

Kate Cook

Executive Vice President, Drug and Biological Products



BACKGROUND • 20+ years with FDA

SPECIALTY • Drug and biologics regulation

EXPERIENCE • Senior FDA Regulatory Official

Kate Cook joins 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 Executive Vice President of Drug and Biological Products, where she provides strategic consulting services and works with clients to bring innovative medical products to patients.

Kate's FDA career began in the Office of Chief Counsel, where she served for more than 15 years as a legal counsel on FDA issues related to biosimilars, vaccines, allergenics, human tissue and cellular products, blood products, medical devices and combination products. She also provided guidance on issues related to human subject protection and advertising and promotion. Kate's FDA experience included serving as Associate Director for Regulations and Policy within 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. She also served as Senior Advisor in FDA's Center for Biologics Evaluation and Research (CBER), where she played a pivotal role in the development and implementation of policies and regulations applicable to biological products, combination products and medical devices regulated by CBER.

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.

Before joining FDA, Kate served as an Assistant District Attorney in the New York County District Attorney's Office. Kate was responsible for the investigation and prosecution of more than 100 felony complaints from arraignment through trial and sentencing, as well as appeals of criminal convictions.

A graduate of Swarthmore College, Kate received her law degree from the New York University School of Law. She continues to provide pro bono and volunteer legal services via the Maryland Legal Aid Bureau and Baltimore City Senior Legal Services.