Susan D. Tiedy-Stevenson, M.S.

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Susan Tiedy-Stevenson's practice focuses on the premarket approvals and clearances of medical devices, diagnostics, and biologic products, as well as GMP issues related to these products.

Susan has more than 18 years of broad-based managerial and hands-on regulatory and quality experience in the biotechnology and medical device industries, having served as Vice President of Regulatory/Clinical Affairs, Quality Assurance, and Quality Control, and Director of Regulatory Affairs and Quality Assurance for in vitro diagnostics, medical device, and biologic product companies. In these positions, Susan was responsible for the negotiation and establishment of preclinical and clinical study programs with contract testing facilities and medical investigators and for the development of regulatory strategies and premarketing submissions to the FDA and international authorities.

Susan has developed, implemented, and monitored device and biological GMP programs for both domestic and international facilities and has served in the capacity of the principal company representative in manufacturing facility inspections conducted by FDA and European inspectors.

Susan has been an invited speaker to workshops and conferences sponsored by the Regulatory Affairs Professional Society (RAPS), the Association of Medical Diagnostic Manufacturers, the Biotechnology Industry Organization (BIO), the Williamsburg BioProcessing Foundation, and as a CIMIT CRAASH lecturer and has made presentations on biotechnology issues and regulations ranging from in vitro diagnostics to manufacturing of cellular therapy products. She has also taught numerous courses on FDA regulatory submission requirements to medical device companies including 510(k) notification, premarket approval applications, and CLIA Waiver applications to domestic and international medical device companies.

Hogan Lovells Publications

20 November 2015 "FDA and CMS Make Case Before Congress for FDA Oversight of Laboratory Developed Tests." *Medical Device Alert*, Hogan Lovells

21 January 2015 "FDA Holds Workshop on Proposed Regulatory Framework for Laboratory Developed Tests." *Medical Device Alert*, Hogan Lovells

05 August 2014 "FDA Notifies Congress of the Proposed Regulatory Oversight of Laboratory Developed Tests." *Medical Device Alert*, Hogan Lovells

05 August 2014 "FDA Issues Final Guidance Regarding In Vitro Companion Diagnostic Devices." *Medical Device Alert*, Hogan Lovells

12 August 2011 "FDA issues draft guidance regarding in vitro companion diagnostic devices, an area of device regulation marked by ambiguity." *Medical Device Alert*, Hogan Lovells

23 February 2011 "FDA finalizes long-awaited Medical Device Data Systems rule." *Medical Device Alert*, Hogan Lovells

Published Works

2009 "Medical Device Clinical Studies." *Medical Device Development: Regulation and Law*, Barnett International

2009 "The Regulation of In Vitro Diagnostics." *Medical Device Development: Regulation and Law*, Barnett International

2009 "Review of Premarket Approval Application." *Medical Device Development: Regulation and Law*, Barnett International

March 2007 "Parallel Universes Collide." *IVD Technology*

Practices

Food, Drug, Medical Device and Agriculture

Medical Devices

Industry Sectors

Life Sciences

Medical Devices

Areas of Focus

In Vitro Diagnostic Devices

Medical Device Investigational Device Exemptions, Medical Device Premarket Approval Applications, and 510(k) Notification Submissions

Medical Device Software

FDA Regulatory Training

Cellular Therapy and Combination Products

Education

M.S., Central Michigan University, 1979

Graduate Studies, University of Pittsburgh, 1974

B.S., Chatham College, 1972