

Dr Donna Gatewood

Alternatives to Animal Testing - Rabies and Beyond

Three R (reduce/refine/replace) efforts to reduce animal use and suffering in product testing have been underway for decades. While there have been some notable successes, the fact remains that extensive animal testing continues, particularly in the area of veterinary vaccines.

Animal testing served an important purpose in the early days of veterinary vaccine production. Manufacturing processes were in many cases quite crude, and extensive final product testing was critical to confirm the safety, purity, and potency of the vaccine. Consider for example rabies vaccines. It was not so long ago that these vaccines were produced by inoculating live virus into mouse or sheep brains, harvesting the infected brains, homogenizing the tissue, and then, in the case of killed vaccine, using an inactivating agent to kill the virus. The inherent variability of these processes warranted comprehensive testing of the final product in animals, and there were no reasonable alternatives.

Fortunately, advancements in science and technology have allowed manufacturers to refine their production processes to the point that consistency in production is achievable. Processes can be very closely monitored and controlled, and in-process testing of antigen can provide substantial information about antigenic content and quality. Concurrent with the advances in science and technology, manufacturers have established robust quality management systems to ensure that appropriate manufacturing controls are in place, adhered to, and documented at every step of the production process.

Traditional regulatory dogma calls for a single assay on final product to confirm product potency. Advancing Three R efforts requires a fresh approach to the way we think about implementing in vitro replacement testing. Recognition of consistency in production, utilization of new and emerging technologies, use of in-process testing, and consideration of assay panels rather than a single test on final product could allow for further successes in reduction of animal use and suffering.

dgatewood@edgevcg.com
1927 Maxwell Avenue
Ames, Iowa 50010
515 231 3610

