Our Expertise in Europe

- REACH
- Non-Clinical Study Program Development
  - CRO Selection
  - Protocol Design & Review
  - Study Monitoring
  - GLP Audit
  - Report Review
- Prepare Non-Clinical Section of IMPD & IB
- Clinical Trials Application
- Marketing Authorization Application
- Orphan Designation Application
- Application to Market Biosimilars
- CTD preparation & Non-Clinical Expert Review
- Respond to Member State Questions
- Non-Clinical Update & Expert Signature for Renewals
- Expert Representation at Member States for Non-Clinical Issues
- cGMP Audits
- Due Diligence
- Expert Witness
- Serve as European Agent
- Literature Reviews
- OECD Testing Guidance
- GHS and SDS Preparation

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About Us

- Serving Clients Since 1999
- Regulatory Affairs and R&D Managers
- Board Certified Toxicologists
- Regulatory Review Managers
- Directors from Industry
- Research Scientists
- Specialists in Risk Assessment
- Highly Experienced & Multidisciplinary Staff
- Occupational & Environmental Exposure Assessment

Let *toXcel* Assist in Meeting Your Goals

- Development of Regulatory Strategy
- Assessment of drug development plan
- FDA Liaison
- Application submission
  - Pre-IND application
  - IND preparation and submission
  - NDA
  - ANDA
  - OTC application
  - Orphan Drug Application
- Environmental Assessment of Human Drugs and Biologics
- Development of Drug Master Files
- Non-clinical Study Program
  - CRO Selection
  - Protocol Design and Review
  - Study Monitoring
  - Good Laboratory Practice (GLP) audit
  - Summary Report Preparation
- Drug Product Labels
- Literature searches/Expert Witness
- U.S. Agent for pharmaceutical companies around the globe

Our Clients

- Pharmaceutical companies
- Biotechnology companies
- Healthcare / consumer products companies
- Food and cosmetics industries
- Chemical manufacturers
- Formulators
- Trade associations
- Law firms

toXcel's North American and European offices work closely together to provide a coordinated regulatory resource for seamless development and execution of strategies designed for cost-effective regulatory approvals leading to domestic, regional, and global export market expansion.