Poster presentation abstract

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Replacing the required LD50 by a TCID50 for infectious virus challenge

Ulrich Arabin

Roman Adamczyk, Ulrich Arabin*

**Corresponding Author: Ulrich Arabin*

GSK
Emil von Behring Strasse 76,
35041 Marburg, Germany,
ulrich.x.arabin@gsk.com
+491622348685

At GSK, animal studies, which are conducted with high standards of humane care and treatment, represent a small but vital part of our procedures in the release and development of vaccines. While GSK continues to work toward an era of non-animal based research and development, we remain committed to acting ethically and practicing good animal welfare when animal use is still required.
Within GSK Vaccines, the Rabies potency assay is identified as one of the most animal consuming tests in the quality control department. This is mainly caused by the fact that two independent performed assays are necessary to prove the effectiveness. A single dilution assay, which can potentially quarter the number of animals and is well known, as described by WHO TRS 941 is not applicable for the rabies potency assay.
Although a simple reduction of animals will increase the variance of the in-vivo assay. Therefore the 2+1 approach would half the number of animals within the groups and perform up to three assays. Within this design, two assays remain the minimum. The third assay is only performed if the combined potency result of the first two assays is not significantly above the specification (LCL ≥ 2.5 IU/ml). If this criterion is not met, the third assay is performed. The result (estimated potency) is reported as release value.
To measure the amount of infectious Challenge Virus Suspension (CVS) a LD50 determination is not necessary in each routine test. A Tissue Culture Infectious Dose (TCID50) determination as already implemented for the quantification of Rabies virus in the production process can be used to measure the consistency of the CVS preparation. To implement a new batch of CVS or after e.g. invalid test with conspicuous survival rates, a LD50 determination can be performed.
This measure will reduce the animal consumption by 40 mice per test.