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Genotoxicity and industry: Utilizing genetic toxicity assays to support pharmaceutical development

The purpose of genotoxicity assays is to prevent human exposure to potential carcinogens. Carcinogenicity testing is not conducted until the last phases of drug development and genotoxicity assays are used as surrogates to predict their outcome by measuring initial key events in the carcinogenic process. During lead optimization, screening assays are used to assist in selection of a drug candidate lacking significant safety hazards. These screening assays include; computerized assessment for the presence of structural features known to represent mutagenic hazards, bacterial reverse-mutation assays (Ames tests), *in vitro* mammalian cell assays and appropriate animal studies. Once identified, drug candidates progress to full development where more extensive genotoxicity testing is conducted in compliance with formalized regulatory guidelines. A positive outcome in any of the *in vitro* assays triggers follow-up testing *in vivo* to better understand the biological relevance of the positive finding. Ideally, *in vivo* follow-up testing is conducted using integrated study designs where genotoxicity endpoints are added on to general toxicology studies. This creates a powerful data set as drug exposure levels, organ toxicity, histopathology, clinical pathology, body weights and clinical observations are obtained concomitantly with genotoxicity endpoints from each biological replicate. This presentation will summarize pathways for enabling first in human drug studies and discuss strategies for developing new chemical entities that are mutagenic, clastogenic, aneugenic or contain genotoxic impurities.

Biography

Daniel J Roberts has a MS in Biotechnology from Johns Hopkins University and is currently a PhD candidate in the Joint Graduate Toxicology Program at the Environmental and Occupational Health Sciences Institute at Rutgers University. He started his genetic toxicology career at Litron Laboratories by assisting with flow cytometric micronucleus kit development while learning how to conduct and direct bacterial reverse mutation assays. He started a flow cytometry lab at Covance Laboratories, Inc., and as a Research Associate in the Genetic and Molecular Toxicology Department, he supported the development of multiple assays including aneugenicity detection, using CREST antibodies and pan centromeric probes, and the flow cytometric rat Pig-a gene mutation assay, to phenotypically evaluate *in vivo* gene mutation. Currently, he is a Research Scientist in the Genetic Toxicology Department of Bristol-Myers Squibb and is responsible for conducting and supporting non-clinical safety studies to ensure worker and patient safety. He is presently serving a 3-year term as a board of director for the Genetic Toxicology Association and was nominated to be the 2016 Chair of the organization. He is actively interested in developing new genetic toxicity assays for hazard identification purposes, with focus on utilizing newer technologies like next generation sequencing to advance the science of genetic toxicology.

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