Hogan Lovells expands Global Regulatory practice with veteran FDA investigator and senior policy advisor

Global law firm Hogan Lovells has added Chris Middendorf to the firm's Global Regulatory practice as a Director of Regulatory Affairs. In this role, Middendorf will assist life sciences clients with regulatory and policy issues, with a specific focus on key product quality and manufacturing issues, and related compliance with U.S. Food and Drug Administration (FDA) requirements for pharmaceuticals and biological products.

Middendorf comes to the Hogan Lovells Pharmaceuticals and Biotechnology regulatory practice after more than 20 years with the FDA and senior level responsibilities involving FDA inspections, compliance, and policy development. At FDA, Middendorf conducted numerous inspections around the globe involving all aspects of current Good Manufacturing Practice (cGMP) regulations, developing scientific and technical expertise in sterile manufacturing and data integrity. His agency tenure included senior positions with country-wide responsibilities for China and then India, each with diplomatic status, and serving as Senior Policy Advisor and aseptic manufacturing "subject matter expert" for the Office of Manufacturing Quality, within the Office of Compliance of FDA's Center for Drug Evaluation and Research.

At Hogan Lovells, Middendorf will join a legal team with years of experience advising clients on cGMP compliance and advocating for them in front of FDA and related agencies. Drawing on decades of "boots on the ground" experience, he will give companies practical advice on day-to-day compliance

issues and broader strategic matters, helping companies prepare for FDA inspections and respond to agency observations. He also will be a key member of the Hogan Lovells team providing detailed due diligence for life sciences transactions.

Middendorf obtained his bachelor’s degree in biology from the University of Cincinnati, and a master’s degree in animal science from Auburn University.