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## Robert john meehan who is he

Joseph Meehan (870) 543-7121NCTRRsearch@fda.hhs.gov Back to NCTR Major Investigators Page O | Background publication Joseph Meehan studied philosophy at Rhodes College and graduated with a bachelor's degree in cum laude in 1981. He studied computer science at the University of Arkansas at Little Rock, and management through the University of London (London School of Economics) before earning a graduate certificate in bioinformatics from Stanford in 2003. Mr. Meehan began his career as a computer programmer at Baptist Memorial Hospital in Memphis before joining NCTR in 1983. From 2001 to 2008, he was systems and network manager and software development manager for NCTR from 2008 to 2012. He is currently a senior adviser in the bioinformatics and biostatistics division. Research interests Mr Meehan serves as head of the bioinformatics software development team, where he is responsible for developing new software for various research applications, including regulatory informatics, toxicogenomics and machine learning. He is NCTR's principal investigator on a joint project to develop and strengthen regulatory review and research tools at the FDA's Center for Drug Evaluation and Research, including efforts to port critical regulatory databases to Oracle, capture pharmacology and toxicology review data from review documents, and retrospectively extract review information from FDA approval letters using a pattern matching and natural language processing. Professional Companies/National and International Groups A member of the American Association for the Advancement of Science (AAAS) 2017 – Present Select Publications Publication titles are associated with the text abstracts on PubMed. 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Zou W., Chen H., Hise K., Tang H., Foley S., Meehan J., Lin W., Nayak R., Xu J., Fang H., and Chen J. *PLoS One*. 2013, 8. Salmonella-characterisation data-processing tools: Application for gel-based fingerprint analysis. Zou W., Tang H., Zhao W., Meehan J., Foley S., Lin W., Chen H., Fang H., Nayak R., and Chen J. *BMC Bioinformatics*. 2013, 14. Microarray Quality Control (MAQC)-II study of common practices for the development and validation of microarray-based predictive models. MAQC Consortium. *Nat Biotechnol.* 2010, 28(8):827-38. Robert Heflich, Ph.D. (870) 543-7121NCTRRsearch@fda.hhs.gov the page of nctr chief investigator O | Publications | Division of Background Scientists Dr. Robert H. (Bob) Heflich earned a PhD in microbiology from Rutgers, State University of New Jersey, in 1976, followed by postdoctoral training with Veronica Maher and Justin McCormick at Michigan State University, to study the mechanisms of DNA repair and mutagenesis in normal human fibroblasts. Dr. Heflich joined NCTR in 1979, where he is currently director of the Division of Genetic and Molecular Toxicology. It maintains an active research program while managing a division of more than 30 scientists and administrative support staff. Dr. Heflich published more than 250 papers in peer-reviewed journals, served as editor-in-chief of environmental and molecular and mutagenesis, and participated in several FDA and international committees dealing with genetic toxicology regulatory issues. Dr. Heflich has been a member of the FDA Senior Biomedical Research Service since 2001 and received the Environmental Mutagen and Genomics Society Service Award in 2006 and the Alexander Hollaender Award in 2018. He was awarded FDA Critical Path funding in 2008 develop a human PIG-A test for use during clinical trials. Since 2009, it has received funding from the FDA's Center for Tobacco Products (CTP) to develop 3-D cell culture models and to evaluate existing genotox tests to regulate tobacco products. In addition, the CTP funded its research into the application of in vitro pig tests to extrapolate the toxicity of tobacco products in vivo. Dr. Heflich served on the following NCTR committees: NCTR Research Scientist Peer Review Committee Chairman 2000, 2009 Senior Biomedical Research Service Credentials Committee Member 2007 – Current Research Interests Over the years, Dr. Heflich has pursued various research interests to modernize the practice of regulatory genetic toxicology, including developing more relevant, human-based in vitro models, and using advanced genetic analysis techniques designed to evaluate sequence changes in genes responsible for human disease. Particular long-term interest includes the development of approaches for measuring and analysing mutations in laboratory animals. Studies have been conducted to evaluate the transgenic genes gpt, lacI, cII and  $\phi$ X174 am3 of reporters and endogenous genes hprt, Tk and Pig-a in mice and rats. The overall objective of these efforts is to use sensitive and predictive in vivo mutation tests for regulatory purposes. Some of its other research interests include the development and characterisation of relevant in vitro tests to assess the risks associated with exposure to tobacco products. The following are descriptions of two recent research activities: One of the more exciting developments of the last 10 years was a step towards a quantitative evaluation of dose data and response to genetic toxicity in order to better estimate human risk. Although it has been known for some time that not all genotoxic carcinogens have linear dose responses, dose response data are rarely used to evaluate the safety of regulated medicinal products. This changed when European regulators accepted in vivo mutation data to support the carcinogenicity threshold of ethylmethane sulfonate, which was found to be a contaminant in a dose of AIDS neflinvir (Viracept) in 2007. Dr. Heflich and colleagues from HESI/LSI (now HESI) have explored ways to quantitatively evaluate genetic toxicology data and develop point of departure (PoDs), which can be used to determine virtually safe doses for human exposure. Dr. Heflich also used these methods to distinguish genotoxicity produced by related tobacco products claiming to have an equivalent or reduced toxicity. These efforts have the potential to make better use of genetic toxicological data for regulatory decision-making. The In vivo Pig Gene Mutation Test is currently being developed as a regulatory test. Dr. Heflich and his colleagues co-invented the test in 2008, and subsequently did discoveries as regards its sensitivity to different types of genotoxins, the expression and persistence of response, its ability to integrate into general toxicological studies and the identification of mutations responsible for inducing the mutant phenotype. Dr. Heflich led the International Workshop on Genotoxicity Testing and Health and Environmental Science Institute working groups that are trying to get regulatory adoption of the test. Although the test already complies with international regulatory guidelines (e.g. international conference on M7 harmonisation), it is currently working on a plan approved by the Organisation for Economic Co-operation and Development (OECD) to develop test guidelines (TG). In April 2020, the OECD approved a detailed review and validation document on the test (see OECD publications below) which clears the way for the development of TG. The approval of the OECD TG will ensure that regulatory agencies largely accept test data. Member of the Professional Societies/National and International Groups of the Environmental Mutagen and Genomics Society (EMGS) 1980 – current editor-in-chief of the Society Journal 2001-2006, Emgs Publications Policy Committee 2001 – Current Chair, Seminars of the Annual Meeting of the EMGS on the Pig Gene Mutation Test 2008, 2009, 2012, 2013, 2014, 2016 Emgs Council 2019 - current member of the Communication and Publications Committee of the FEDERATION of American Societies for Experimental Biology (FASEB), member of the FASEB Communication and Publications Committee 2007-2010 Member of the Scientific Policy Committee faseb 2010 Health and Environmental Sciences Institute (HESI), HESI Pig Development Working Group Test as Genotoxicity Test in Vivo 2009 - Current Chair of the HESI Working Group on The Development of the Pig Test as a Genotoxicity Test in Vivo 2012 - Current International Working Party on Genotoxicity Testing (IWGT), Member of the Transgenic Mutations Committee 2002-2003, Committee on Genomixins only for in vivo 2005-2007, member of the Committee on Non-Relevant Genotoxins In Vivo 2005-2007, Committee on the integration of Genetox tests into the general tox protocols 2009-2011 Member, Committee on New In vitro Tests 2016-2020 Member of the Committee on 3D Tissue Models 2016-2020 Leader (rapporteur), Committee on Pig Gene Mutation Test and In Vivo 2012-2015, Member of the Institute of In vitro Sciences, Steering Committee for In vitro Model Conferences for the Assessment of Tobacco Smoke Toxicity 2014 Member of the Organisation for Economic Co-operation and Development (OECD), OECD Expert Working Group on TG487 (Technical Guidance on the Micronucleus Test) in vitro) 2007 member of the OECD Expert Working Group on developing guidance on transgenic in vivo tests (TG488) 2008-2013, 2018-2020, OECD Expert Working Group, which reviews older genetic toxicological TG for 2011-2015, member of the OECD Expert Working Group on (guidance on the hprt in vitro test) 2015-2018, OECD Expert Working Group on Revision of TG471 (Bacterial Gene Mutation Tests) 2019 - Current Chair of the OECD Expert Working Group on The Development of the OECD TG Pig Test 2015 - Current Sigma Xi Member 1975 - Current Treasurer, Central Arkansas Chapter 1990-1996 Publication names selected publications are associated with text abstracts at PubMed. 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