



International Alliance for
Biological Standardization

Europe



Marjorie A. Shapiro

Retired Regulator
USA

E-mail: shapirom@comcast.net

Dr. Marjorie Shapiro received her Ph.D. in immunology from the University of Pennsylvania where she studied molecular mechanisms underlying antibody diversity. She was at the FDA for over 30 years and is known for her expertise in therapeutic monoclonal antibodies and related products such as antibody-drug conjugates, bispecific antibodies, antibody cocktails, Fc-fusion proteins and biosimilar mAbs. She worked on several guidance documents while at the FDA, including several concerning the development of monoclonal antibodies, and the Platform Technology Designation Guidance document.