Validation of Alternative Methods for Toxicity Testing

Abstract:
Alternative approaches to animal testing are gaining momentum with an increasing number of test methods obtaining international acceptance, thanks in large part to the validation efforts conducted on these assays. The principles and process of validation were first established in the 1990s in Europe and USA, and further gained international recognition ensuring the broader acceptance of alternative test methods at a regulatory level. If these principles were successful in pioneering the regulatory acceptance of alternative methods for less complex endpoints, an evolution of concepts is needed to embrace emerging technologies and the increased complexity of endpoints. Innovative concepts and approaches of scientific validation can help to ensure the continued regulatory and international acceptance of novel alternative methods and technologies for toxicity testing such as human-based in vitro models derived from induced pluripotent stem cells and significant advances in bioengineering. This chapter provides a historical overview of the establishment and evolution of the principles of the scientific validation of alternative methods for toxicity testing as well as the challenges and opportunities for adapting those principles to keep pace with scientific progress whilst ensuring human safety and best serve the needs of society.

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