

Kristin Zielinski Duggan

Counsel

Washington, D.C.

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



Phone

+1 202 637 8894

Fax

+1 202 637 5910

Email

kristin.duggan@hoganlovells.com

Practices

Medical Device and Technology
Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Advisory Panel Preparation

Digital Health

Medical Devices

litigation, as well as with due diligence for investments and acquisitions.

Kristin's practice covers products in many therapeutic 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

Education and admissions

Education

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

- Hogan Lovells Publications
 - Helping companies navigate the COVID-19 pandemic
- Press Releases
 - Hogan Lovells' Medical Device & Technology practice reflects on its COVID-19 work and looks ahead to what may come next
- Press Releases
 - Hogan Lovells advises Vayu Global Health Innovations in obtaining Emergency Use Authorization for bCPAP device to alleviate ventilator shortage due to COVID-19
- News
 - FDA loosens restrictions on gynecologic power morcellators, recommends use only with containment
- News
 - Guidances galore: FDA finalizes multiple digital health guidance documents
- News
 - FDA's new decision tree for medical device PMAs and De Novos accompanies final uncertainty guidance