投稿 ▶総説

# 現行ウイルス試験法の再評価：*in vitro* 試験 / *in vivo* 試験

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Re-evaluation of *In vitro* and *In vivo* Viral Tests for Biological Medicinal Products

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**Summary**

Viral testing is needed for medicinal products that are manufactured using raw materials of biological origin in order to ensure safety. The International Conference on Harmonization (ICH) Q5A Guideline, Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human Origin or Animal Origin, has included conventional *in vitro* and *in vivo* viral tests since 1999. ICH Q5A is currently undergoing revision to take account of new technologies for detecting viruses. Under these circumstances, re-evaluation of the *in vitro* and *in vivo* tests is crucial for developing a flexible and effective framework of virus testing. This study focuses on comparative studies of the *in vitro* and *in vivo* tests.

**Key words**

Virus test, *In vitro* test, *In vivo* test, Retrovirus test, ICH Q5A