Greenleaf Health

Chris Leptak, M.D., Ph.D.

Executive Vice President, Drug and Biological Products

BACKGROUND
- 14 years at the FDA

SPECIALTY
- Drug and Biological Products

EXPERIENCE
- Director, Biomarker Qualification Program within the Center for Drug Evaluation and Research (CDER)
- Acting Office Director, Office of Drug Evaluation Science (ODES) within Office of New Drugs (OND), CDER

Chris joined Greenleaf in 2021, bringing 14 years of FDA regulatory experience to his role as Executive Vice President of Drug and Biological Products. He specializes in the regulatory use of novel clinical endpoints, including surrogates for both traditional and accelerated marketing approval.

While at the FDA, Chris began as a medical officer in the gastroenterology division. With his immunology expertise, his primary focus was on immunomodulator drug and biologic product development. After joining OND's Guidance and Policy team, he became OND's first biomarker and companion diagnostic lead, responsible for developing guidance and evidence requirements to support regulatory acceptance. As CDER's lead for implementation of the 21st Century Cures legislation for Section 3011 Drug Development Tools, he supervised staff responsible for Clinical Outcomes Assessments, biomarkers, and innovative drug development tools and approaches. As part of OND's modernization effort, he led the creation of ODES, served on OND's Senior Management Council, and supervised groups responsible for safety analytics as well as regulatory research in addition to the qualification programs. Chris served as the Chair of CDER's Drug Development Tools Committee, the group of senior staff responsible for advice for novel surrogate endpoints and acceptance of DDT qualification submissions. He worked closely with all OND offices and divisions as well as CDER, CBER, and CDRH and founded and chaired an FDA-wide biomarker working group. Chris is frequently invited to speak and serve as a panelist at scientific conferences.

At Greenleaf, Chris draws on his expertise as a recognized expert on biomarkers and regulatory science to provide authoritative scientific advice and technical direction on critical aspects of drug development, particularly those that involve the broadest and most complex topics. His familiarity with regulatory precedent and policy enables him to formulate options and alternatives for novel ideas and approaches.

Chris completed a combined B.S./M.S. in Molecular Biophysics and Biochemistry from Yale University in 1990. His graduate work included an M.D. and Ph.D. in Microbiology/Immunology at the University of California, San Francisco in 1999. He completed his residency in Emergency Medicine at Harvard's Brigham and Women's Hospital and Massachusetts General Hospital in 2003.

In addition, Chris brings scientific and collaborative leadership experience from his roles on the Foundation for the National Institutes of Health Biomarkers Consortium Executive Committee and European Innovative Medicines Initiative TransBioLine Biomarker Development Scientific Advisory Board.