Mark Kramer

Executive Vice President, Medical Devices and Combination Products

BACKGROUND	• 17-year FDA career that included leading interdisciplinary review teams in CDRH and directing the Office of Combination Products • M.S. in biomedical engineering
SPECIALTY	• FDA regulation of combination products and medical devices
EXPERIENCE	• Founding Director of the FDA's Office of Combination Products • 14 years as a strategic regulatory consultant for medical device, combination product, drug, and biological product clients

Mark Kramer is Greenleaf's primary expert on combination products, providing clients with unique insight from his experience establishing and leading the FDA's Office of Combination Products (OCP). As Director of OCP from 2002 to 2007, Mark oversaw the development of significant regulations, policies, and practices currently in effect for combination products, including the primary mode of action rule, the cGMP rule, the adverse event reporting rule, numerous guidance documents clarifying the regulation of combination products, and the intercenter consultation process. Mark also has a firsthand understanding, through his management of the FDA's Product Jurisdiction Program, of how the Agency assigns combination products to Centers for review and determines the regulatory identity of drugs, devices, and biological products for which jurisdiction is unclear or in dispute.

Mark's work at Greenleaf is informed by his training as a biomedical engineer and a career of more than 35 years in medical product regulation that has united technical, front-line regulatory skills with strategic advising and leadership. He ran an independent consulting practice for over 13 years (2009-2022), advising approximately 200 clients from across the globe, including sponsors of medical devices, combination products, drugs, and biological products, as well as breakthrough and orphan products. In addition to helping clients develop and refine their regulatory strategies, Mark supported sponsors' regulatory submissions and FDA interactions at all stages of the regulatory process: authoring, strengthening, and submitting initial submissions; developing and critically reviewing responses to FDA-identified deficiencies; preparing for Agency and advisory panel meetings; and advising on cGMPs and adverse event reporting. Clients further benefited from his knowledge of FDA expectations for key device concerns, such as biocompatibility, electrical safety, electromagnetic compatibility, as well as his biomedical engineering background, which enhanced his reviews of design control documentation for devices and combination products. Mark has also served as an expert witness, testifying in depositions and trials, in a variety of litigation matters and provided regulatory expertise for due diligence activities.

During his 17 years at the FDA, Mark also gained extensive hands-on experience in device evaluation as a lead reviewer and supervisor for a broad range of products: cardiovascular, anesthesiology/respiratory, urology, gastroenterology, surgical, and dental. He managed interdisciplinary review teams as Chief of the Urology and Lithotripsy Devices Branch and as Chief of the Anesthesiology and Defibrillator Devices Branch of CDRH's Office of Device Evaluation and directed the Center's education and training programs for staff and industry. Beyond his deep experience at the Agency, Mark spent three years in industry as Chief Regulatory Strategist for GE Healthcare's medical device business, with executive responsibility for regulatory strategies, processes, and decisions throughout the U.S., Canada, and Latin America.

Mark has served as a board member of the Regulatory Affairs Professionals Society (RAPS), and in 2021 was awarded the RAPS Founders Award. He is also a longstanding adjunct faculty member with the Regulatory Affairs Master's Program at St. Cloud State University (Minnesota). He earned an M.S. in biomedical engineering from Rensselaer Polytechnic Institute in New York and a B.A. in mathematics from Rutgers College of Rutgers University.