Greenleaf Health

Lisa Parks

Senior Vice President, Regulatory Policy

BACKGROUND	• 20+ years in drug dispensing and pharmacy operations • 15+ years of regulatory, legislative, and policy expertise from the FDA and a leading trade association
SPECIALTY	• Science, regulatory, and legislative policy development and analysis
EXPERIENCE	• The FDA's Office of Generic Drugs, Office of Pharmaceutical Science, Office of Executive Programs, and the generic and biosimilar pharmaceutical industries

Lisa joined Greenleaf Health after serving for eight years as the Vice President of Sciences and Regulatory Affairs at the Association for Accessible Medicines (AAM), a leading generic and biosimilars trade association in Washington, D.C. In this role, she developed and promoted regulatory and scientific affairs initiatives, internal and external communications and relations, and training/knowledge-sharing opportunities for member companies. She was AAM's primary liaison with the FDA and facilitated discussions and efforts with the FDA, lawmakers, and industry stakeholders on numerous topics that impacted the generic and biosimilar industry. Lisa served as the industry lead negotiator for the Generic Drug User Fee Amendment (GDUFA) II and III negotiations with the FDA and co-lead for the Biosimilars User Fee Act (BsUFA) II and III negotiations for AAM's Biosimilars Council. She also led the implementation phase of both the GDUFA II and BsUFA II user fee programs for AAM.

Lisa's career with the FDA's Office of Generic Drugs (OGD) began in 2008 in the regulatory affairs division. Her keen ability to facilitate discussions and build consensus around intricate regulatory policy issues was quickly recognized by senior CDER leadership, and she was appointed to lead the implementation of GDUFA I for the OGD. Due to her accomplishments, CDER leadership appointed her for further work in planning for and standing up the Office of Pharmaceutical Quality and other modernization initiatives.

In 2022, Lisa launched Daedal Regulatory Strategies, LLC to assist entities in better interpreting and navigating discussions with the FDA on complex regulatory and policy issues. In August 2022, Lisa joined Greenleaf as the Senior Vice President of Regulatory Policy in order to work alongside fellow experts and former FDA colleagues in helping clients advance their interactions and dialogue with the Agency.

Lisa holds a pharmacy degree from the Massachusetts College of Pharmacy in Boston, MA.