

## 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

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### Practices

Medical Device and  
Technology Regulatory

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

## Latest thinking and events

### Insights and Analysis

Life Science Law Update – Key developments for pharma and device companies in EU and EU Big Five

### News

FDA authority to conduct bioresearch monitoring inspections expanded by appropriations legislation

### News

U.S. Congress embraces FDA's approach to clinical trial diversity in new Omnibus legislation

### News

Cell, tissue and gene therapies – Regulatory challenges and responses in Australia

### News

FDA Breakthrough Devices Program guidance targets health inequality

### News

Seeking harmony: FDA to align its human subject research regulations with Common Rule