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Implementation of 3Rs to quality control of biologicals and lot release tests in Japan

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Animal experiments have been taking essential parts in tests for quality control and lot release of biologicals for a long time and remain indispensable at present. On the other hand, the increasing requirement for animal welfare is the driving force for us to implement the 3Rs (Replacement, Reduction and Refinement) in biological QC and lot release.

In Japan, efforts for the implementation of 3Rs so far resulted in the removal of tests (typically the innocuity test) and improvement of methods (potency test etc.) in Japanese Minimum Requirement for Biological Products.

The framework for the implementation is :

- (1) accumulation of sufficient data for removal or modification of animal tests, in many cases by collaborative studies with manufacturers.
- (2) proposal for the removal/modification of tests to the internal committee of NCL=NIID (now JIHS).
- (3) proposal to the superior committee that includes the NCL and NRA=MHLW (Ministry of Health, Labour and Welfare), PMDA (Pharmaceuticals and Medical Devices Agency).
- (4) approval and public notice in the Official Gazette.

