Pharmaceutical Services

- United States

Toxicology & Regulatory Affairs Services—US

Whether your company is newly emerging or has extensive regulatory experience, the FDA drug approval process can be both costly and time-consuming. In today's complex regulatory environment and challenging economy, it pays to consult with experts that have the experience to meet your development milestones and regulatory timelines without delays. ***toXcel***, LLC has the experience and expertise to help our clients make the best use of their time and resources by providing them with the following services:

- Development of regulatory strategy
- Assessment of drug development plan
- FDA Liaison
- Schedule and participate in pre-submission meetings with FDA
- Application submission
    - Pre-Investigational New Drug (Pre-IND) Application
    - Investigational New Drug (IND) preparation and submission
    - New Drug Application (NDA)
    - Abbreviated New Drug Application (ANDA)
    - Over the Counter Drug Application (OTC)
    - Orphan Drug Application
    - Environmental assessment of human drug and biologics applications
- Development of Drug Master Files (DMFs)
- Non-clinical study program development
    - CRO selection
    - Protocol design and review
    - Study monitoring
    - Good Laboratory Practice (GLP) audit
    - Summary report preparation
- Drug product labels for both Rx and OTC drugs
    - Label development, review, and submission
    - Electronic Labeler Code request
    - Electronic Facility Registration
    - Electronic Drug Product Listing
- Safety evaluation of product packaging and delivery systems
- Electronic submission of establishment registration and annual drug amount reporting
- OTC monograph compliance review
- Over-the-counter (OTC) monograph order requests (OMORs)
- Literature searches
- Expert witness testimony
- Registration in UK and European Union
- U.S. Agent for pharmaceutical companies around the globe
    - Register your establishment and list your product(s)
    - Serve as your liaison between your company and FDA
    - Interact with federal authorities to resolve customs disputes and issues

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