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Global Perspective and Future Considerations for Decreasing Testing In Animals

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Around the world, many countries have policies or legislation that encourage reduction, replacement, or refinement of use of animals in product testing. Within the EU, this 3R's approach is mandatory, whereas in the US, the approach is encouraged, but not thoroughly enforced. In many countries in the rest of the world, there is no legislation at all to even encourage the 3R's. This uneven approach makes it very challenging for multinational companies, like most vaccine companies are, to comply with requirements in all markets. For European companies, they cannot conduct the animal testing with in vitro alternatives are accepted so it becomes essentially illegal for them to comply with countries' requirements that have not abandoned the animal tests. In addition, double testing is not consistent with a Quality approach.

In addition to potency and certain safety testing (e.g., completion of inactivation), additional tests should be considered for application of the 3R's. Most vaccines are still required to conduct abnormal toxicity testing (e.g., the target animal batch safety test) even though many countries have eliminated them. All viral vaccines are tested for adventitious agents, even though there are acceptable in vitro alternatives that have been in existence for decades and new alternatives that are ostensibly broader and potentially as sensitive or suitably sensitive are being validated.

Many of the old animal methods are accepted despite having never been validated in accordance with the principles exposed in ICH Q2(R1), which are now expected. New in vitro methods cannot be directly compared to old animal methods because the read-outs differ significantly as well as other reasons. Thus, it will take leadership on the part of regulators throughout the world to let go of old-fashioned and accepted animal tests in favor of more modern, more complex, and less wide-spread technologies. But, in this century, there is a mandate to reduce, replace, and refine the use of animals in product testing.

