

## 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.

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

### Contacts

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

Janice M. Hogan,  
Philadelphia

Kristin Zielinski Duggan,  
Washington, D.C.

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### Practices

Medical Device and  
Technology Regulatory

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## Latest thinking and events

### News

FDA quietly withdraws plans for a Devices Referencing Drugs regulatory approval pathway

### News

FDA updates FAQ on COVID-19 tests and validation

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies

### News

COVID-19 update: Facilitating diagnostic test availability for asymptomatic testing, sample pooling

### News

COVID-19: Daily Report for Life Sciences and Health Care Companies (22 - 26 June 2020)

### News

USPTO Alert – New fast track for certain COVID-19 trademark applications