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. Pivotal to this is a well-structures non-clinical safety program where information and timing can be critical to each stage of development. ***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
- Non-clinical protocol design and review
- Study Monitoring and Laboratory audit
- Report review
- Support to market biosimilar medicines
- Common Technical Document (CTD) preparation, section 2.4 and 4, 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
- Due Diligence
- Expert witness
- Literature reviews and searched, especially for generic applications

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