

Blix Winston

Curriculum Vitae - F. Blix Winston, MPA, MS

EXPERIENCE

Mr. Winston worked for 27 years in the U.S. Food & Drug Administration, gaining a broad range of contacts and knowledge of how the agency works. With more than 17 years of experience with the Center for Devices and Radiological Health (CDRH), Mr. Winston has a comprehensive understanding of FDA laws and medical device regulation. Assisting thousands of U.S. and foreign medical device firms at the Division of Small Manufacturers Assistance (DSMA), and managing the Operations Branch, he developed a unique perspective on the needs of the device industry. With his in-depth knowledge of FDA regulatory requirements he was able to provide direct regulatory assistance that saved companies time and resources and to design and conduct 1-3 day workshops that served the needs of both small and large companies. In addition to planning and conducting workshops for the medical device industry Mr. Winston trained FDA and CDRH staff, such as medical device reviewers, as well as foreign government officials from India, Malaysia, Japan, the People's Republic of China, Korea, Australia, Taiwan, Canada, Denmark, France, Argentina and Brazil. His military training in clinical laboratory medicine and hospital lab experience served as a springboard to a toxicology and pharmacology research position in FDA. After working in various administrative positions following completion of a three-year rotation as an FDA management intern he spent the majority of his career in CDRH. He retired from FDA in 2002, teaches Medical Device Regulation at a local college, and provides consulting services to the medical device industry.

EDUCATION

1972 Bachelor of Science (BS), University of Maryland

1981 Master of Public Administration (MPA), University of Southern California - Washington Public Affairs Center

1985 Master of Science (MS), Pastoral Counseling, Loyola College of Maryland

EMPLOYMENT

2003-2006 Associate Professor, Hood College, Frederick, Maryland. Teaches FDA

Regulation of Medical Devices

1998-2002 Chief, Operations Branch, Division of Small Manufacturers Assistance (DSMA), U.S. Food & Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Acting Chief, 1997-1998

Managed the Operations Branch. Responsible for work scheduling, DSMA regulatory workshops, 510(k) Status Reporting Program, support to the Office of the Center Director, workshop support for the Third Party Review program which trained recognized third parties outside of the U.S. to conduct Premarket Notification review for FDA, workshop support for the EU Mutual Recognition Agreement, Center-wide committee work, and special projects such as the FDA CDRH Science Review.

1990-1997 Consumer Safety Officer, Operations Branch, DSMA, CDRH, FDA.

Provided direct regulatory assistance to literally thousands of medical device firms on all aspects of medical device regulatory requirements covering marketing, manufacturing, import/export and regulatory compliance.

Developed, coordinated, and ran the DSMA workshop program which offered 30 annual training workshops in the U.S. and abroad. Presenter at DSMA, industry-sponsored, and international workshops on all aspects of regulatory requirements and current good manufacturing practices. Developed and wrote FDA and industry guidance and co-authored DSMA manuals such as the Premarket Notification 510(k) manual and The Regulation of AIDS-Related Medical Devices.

1983-1990 Program Analyst, Office of Management Services, CDRH, FDA.

Responsible for the CDRH Annual Operating Plan, program assessment, yearly planning, and conducting management meetings and retreats.

1974-1983 Various positions with FDA including:

• 1974-1977. Zoologist, Center for Veterinary Medicine, Pharmacology & Toxicology Research Group.

• 1977-1979. FDA Management Intern

• 1979-1983. Program Analyst with the Associate Commissioner for Planning & Evaluation's Evaluation Studies Group.

1985-2002 Counseling Therapist, Affiliated Community Counselors, Rockville, Maryland.

PUBLICATIONS

Chapter 126, United States Food & Drug Administration, in Clinical Engineering Handbook, 2004, Ed. Joseph F. Dyro, Elsevier Academic Press, 200 Wheeler Road, 6th Floor, Burlington, MA 01803