Greenleaf Health

Sarah McGarry, M.D.

Senior Vice President, Drug and Biological Products

BACKGROUND	• 18 years with the FDA
SPECIALTY	• FDA review process for drugs and biological products
EXPERIENCE	• CDER, Division of Antivirals • CDER, Office of New Drug Policy • CBER, Division of Epidemiology

Sarah McGarry joined Greenleaf Health after an 18-year career with the FDA. Through her different agency roles and experiences, Sarah developed a broad understanding of the FDA regulatory review process, which she uses to advise drug and biologics clients on how to navigate this process and work effectively with the Agency.

At the FDA, Sarah began as a medical officer in the antivirals division in the Center for Drug Evaluation and Research (CDER), where she was the primary reviewer on the application leading to the approval of a first-in-class HIV treatment (raltegravir) and team leader on the review leading to approval of a first-in-class hepatitis C treatment (sofosbuvir). She later became Acting Deputy Division Director in the epidemiology division of the Center for Biologics Evaluation and Research (CBER), where she provided leadership and management of postmarket surveillance and adverse biologic reactions.

Sarah rejoined CDER's antivirals division as an Associate Director of Bioinformatics and served as a subject matter expert in medical science and drug regulatory review processes. In that capacity, she led a team responsible for modernizing the FDA's review of marketing applications. Sarah obtained FDA guidance and policy experience as a member of the clinical advisors team in the Office of New Drugs (OND) policy group before returning to the antivirals division during the COVID-19 pandemic. As a team leader, she played a significant role in anti-SARS-CoV-2 monoclonal antibody and small molecule emergency use authorizations as well as in the approval of Paxlovid (nirmatrelvir co-packaged with ritonavir).

At Greenleaf, Sarah draws upon her expertise to provide scientific advice and technical direction on critical aspects of drug development. Her familiarity with regulatory precedent, complex regulatory issues, and policy enables her to formulate options for advancing novel ideas and alternative approaches. With her substantial experience on the review teams for novel products requiring advisory committee meetings, Sarah is able to guide clients through the FDA advisory committee process and help prepare them for the questions and concerns that might arise during a meeting.

Sarah completed a B.S. in biology at Dartmouth College in 1993 and her M.D. at Georgetown University Medical School in 1997. She completed her residency in internal medicine and fellowship in infectious diseases at Duke University in 2003.