



Regulatory Affairs.

Premier Research's regulatory affairs experts help you navigate the daunting maze of regulations and guidelines, create high quality submissions, and develop successful strategies for interacting with the agencies in the United States and Europe.

Services

- Regulatory Consulting
- Regulatory Operations
- Electronic Submissions/eCTD
- U.S. Authorized Representative
- EU Legal Representative
- EU CTA Applicant
- EU Registered Company for Marketing Authorization Applications
- Regulatory Agency Liaison
- Regulatory Due Diligence
- Device Classification and Strategy
- Critical Literature Review
- CE Mark Process

Benefits

- Effectively manage your relationship with the regulatory agencies, acting as United States Authorized Representative or the EU Applicant
- In-house regulatory consultants provide guidance on development and regulatory strategy
- Complete service from Phase 0 to marketing authorization in the United States and Europe

Expertise: The People

- Established relationships with the FDA, the EMEA, and the EU Competent Authorities
- Experience from big and small pharmaceutical companies, CROs, and Regulatory Agencies
- Management of multiple submissions in a broad array of FDA Divisions
- Experience with CTA submissions in accordance with the Clinical Trial Directive in Europe in a variety of Member States
- Individual know-how in medical device and combination products

Case Study: Meeting Aggressive Timelines for a New Drug Application

A small, specialty pharmaceutical company contracted Premier Research to prepare and submit an NDA for an opioid analgesic which included regulatory strategy and oversight, as well as a full spectrum of biometrics and medical writing activities.

At the sponsor's pre-NDA meeting in August, multiple changes to the pooling strategy were requested by the FDA which would have made the planned submission date impossible. Premier Research's regulatory experts were able to negotiate a less onerous pooling strategy at the meeting which still appeared to result in a delay to the planned submission.

In spite of the unexpected changes and the resulting significant increase in the complexity of the NDA, the Premier Research team was able to apply a uniquely creative and aggressive approach to completing all the modules nearly simultaneously which allowed the client and its development partners to meet their ultimate goal of a year-end submission. The NDA was submitted in eCTD format on December 30th.

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