

Lecture: strategies to reduce animal numbers for testing biologicals

An up-date of three Rs progress in the area of vaccine quality control

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At the 2006 MEGAT conference I gave a presentation entitled "Towards eliminating the use of animals in regulatory required vaccine quality control". Two years have gone since then. The question one might ask is: "Where are we now?" Well, certainly not at a total replacement. The fact is that laboratory animals are still extensively used for this area of testing, and also will be used in the near future. However, significant progress has been made the last few years. My presentation will provide an up-date. Part of it will deal with some case studies coming from my own area of interest. Information will be given about an ECVAM sponsored pre-validation study and an up-coming international validation study, commissioned by the European Pharmacopoeia, of a serological alternative to the lethal challenge and animal demanding (Kendrick) test in the estimation of batch potency of whole cell pertussis vaccine. Also, I will address a promising *in vitro* alternative to the heavily criticised Histamine sensitisation (HS) test in the safety evaluation of a-cellular pertussis vaccines. I also will focus on the consistency approach; a new strategy in vaccine quality control that ultimately might result in vaccine quality control without the need for animal use. Reference will be given to two ECVAM workshops on this issue and to the outcome of a recent EDQM conference in Dubrovnik.

Is it all positive news I have to tell. Well, there are some developments that need to be monitored in a critical way, such as the extensive use of fish for fish vaccines and the lack of harmonisation in vaccine quality control. However, the general conclusion of my presentation will be one of moderate optimism.

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