International Alliance for
Biological Standardization

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Dr. Arifa S. Khan is Supervisory Microbiologist and Head of the Molecular Retrovirology Unit in the Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration. She moved from NIAD/NIH to CBER in 1991, where she is currently leading efforts on high-throughput sequencing for detection of adventitious viruses and endogenous retroviruses for safety evaluation of cell substrates and biologics. Her primary regulatory responsibilities include viral vaccines, such as HIV-1, influenza virus, RSV and SARS-COV-2. Dr. Khan also provides expert consultation on viral safety and testing to OTAT/CBER and CDER. She has been involved in the licensure of several viral vaccines and contributed to the development of various guidances and guidelines from the FDA, ICH, PHS, USP, and EDQM. She is currently the FDA Deputy Topic Lead in the Implementation Working Group for the ICH Q5A(R2). Dr. Khan obtained her Ph.D. in Microbiology from the George Washington University, Washington, D.C. She has authored more than 100 publications.