Greenleaf Health

Grace E. McNally

Senior Vice President, Regulatory Compliance

BACKGROUND

- 33 years with the FDA

SPECIALTY

- Pharmaceutical CGMP and Quality Systems
- CGMP Compliance Management

EXPERIENCE

- FDA
  - CDER Office of Pharmaceutical Quality (OPQ) Policy
  - CDER OPQ Office of Process and Facilities
  - CDER Office of Compliance (OC)
  - ORA Investigator, drugs and medical devices

Grace joined Greenleaf Health after a 33-year career with the FDA. Through her many agency roles and experiences, Grace developed a broad understanding of the quality requirements and initiatives intended to assure that high-quality pharmaceuticals and devices are available to patients. For 13 years Grace served as an Investigator for the Office of Regulatory Affairs (ORA) in the Philadelphia and Denver district offices, where she developed expertise in quality systems and current good manufacturing practice (cGMP) for pharmaceuticals and medical devices. She conducted drug and device inspections, both domestically and abroad.

Grace later drew upon her ORA experience when she joined the Center for Drug Evaluation and Research (CDER) as a Compliance Officer in the Office of Compliance (OC), evaluating violative facility inspection results and initiating risk-based enforcement or other agency action. She also served as a Senior Policy Advisor and helped CDER realize the goals of the Pharmaceutical Quality for the 21st Century initiative. During her tenure with OC, she developed cGMP guidance for drugs and combination products, helped craft revisions to cGMP regulations, and supported implementation of several ICH quality guidelines as well as new legislation impacting CDER's quality program. Grace led development of the 2011 guidance, "Process Validation: General Principles and Practices," and following its publication, provided regular training to FDA staff and presented on the guidance at numerous industry conferences. In the international realm, she contributed to information-sharing initiatives with EU and other regulatory counterparts designed to minimize duplication and redirect inspection resources toward higher risk areas.

With the formation of the Office of Pharmaceutical Quality (OPQ) in 2015, Grace continued to be involved in agency initiatives aimed at modernizing the regulation of pharmaceutical manufacturing and product quality. Selected to serve as an acting branch chief in the new Office of Process and Facilities (now Office of Pharmaceutical Manufacturing Assessment), she helped establish processes to better integrate quality review and inspection and improve quality drug assessment for NDAs, ANDAs, and CDER-led BLAs. In 2016, she was selected as the Director, Division of Regulations, Guidance and Standards within the Office of Policy for Pharmaceutical Quality (OPPQ). In that role, she oversaw the development of cGMP and CMC guidance covering the product quality lifecycle, oversaw the quality aspects of citizen petition responses, and guided OPQ staff in establishing policies and programs — e.g., emerging technology, quality metrics, and quality management maturity — to facilitate advancements in drug manufacturing and pharmaceutical quality management systems.

At Greenleaf, Grace will provide strategic guidance and support to pharmaceutical and medical technology companies in areas including: strengthening corporate quality systems, developing compliance strategies, ensuring inspection readiness, assisting industry clients and legal counsel in developing and communicating corrective actions plans in response to compliance issues that meet FDA expectations and that achieve and sustain compliance, conducting audits and mock inspections, and providing training, coaching and mentoring. Grace will continue to communicate expert advice through presentations at FDA and industry conferences and through articles published in industry journals.

Grace holds a B.S. in Physics from Boston College, Chestnut Hill, MA.