Abstract

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Drivers and Barriers to Replacing the NIH Test for Rabies Vaccine Potency Testing

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The use of animals in batch release testing of vaccines very often is a regulatory obligation and represents around 80% of the total number of animals used in the vaccine industry. This heavy reliance on animal experimentation meets serious ethical, scientific and economic objections. Additionally the use of 3R models is stimulated through (European) legislation. Nonetheless, the acceptance and use of available 3R methods is highly challenging, raising the question which factors influence the acceptance and use of 3R models for regulatory purposes and how to optimise this process? To examine the influencing variables and to define optimizing options, this presentation focusses on a survey (1.) and a case study (2.) regarding rabies vaccine potency testing to elucidate the factors influencing the acceptance and use of 3R models for rabies vaccine potency testing purposes in general and the Serum Neutralisation Test developed by the Paul Ehrlich Institut in Germany, in particular. The findings are put into the broader perspective of technology transition. Through this additional step, the broader mechanism behind the existing inertia is described and input is given for the discussion between regulatory authorities and industry on how to enhance the regulatory acceptance and use of 3R models.

References

1. Schiffelers, M.J., Blaauboer, B., Bakker, W. and Hendriksen, C. (2014). Replacing the NIH test for rabies vaccine potency testing: a synopsis of drivers and barriers, Biologicals 42, 4, 205-217.

2. Schiffelers, M.J.W.A., Blaauboer, B.J, Bakker, W.E., Hendriksen C.F.M. (2015). Regulatory acceptance & use of serology for inactivated veterinary rabies vaccines: a process reconstruction and lessons learned. ALTEX 32(3)