Hogan Lovells

Advisory Panel Preparation

You've spent many years developing and testing your product to bring it to market. A make-or-break step in this process can be securing a positive recommendation from the relevant U.S. Food and Drug Administration (FDA) advisory panel. To achieve that goal, preparation is essential.

Having assisted numerous companies navigate the panel preparation process, we are ready to help you navigate the process to obtain a successful outcome. Using our broad experience, we help anticipate potential panel and FDA questions, craft persuasive briefing documents, prepare experts for testimony, and coordinate a cohesive and compelling presentation of the clinical data.

We also have extensive experience preparing companies for issues-focused panel meetings that are not product specific, as well as reclassification panel meetings.

Representative experience

Despite client's 2 non-approvable letters before our work, we helped with PMA amendments & secured unanimous Advisory Panel approval recommendation.

Ran PMA & Advisory Panel process & gained approval for novel, non-invasive screening test using advanced DNA technology detecting colorectal cancer.

Contacts

Gerard J. Prud'homme, Washington, D.C.

Janice M. Hogan, Philadelphia

Kristin Zielinski Duggan, Washington, D.C.

Practices

Medical Device and Technology Regulatory

Managed PMA & Advisory Panel Process & facilitated approval for novel tissue glue product that removes need for abdominoplasty post-surgical drains.

Latest thinking and events

News

Building a resilient tech strategy: Joint ventures

News

Long-awaited update of the French "Convention Unique" for clinical trials finally published

News

FDA issues ambitious new draft guidance to promote clinical trial diversity

News

FDA updates "cybersecurity in medical devices" guidance, seeks industry input

News

Clinical trials in Spain: Takeaways from the new code of conduct (Part 1)

News

FDA finalizes guidance on premarket pathways for combination products