Greenleaf Health

Katie McCarthy

Vice President, Regulatory Affairs

SPECIALTY	• Specializes in domestic and global biosimilars policy, drug safety, and bioethics, as well as implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA) and FDA policies and processes, including Risk Evaluation and Mitigation Strategies (REMS)
EXPERIENCE	• Previous experience in electronic prescribing and health information technology

Katie McCarthy brings more than 10 years of policy experience to Greenleaf, where she serves as Vice President of Regulatory Affairs. Katie specializes in scientific and regulatory issues affecting pharmaceutical and biotechnology companies.

In her role at Greenleaf, Katie focuses on a variety of topics, including: domestic and global biosimilars policy, drug safety, implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA), and FDA policies and processes, including Risk Evaluation and Mitigation Strategies (REMS).

Katie's background is primarily in drug development and policies affecting healthcare professionals and the patient communities they serve. She has been extensively involved in projects that span a number of therapeutic areas, from preclinical safety assessment to clinical safety and efficacy. Her work includes emerging electronic prescribing efforts, privacy and health information exchange, and related bioethical considerations in the clinical development process, including institutional review board (IRB) review and informed consent.

Katie holds a Master's of Public Health from George Washington University and a B.A. from St. Cloud State University, Minnesota.