



NIHS特別講演会 (殿町 # 8)

演 題

Research conducted by US FDA/NCTR's Division of Genetic and Molecular Toxicology



講 師

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要 旨

The Division of Genetic and Molecular Toxicology (DGMT) dates back nearly 50 years, to the founding of the U.S. Food and Drug Administration's National Center for Toxicological Research (USFDA/NCTR) in 1972. The DGMT presently has 33 employees, 12 of whom are Principle Investigators. The Mission of the DGMT is to 'Improve public health by providing FDA with the expertise and tools necessary for comprehensive assessment of genetic risk and by strengthening approaches to integrate knowledge of genetic risk into regulatory decision making'. In addressing its mission, DGMT conducts a variety of research projects requested by regulators from the FDA Product Centers. These could involve small projects, such as performing in vitro testing on a suspected drug impurity, to large multi-year projects, such as gaining regulatory acceptance for the in vivo *Pig-a* gene mutation assay or developing an in vitro organotypic airway model for evaluating the toxicity of inhaled substances. DGMT scientists also are exploring ways of using error-corrected next generation sequencing to evaluate the genetic toxicity of difficult-to-evaluate FDA-regulated substances, such as nanomaterials, and off-target sequence changes caused by gene editing. Although genetic toxicity data have been used by FDA regulators for many years, advances in the science, improvements in testing methods, and new products continue to make work done by the DGMT an important part of FDA's research portfolio.

こ 略 歴

Dr. Heflich received a Ph.D. in Microbiology from Rutgers-The State University of New Jersey in 1976, followed by postdoctoral training with Veronica Maher and Justin McCormick at Michigan State University. He joined the U.S. FDA's National Center for Toxicological Research in 1979.

2013~, Director, Division of Genetic and Molecular Toxicology, NCTR, U.S. FDA.

他、*Environmental and Molecular and Mutagenesis*誌の編集委員長を歴任、米国環境変異原学会のAlexander Hollaender Awardを受賞、書籍、原著論文等、250篇以上の著作。*Pig-a*遺伝子変異試験のOECDガイドライン化へ代表として尽力中。

日 時

2019年6月17日 (月)

14 : 00 ~ 15 : 00 開場 13 : 30

国立医薬品食品衛生研究所 2階 共用会議室

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