Hogan Lovells

Susan D. Tiedy-Stevenson

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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

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

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 updates FAQ on COVID-19 tests and validation
- Press Releases
  - Hogan Lovells' Medical Device & Technology practice reflects on its COVID-19 work and looks ahead to what may come next
- Webinar
  - COVID-19 Webinar: Considerations for the Food and Agriculture Sector When Testing Employees for Coronavirus
- Press Releases
  - Hogan Lovells and Wanda Henry Co. advise Sansure Biotech, Inc. in obtaining FDA Emergency Use Authorization for COVID-19 molecular test kit
- News
  - FDA's revised COVID-19 test kit policy requires EUAs for serology tests
- News

Areas of focus

Advertising and Promotion Compliance

In Vitro Diagnostics

Medical Devices

Combination Products, FDA Jurisdictional Issues, FDA Postmarket Compliance Issues

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

- Senate bill proposes laboratory developed tests to be regulated under CLIA process