Greenleaf Health

Thomas R. Berry, Pharm.D.

Senior Vice President, Regulatory Compliance

BACKGROUND	• 20 years with the FDA and 10 years as a clinical/hospital pharmacist
SPECIALTY	• Compliance strategies I Inspection readiness I Pharmacovigilance Cannabis I Recalls
EXPERIENCE	• ORA Pharmaceutical Program expert • FDA Cannabis Products Council member • FDA Emergency Use Authorization investigations policy • ORA Pharmaceutical Division Compliance Director • ORA Bioresearch Monitoring Program Division Director • ORA domestic and international investigator for drugs, BIMO, and pharmacovigilance

Tom Berry brings more than 20 years of extensive regulatory experience to his role as Senior Vice President, Regulatory Compliance at Greenleaf Health.

Tom is a retired Captain with 23 years in the U.S. Public Health Service (USPHS) and six years as an Army Pharmacy Officer. He was assigned to multiple positions over his 20 years with the FDA, most recently as a Pharmaceutical Program Expert in the Office of Regulatory Affairs (ORA), responsible for providing guidance to ORA field components, drafting FDA policy, reviewing proposed guidance and legislation, and representing ORA on FDA committees. He also trained "new hire" investigators and was a cadre member for courses in Food and Drug Law, Evidence and Development, and New Hire Fundamentals. Tom was an original author of "FMD-153 Investigations of Facilities engaged in the Manufacturing, Packaging, Labeling, and Testing of Medical Products that may be subject to an Emergency Use Authorization (EUA)." As the past Director of Compliance, Denver District and member of the FDA Cannabis Product Council, he is familiar with FDA cannabis oversight operations and cannabis regulatory history to include "Brownie Mary," Charlotte Figi, Colorado Amendment 64, and the 2018 Farm Bill.

Tom began his FDA career as an investigator for eight years in the Raleigh, NC resident post, where he was a domestic and international drug, bioresearch monitoring (BIMO), and pharmacovigilance investigator. He was selected as a Compliance Officer in Denver and subsequently as the Director of the Compliance Branch, with responsibility for assessment of inspection reports, initiation of compliance actions, and evaluation of compliance action effectiveness.

After ORA Program Alignment in May 2017, Tom conducted a 180-day detail to establish the BIMO Program West Division responsible for the oversight of BIMO operations in the Western 27 States. He subsequently assumed his permanent position as Director of Compliance, Office of Pharmaceutical Quality Operations IV, with oversight of the pharmaceutical operations in the Western 13 States and global inspection regulatory assessments.

At Greenleaf, Tom provides strategic guidance and support to pharmaceutical, pharmacovigilance, and cannabis companies, including: developing compliance strategies; performing due diligence activities; ensuring inspection readiness; assisting industry clients and legal counsel in developing and communicating corrective action plans that meet FDA expectations and that achieve and sustain compliance; conducting audits and mock inspections; and providing training, coaching, and mentoring. Tom continues to communicate expert advice through presentations at FDA and industry conferences and articles published in industry journals.

Tom received a B.S. in pharmacy and a Pharm.D. from Creighton University and completed an ASHP-certified residency at Fitzsimons Army Medical Center.