Trials Application (CTA)
- Marketing Authorization Applications (MAA)
- Application for orphan designation
- Application to market biosimilar medicines
- Common Technical Document (CTD) preparation and non-clinical expert signature
- Respond to Member State questions
- Non-clinical update and expert signature for renewals
- Expert representation at Member States for non-clinical issues
- cGMP Compliance Audits
- Due Diligence
- Expert witness
- Literature reviews
- Serve as European Agent

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