WC8 Session 1-4: Regulatory Testing Paradigms and Validation of Alternative Test Methods for Detecting Estrogen Active Substances: Impact on the Three Rs

BG1Luc ER TA test method: Results of an international validation study and proposed performance standards.

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The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) recently convened an international peer review panel to assess the validation status of the BG1Luc ER TA test method (also known as the LUMICELL™ assay). The BG1Luc ER TA test method uses transactivation of an estrogen responsive luciferase reporter gene in human ovarian cancer cells to assess compounds for in vitro estrogen agonist and antagonist activity. This test is intended to be used as one component of a multi-test screening strategy as described in US EPA's Endocrine Disruptor Screening Program (EDSP) and offers potential benefits over the existing method, OPPTS 890.1300. BG1Luc ER TA is the only method validated to assess ER TA in vitro activity up to the 1 mM limit currently required in the US EPA's EDSP and is the only ER TA method to be validated for the detection of anti-estrogenic substances. This talk will provide an overview of the validation report and discuss performance standards that may be applicable to the OECD concept of developing a Performance Based Test Guideline.