



# PHARMACEUTICAL 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 drug listing via Structured Product Labeling (SPL) using FDA's Electronic Submissions Gateway
- OTC monograph compliance review
- Literature searches
- Expert witness
- Registration in 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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