International Alliance for
Biological Standardization

Globally Harmonized Specifications: Current State and Future Opportunities
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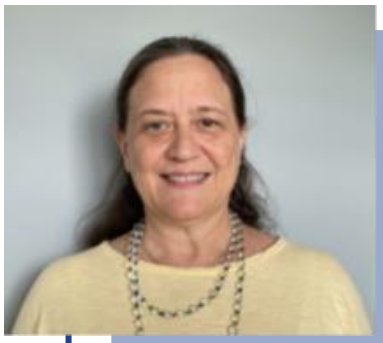

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Dr. Robin Levis has worked at the US Food and Drug Administration since 1995. She is currently the Deputy Director of the Division of Viral Products in the Office of Vaccines Research and Review at CBER/FDA; a position she has held since 2006. Prior to this position, she served as the Regulatory Coordinator for the Division of Viral Products (2002-2006) and served as a Senior Staff Fellow in the Laboratory of Vector Borne Viral Diseases (1995-2002). Her initial research work at the FDA related to flavivirus replication and the role of the NS1 protein. She then transitioned to be the lead CMC reviewer for licensed rabies virus vaccine products and rabies vaccine and related products under development. Her work with rabies virus vaccines was related to the development of an alternative, in vitro potency assay as an alternative to the currently licensed NIH potency test.

In addition to her work in the Office of Vaccines at CBER, she serves as the CBER representative to ICCVAM, as an observer to EDQM Group 15 for vaccines, and serves on several vaccine working groups for the Coalition for Pandemic Preparedness Innovations. Her role on these International working groups is to provide regulatory support to CMC development and product quality.