

Kate Cook

Principal, Regulatory Policy



BACKGROUND • 20+ years with the FDA

SPECIALTY • FDA medical product regulation and regulatory policy

EXPERIENCE • Senior FDA regulatory official, in both CBER and CDRH

Kate Cook joined Greenleaf following a distinguished career of more than 20 years with the U.S. Food and Drug Administration (FDA). During her FDA tenure, Kate provided crucial direction on strategic initiatives related to the regulation of drugs, biological products, and medical devices. Kate continues her commitment to public health at Greenleaf as Principal, Regulatory Policy, providing strategic consulting services and working with clients to bring innovative medical products to patients.

Kate's FDA career began in the Office of the Chief Counsel, where she served for more than 15 years as a legal counsel on FDA issues related to biosimilars, gene therapy, vaccines, allergenics, human tissue and cellular products, blood products, medical devices, and combination products. She also provided guidance on human subject protection and advertising and promotion. Kate went on to serve as Associate Director for Regulations and Policy within the FDA's Center for Devices and Radiological Health (CDRH), where she led strategic development and implementation of policies and regulations applicable to medical devices and radiation-emitting products. Later, as Senior Advisor in the FDA's Center for Biologics Evaluation and Research (CBER), she played a pivotal role in the development and implementation of regulations and regulatory policy related to biological products, combination products, and medical devices regulated by CBER.

From 2016 to 2021, Kate was Executive Vice President with Greenleaf's Drug and Biological Products Team. In 2021, she was enlisted to support the federal government's pandemic response efforts. She returned to Greenleaf as Principal, Regulatory Policy, and now leads the firm's services focused on supporting clients with expertise and guidance on FDA regulatory policies and programs.

Kate is the recipient of numerous FDA awards, including the FDA Award of Merit, the Secretary's Award for Distinguished Service, the Commissioner's Special Citation, and the CDRH Director's Special Citation.

A graduate of Swarthmore College, Kate received her law degree from the New York University School of Law.