Alternative Methods Applied to Pharmaceuticals and Biomaterials

The term "alternative" is employed to describe the test method in association with the principles of the 3Rs - Replacement, Reduction and Refinement. In accordance with this principle, an alternative method can be used to replace animal testing, reduce the quantity of animals required for each assay, or refine an animal testing method to minimize pain and suffering.

There are different platforms available to create alternative methods including in vitro models and computer-based systems. A few elements may be considered in terms of safety when it comes to the development of a new drug or biomaterial. First it is important to identify the chemical identity and the composition, as well as chemical structure, impurities and functional groups, followed by the determination of the physical chemical properties. As a next step, the kinetics aspects, e.g. absorption, distribution, metabolism and excretion should be evaluated. The mode and/or mechanism of action or adverse outcome pathways as well as the chemical and biological interaction must be determined. Finally, the responses found in alternative assays can lead to a proper safety assessment for drugs and biomaterials without the need for animal experimentation.

Within this context, this thematic issue focused on alternative assays applied to replace animal testing in order to assess the safety and biological activity of currently available and novel drugs and biomedical devices. The manuscript entitled "Epithelial organotypic cultures: a viable method to address the mechanisms of carcinogenesis by epitheliotropic viruses" describes the mechanism of carcinogenesis, a topic that was initially researched mainly in animal models.

In another context, some alternative methods have also been employed in biomaterials, as the authors of “Current Methods Applied to Biomaterials – Characterization Approaches, Safety Assessment and Biological International Standards” extensively described. This review shows that using alternative tests for biomaterials has almost replaced animal tests, following an actual tendency. Finally, the last two manuscripts, “Validation cytotoxicity assay for lipophilic substances” and “Alternative methods to animal studies for the evaluation of topical/transdermal drug delivery systems” are important both for medicine and cosmetics formulation, as the authors showed the importance to characterize the lipophilic substances, even a difficult issue in cytotoxicity assays, and the importance of permeation in cosmetics and medical products.

Overall this special issue has addressed aspects concerning alternative assays applied to replace animal testing in order to assess the safety and biological activity of currently available and novel drugs and biomedical devices and contain materials that follow the topics in trends and published worldwide. This issue shows balanced viewpoints of experts contributing to minimize the use of animal tests, in an attempt to act as a primary reference for industrial, commercial and research perspective in an extensive field of science.

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