

CONTRIBUTION OF "IN VITRO" ASSAYS TO PRECLINICAL AND PREMARKETING TESTING IN IMMUNOTOXICOLOGY

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SUMMARY

An attempt to replace the "in vivo" testing by "in vitro" exposure of cells to drugs is discussed from the point of view of the limitations of these artificial test conditions. The critical reminders are evaluated, the most important ones being the pharmacokinetics, pharmacodynamics and metabolism of drugs in the body what may be a cause of the discrepancy between "in vivo" and "in vitro" exposure assays. Various sensitivity of different cell types and of different phases of the generation cycle represent the crucial importance in the immune response and in the drug-cell interactions. The "in vitro" assays are technically sophisticated and mostly based on the tissue-culture techniques. However, both in immunology and immunotoxicology standardization, validation and usage of rules of Good Laboratory Practice are required. Finally, possibilities and contribution of "in vitro" assays to immunotoxicology are listed. It is apparent that for establishment of common rules these studies require intensive international and interlaboratory cooperation and coordination.

Key words: immunotoxicology, exposure "in vitro", immunological techniques

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