MEDELIS
Clinical answers, faster.

REGULATORY APPROVAL CONSULTING

Navigation through the FDA and European Regulatory Maze

A KEY ELEMENT TO SUCCESSFULLY BRINGING YOUR DRUG TO MARKET IS AN UNDERSTANDING OF HOW TO NAVIGATE THE REGULATORY AGENCIES IN THE U.S. AND EUROPE

To prevent unnecessary delays — which extend timelines and increase costs — it's vital to have an effective regulatory approach and prepare a strong regulatory submission.

OUR OFFERING

The Medelis team can provide flexible services ranging from answering specific regulatory questions, to writing, compiling and filing regulatory submissions, to setting up and leading regulatory meetings on your behalf.

Whether it's higher-level regulatory activities, or collecting regulatory documents and preparing submissions, the Medelis regulatory experts can assist you by charting the straightest course through the regulatory maze.

VALUE

Having the right regulatory approach, and anticipating any potential issues before your regulatory submission, provides you with:

- A reduced risk of regulatory delays
- Assistance with collecting and preparing study-specific SOPs and regulatory documents
- Comfort that you're delivering strong regulatory submissions over the lifetime of your product
- A potentially lower cost of study resulting from a straight path through the governing entities

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ABOUT MEDELIS:

As a single-source provider for clinical trial planning, trial management and drug development planning, including regulatory guidance and consulting, Medelis is helping biotechnology and pharmaceutical companies by delivering the best total solution—and all the support required—to optimize the return on your clinical research investments. And we accomplish that in the quickest, most responsive way possible.

OUR EXPERIENCE:

Medelis' medical founders, team physicians and advisors are internationally-recognized oncology thought leaders. They organize and chair sessions at national and international oncology meetings and serve as officers and board members of professional oncology organizations, including The American Association for Cancer Research and The American Society of Clinical Oncology.

Our clinical operations team and medical personnel have critical first-hand experience in the complex issues often associated with oncology clinical trials, and have handled most targets in oncology, which means that highly experienced resources will be working on your study.

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