International Alliance for Biological Standardization

Maintaining the Quality of Vaccines through the Use of Standards:
Current Challenges and Future Opportunities
Library and Archives Canada, Ottawa, Canada
June 21-22, 2023
Abstract

Principles and Practices for Reference Standards

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Reference standards are essential to the development and control of biological products. USP recommends reporting potency of test articles relative to a reference standard, while some laboratories use these also or instead as a control. However, considering their importance to managing biologicals quality there is no consensus on the source of a reference standard, the basis and means of reference standard qualification and stability evaluation, or the use of a primary standard. This talk will discuss principles and practices related to reference standards used to report potency of biological products andpropose strategies for their acquisition and evaluation. Those proposals will borrow from practices related to quality by design for analytical methods, highlighting fitness-for-use of a references standard as well as reduction of uncertainty and the decision risks associated with their uses during development and quality control.