KING & SPALDING

Steven Niedelman

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Steven Niedelman serves as lead quality systems and compliance consultant to the FDA and Life Sciences practice at King & Spalding.

Steven specializes in regulatory, enforcement and policy matters involving industries regulated by the Food and Drug Administration. He provides strategic advice, insight and guidance to the medical device, pharmaceutical, biologics and food industries to ensure compliance with the requirements of the federal Food, Drug and Cosmetic Act.

Steven joined King & Spalding from Crowell & Moring LLP, where he was a senior consultant in its health care group. Previously, he was executive vice president of Quintiles Consulting.

Steven consults with manufacturers, importers and new product developers, as well as with firms involved in or facing enforcement actions. He helps firms develop corrective action plans so their business needs are properly balanced with regulatory requirements in order to achieve compliance without compromising objectives. He provides training and guidance to industry professionals on all FDA requirements, including quality systems requirements, inspection preparedness and post-market obligations, as well as to executives concerning their management responsibilities as well as FDA expectations.

After a distinguished 34-year career, Steven retired from the FDA in 2006. At the agency, he served as deputy associate commissioner for Regulatory Affairs and as chief operating officer of the Office of Regulatory Affairs. He ensured consistent interpretation of FDA's regulatory policies by directly overseeing offices at the headquarters of the Office of Regulatory Affairs, including the Office of Regional Operations, Office of Enforcement and Office of Criminal Investigations. Additionally, he assisted in the day-to-day management of FDA's nearly 3,400 field staff responsible for investigative and laboratory operations.

While at ORA, Steven served as the principle liaison to the Center for Devices and Radiological Health, and was a member of the Global Harmonization Task Force Steering Committee, the FDA/Medical Device Industry Grassroots Initiative Steering Committee and the CDRH Post Market Initiative Steering Committee. He also served on the steering committee to the pharmaceutical "cGMP for the 21st Century" initiative, as well as the Counterfeit Drug Task Force.

Prior to joining the Office of the Associate Commissioner, Steven was the director and deputy director of the FDA's Office of Enforcement, where he was responsible for oversight and consistency of compliance policy, enforcement and recall activities to ensure fair implementation by the agency's five product centers. During his tenure, he presided as the Chairman of FDA's Compliance Policy Council.

Steven currently participates as a member of the Medical Devices Committee at the Food and Drug Law Institute, and as a member of the Editorial Review Board for FDA News GMP publications directed at the pharmaceutical and medical device industries. He has also served as vice president of the FDA Alumnae Association.

Before joining the Office of Enforcement, Mr. Niedelman spent nearly 24 years in the Office of Compliance at the Center for Devices and Radiological Health in a number of management positions. During nearly 24 years at CDRH, he was responsible for implementing many of the newly-created statutory requirements and drafting and shaping many of the regulations and policies affecting the sale, distribution and promotion of medical devices. He began his FDA career in 1972 as an investigator in FDA's New York District Office.

Insights

CLIENT ALERT
April 20, 2021
FDA Reverses HHS Exemption of Class I and Class II Medical Devices from Section 510(k)

February 5, 2021
FDA Appoints Renowned Cybersecurity Researcher to Head Agency's Medical Device Cybersecurity Efforts

October 2, 2020
FDA Finalizes Rule and Guidance to Implement Safe Importation Action Plan Aimed at Lowering Prescription Drug Prices

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Events

SPEAKING ENGAGEMENT
December 23, 2020
Eric Henry, Steve Niedelman to Speak on Global Medical Device Podcast

WEBINAR
September 9, 2021
14th Annual King & Spalding Medical Device Summit

February 23, 2021
FDA Inspections in 2021 for Drug and Device Manufacturers

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News

IN THE NEWS
April 23, 2021 • Source: Medtech Insight
Steve Niedelman explains the steps that companies should follow to prepare for a regulatory

meeting with the FDA

January 19, 2021 • Source: BioProcess Online
BioProcess Online profiles Steven Niedelman and Christina Markus

December 7, 2020 • Source: CenterWatch
Steve Niedelman explains why a chain-of-custody data map should be a central part of every clinical trial site

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