

Validation of Innovative Technologies and Strategies for Regulatory Safety Assessment Methods: Challenges and Opportunities

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Advances in understanding of the pathways and mechanisms by which substances cause adverse health effects along with innovative technologies are providing new opportunities to develop test methods and strategies that may improve safety assessments. These include high throughput screening and other approaches to rapidly measure various molecular, genetic, and cellular perturbations caused by test substances. Integrated testing strategies that combine biomarker assays with existing test methods or with one or more sensitive biomarker assays are being developed. However, before such test methods and strategies can be used for regulatory decision-making, they must undergo validation studies to determine their usefulness and limitations for specific purposes. Validation studies must be designed to adequately determine the extent that reproducible results can be obtained in different laboratories, and to adequately determine the extent that the proposed use of the test method can provide equivalent or improved protection compared to existing methods. Reference substances must be selected for which there is high quality data and that cover the spectrum of chemistry and biological activity for which the new method is applicable. The adequacy and reliability of proposed dose- or concentration-setting procedures must also be evaluated. Comprehensive and optimal validation study designs are expected to expedite the validation and regulatory acceptance of new test methods and approaches that support improved safety assessments and contribute to reduced animal use for regulatory testing. NOTE: The views expressed above do not necessarily represent the official positions of any federal agency.