

Susan D. Tiedy-Stevenson

Senior Director
Washington, D.C.

Biography

Susan Tiedy-Stevenson assists clients in obtaining FDA marketing approvals and clearances for diagnostic tests and medical devices. She works with clients throughout the life cycle of product development in assessing FDA quality system requirements, clinical and analytical development, and implementation of post-marketing strategies. Susan is attuned to the needs of large corporations and start-up companies in formulating practical solutions to address FDA regulatory requirements.

She has deep insight into the FDA's biologics and medical device regulation of in vitro diagnostics (IVD) assays and related instruments, accessories, laboratory developed tests, and drug companion diagnostics. Susan also assists clients concerning FDA regulation of non-IVD medical devices including, in part, diabetes diagnostic and treatment devices and standalone software diagnostic applications.

Previously, Susan held executive management positions in regulatory, clinical, and quality for IVD, medical device, and biologic product companies and was responsible for preclinical and clinical study programs, development of regulatory strategies and premarketing submissions to the FDA and international authorities, and establishment and monitoring of good manufacturing practice programs compliant with FDA



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Practices

Medical Device and Technology
Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Advertising and Promotion
Compliance

In Vitro Diagnostics

Medical Devices

Combination Products

regulations.

Representative experience

Obtained the first HPV test for cervical cancer and continued to secure additional FDA approvals for HPV assays *

Secured the FDA's first ever Clinical Laboratory Improvement Amendments (CLIA) waiver approval for doctor office syphilis testing.

Obtained PMA approval and 510(k) clearances for a variety of medical devices.

Trained companies and entrepreneurs on FDA premarketing and CLIA waiver submission requirements.

*Matter handled prior to joining Hogan Lovells.

Latest thinking and events

■ News

- FDA issues new policy for evaluating impact of viral mutations on COVID-19 tests

■ Hogan Lovells Publications

- Life sciences and health care horizons 2021

■ Hogan Lovells Publications

- Podcast: Talking the cure

■ Press Releases

- Hogan Lovells guides Integrum AB in FDA approval of prosthetic for above-the-knee amputations

■ Press Releases

- Hogan Lovells advises Lucira Health in obtaining the first FDA Emergency Use Authorization for an at-home COVID-19 testing kit

■ News

- FDA Pre-Cert update: “more work needed” to refine Streamlined Review Framework

Education and admissions

Education

M.S., Central Michigan University, 1979

Graduate Studies, University of Pittsburgh, 1974

B.S., Chatham College, 1972

Memberships

AMDM Companion Diagnostics Working Group

Regulatory Affairs Professional Society
