Hogan Lovells

Kristin Zielinski Duggan

Partner

Washington, D.C.

Phone

+1 202 637 8894

Fax

+1 202 637 5910

Email

kristin.duggan@hoganlovells.com

Biography

With a background in biology and economics, Kristin Zielinski Duggan provides strategic advice to companies on scientific and U.S. Food and Drug Administration (FDA) regulatory challenges, while always keeping business needs in mind. For over 20 years, she has been counseling cutting-edge companies regarding the development and regulation of medical devices, pharmaceuticals, and combination products.

Kristin has a wealth of experience with the entire FDA regulatory process and agency interactions, from devising regulatory strategy for innovative products to pre-submission meetings; to assisting with preclinical and clinical programs and IDEs; to preparing regulatory submissions (510(k)s), de novo petitions and premarket approvals (PMAs); to appeals of agency decisions. Having prepared companies for dozens of advisory panel meetings over the years – including panel meetings to review 510(k) notices and PMAs, general issues panels, and classification panels – Kristin is a top thought leader in this area. She has been involved with all of the meetings of the Medical Devices Dispute Resolution Panel (MDDRP) to date.

Kristin also assists companies with compliance challenges, including 483 and Warning Letter responses, adverse events reporting, recalls, Department of Justice (DOJ) investigations, and product liability litigation, as well as with due diligence for investments and acquisitions.

Kristin's practice covers products in many therapeutic

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Advisory Panel Preparation

Digital Health

Medical Devices

Education and admissions

Education

areas, including software products, cardiovascular products, orthopedic and gynecologic implants, plastic and reconstructive surgery devices, radiology devices, gastroenterology devices, wound care products, dental implants, endoscopes and minimally-invasive surgical solutions, and in vitro diagnostics.

Kristin previously served as Vice President for Strategic Consulting at a Washington, D.C.-based scientific consulting firm. Throughout her career, she has published and presented on various FDA regulatory issues. She is also an adjunct professor teaching an experiential seminar on FDA Regulation of Medical Products (Medical Devices, Drugs, and Biologics), which is part of the Executive Master of Science in Health Systems Administration (EMHSA) program at Georgetown University's School of Nursing and Health Studies.

Representative experience

Helped manage PMA and advisory panel process and secure approval for novel, non-invasive treatment for brain cancer.

Negotiated with FDA to accept a literature review instead of a clinical study for a modification to the materials included in a dental implant.

Prepared 510(k) submission for novel stereotactic neurological guidance system; negotiated outstanding issues, resulting in market clearance.

Awards and rankings

- Healthcare: Life Sciences, *Legal 500 US*, 2018

Latest thinking and events

- News
  - FDA launches list of AI and machine learning-enabled medical devices
- News
  - FDA warns over use of robotically-assisted surgical devices

J.D., Georgetown University Law Center, 2015

B.A., University of Virginia, 1998

Memberships

Member, Regulatory Affairs Professionals Society (RAPS)

Bar admissions and qualifications

District of Columbia

Maryland

- Press Releases
  - Hogan Lovells leads NONAGON to FDA 510(k) clearance for smartphone compatible telehealth device
- News
  - Life sciences and health care horizons 2021
- Press Releases
  - Hogan Lovells welcomes the New Year and 25 new partner and 60 new counsel promotions
- Sponsorships and Speaking Engagements
  - Virtual Happy Hour: Update Magazine Authors Discuss FDA Advisory Panel Meetings