Non-Animal Testing Technologies and Strategies Used for Chemical Hazard and Risk Assessment

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Presenter biography

Dr. Gertrude-Emilia Costin received her Ph.D. (Cum laude) in 2001 from the Institute of Biochemistry of the Romanian Academy. She continued her work on intracellular trafficking and maturation of melanosomal proteins during postdoctoral training at the National Cancer Institute, National Institutes of Health (NIH). After completing her postdoctoral fellowship at NIH, Dr. Costin worked as Senior Research Scientist for Avon Products, Inc. – Global R&D. She joined The Institute for In Vitro Sciences, Inc. (IIVS) in 2007 where she currently works as Study Director and Manager of Scientific Services. She is in charge of a wide range of safety and efficacy commercial studies and research projects using *in vitro* testing strategies. Her main area of expertise is in the use of *in vitro* test methods for the dermal safety assessment of ingredients and final formulations manufactured by the personal care or pharmaceutical industry as well as products to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is regulated by the U.S. Environmental Protection Agency (EPA). As part of IIVS' mission in education, Dr. Costin is involved in educational workshops focused on non-animal research and testing using diverse *in vitro* assay systems to assist the needs of the pharmaceutical and personal care industry as well as chemical manufacturers.

Presentation abstract

Industry's product stewardship responsibilities focus on ensuring worker safety by properly evaluating and assigning warning statements and by providing instructions for the personal protective equipment usage when handling chemicals. In addition, companies are required to classify materials according to Dangerous Goods regulations, and to operate internationally according to the EU REACh (The European Union's regulation: Registration, Evaluation, and Authorization of Chemical substances), the UN's Globally Harmonized System (GHS) of Classification and Labeling of Chemicals, and the World Health Organization's harmonization standards for Chemical Risk Assessment. Historically, the toxicological hazard and risk assessment of industrial chemicals, biocides, pesticides, pharmaceuticals, etc. has relied on animal studies to ensure human health or safety. Ethical considerations and scientific reasons modernized the predictive toxicology through the infusion of non-animal test methods, models and strategies many of which have been validated for regulatory purposes. These technologies support effective global product stewardship principles and also ensure adherence to the 3 Rs which call for the Replacement, Reduction and Refinement of animal use to label products or to prescribe certain procedures for transport. The *in vitro* testing technologies available today are of various complexities, ranging from simple cell monoculture test systems to more complex such as explants or reconstructed organotypic tissue model and emerging organ-on-a-chip platforms. This presentation will provide examples of several validated non-animal testing technologies and strategies that can be used within international regulatory frameworks. The current global regulatory climate favorable for further advancement of *in vitro* testing methods would not have been achievable without the joint efforts by industry, regulatory agencies and animal welfare organizations which are the key to successful legislative changes for the safety assessment and labeling of chemicals.