David Berger

David Berger is a Senior Managing Director at Ankura based out of New York.

He has over 20 years of strategic leadership experience and has served as General Counsel and Chief Compliance Officer for several life sciences companies. Having served in these roles, David has a particular expertise and understanding of how to develop, implement, and manage successful compliance programs for companies, considering their business circumstances and sensitivities.

David has regularly advised numerous boards of directors and C-suite executives on compliance and ethics matters, both prospectively and in response to governmental actions. He has also assisted in the development of strategy and action plans with respect to governmental actions such as CIDs and subpoenas, and resultant settlements including CIAs and DPAs. Additionally, he has advised on interactions with the U.S. Congress, DOJ, FTC, FDA, and DEA, and has appeared before each of these as well.

David has assisted clients with developing programs, policies, and procedures, training executive management and sales organizations, conducting compliance audits and effectiveness assessments, monitoring world-wide risk management profiles for international organizations with offices in high-risk jurisdictions, harmonizing compliance programs across regions, business units, and new acquisitions, negotiating CIAs and DPAs, performing pre-IRO work, implementing CIAs, and serving as IRO and compliance expert to the board of directors.

Prior to joining Ankura, in a previous role, David led the Global Regulatory, Quality and Patient Safety group, providing advisory support to life sciences companies with respect to FDA (and equivalent international agencies) regulations and requirements for bringing drugs, devices, and diagnostics to market and keeping them on the market. More specifically, he assisted clients

with establishing global regulatory strategy, target product profiles, labeling and regulatory submissions (IND, NDA, ANDA, 505(b)(2), BLA, 510(k)), quality management systems, product lifecycle strategies, developing strategies for regulatory affairs and quality assurance teams in connection with FDA matters and proceedings (including Type A, B, and C meetings and appeals), leading multi-disciplinary teams in response to Warning Letters and 483s and conducting mock audits, establishing promotional review committees, policies, and procedures, as well as databases for collateral, advising on pharmacovigilance matters, reviewing advertising and promotional collateral for compliance with OPDP/FDA rules, regulations and guidance, and managing and overseeing clinical trial agreements (including informed consent forms, study protocols, and IRB proceedings).

David has deep experience with mergers and acquisitions, having led due diligence, negotiations, and post-deal integration across a number of organizations and deal structures, from transformational multi-billion-dollar transactions to discrete asset purchases and sales. He has served as Integration Team Lead for various transactions and has advised on pre- and post-merger strategy, organizational design, and change management issues.

During David’s tenure as General Counsel, he regularly provided advice on IP strategy, as well as branded and generic product launches.