

David Elder

Principal, Regulatory Compliance



BACKGROUND • 23 years with the FDA

SPECIALTY • Corporate quality systems; compliance strategies; inspection readiness

EXPERIENCE • Senior FDA regulatory official and retired Captain in U.S. Public Health Service

David Elder brings more than 35 years of extensive regulatory experience to his role as Principal, Regulatory Compliance at Greenleaf Health.

A 23-year veteran of the U.S. Food and Drug Administration (FDA) and U.S. Public Health Service (USPHS), David served as a senior FDA official with prominent roles in domestic and foreign inspections, recalls and emergencies, and compliance actions involving hundreds of situations. He has testified in federal court and before Congress, initiated and approved enforcement actions, and represented the FDA during national media events. Additionally, David has received numerous honors, including the Distinguished Service Medal.

David began his FDA career as an Investigator in the Boston District Office where he conducted domestic and foreign inspections and investigations in various program areas. He was selected as a Compliance Officer and later as the Director of the Compliance Branch with responsibility for assessment of inspection reports, initiation of compliance actions, and evaluation of compliance action effectiveness.

David transferred to FDA headquarters when he was selected as the Director of the FDA Office of Enforcement in 2003, a position he held for the next six years. In this Senior Executive Service position, David led the Office with responsibility for agency enforcement policy, agency recall policy and operations, and enforcement strategy and case review. In 2009, David transferred from the Office of Enforcement to the Office of Regional Operations where he led the Office with responsibility for policy and operations related to foreign inspections, domestic inspections, import operations, and field science. In both roles, David served as a principal advisor to the FDA's Associate Commissioner of Regulatory Affairs.

Prior to joining Greenleaf, David served as Vice President with PAREXEL International. He traveled to client locations across the U.S. and in 14 foreign countries to conduct audits and mock inspections; provide training, coaching, and mentoring; and advise clients on the development and communication of corrective actions that meet FDA expectations and that achieve and sustain compliance.

At Greenleaf, David continues to provide strategic guidance and support to pharmaceutical and medical technology companies in areas including: strengthening corporate quality systems; developing compliance strategies; supporting inspections and ensuring inspection readiness; assisting industry clients and legal counsel in developing and communicating corrective action plans in response to compliance issues; verifying completed corrective actions; executive training and coaching; and performing due diligence. David also communicates expert advice through presentations at FDA and industry conferences, articles published in industry journals, and FDLI's 2022 book, *How FDA Really Works: Insights from the Experts*.

David received a B.S. in electrical engineering from Boston University and attended executive management courses at Harvard University.