

Name: Robin Levis

Email: robin.levis@fda.hhs.gov

Session: Webinar

Country: United States

George Baer Award:

Title: Human rabies vaccines and alternate potency assays

Authors: R Levis

Abstract: Human rabies vaccine potency is currently measured using the NIH potency test, a test which measures protection against rabies virus challenge in immunized mice. While the test is well accepted as a measure of vaccine potency/efficacy, it has been recognized for decades that the assay has several critical problems. These include; the expense and length of the test, the use of a large number of animals, a lethal challenge step, and a high degree of variability between assays. Vaccine manufacturers and regulatory authorities for both veterinary and human vaccines have been working for some time to develop an alternative assay to measure vaccine potency. Despite significant discussion and the development and testing of several alternative assays it has been difficult to move forward with the licensure of an alternative potency assay. This presentation will introduce considerations for an alternative potency assay based on an ELISA assay to measure the rabies G glycoprotein and provide a report of an ongoing pre-collaborative study and future strategies as discussed at a recent workshop of the EPAA rabies working group.