

Katie McCarthy

Executive Vice President, Regulatory Policy



SPECIALTY

- Strategic regulatory policy development, guidance, and analysis

EXPERIENCE

- 20+ years of legislative and regulatory policy expertise
- 15+ years of regulatory and science policy development and biopharmaceutical consulting experience

Katie McCarthy joined Greenleaf in 2015 and brings over 20 years of legislative and regulatory policy experience to her role as Executive Vice President of Regulatory Policy. Katie specializes in scientific and regulatory policy and development issues affecting FDA-regulated medical product developers, including innovator, generic, and biosimilar biopharmaceutical companies and medical device manufacturers.

In her role at Greenleaf, Katie specializes in a broad range of policy areas impacting the research, development, and delivery of drug and biologic products and medical devices, as well as the healthcare professionals and the patient communities they serve. Katie focuses on a variety of regulatory priorities, including: domestic and global biosimilars policy, drug safety, implementation of medical product user fee agreements, and legislative initiatives that may influence the regulatory landscape and healthcare ecosystem. 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.

Prior to joining Greenleaf, Katie worked for the Biotechnology Innovation Organization, a trade association that represents the leading biopharmaceutical developers and manufacturers, as well as independently consulted on regulatory policy for industry leaders. Katie also worked on Capitol Hill, where she helped to improve the regulatory environment through legislative accomplishments.

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