

**The 2<sup>nd</sup> Workshop for In Silico Expert Judgment in ICH-M7  
(Sponsored by JEMS, and cosponsored by BMS)**

**Subject:** Expert Judgment for in silico Ames Mutagenicity  
**Date:** May 23, 2017  
**Venue:** National Cancer Center Research Institute, International Conference Hall, Tokyo, Japan <http://www.ncc.go.jp/en/about/access.html>  
**Registration:** Start from April 17 at JEMS website (<http://www.j-ems.org>)  
**Registration fee:** 5,000JPY (JEMS member), 10,000JPY (non-member)  
**Contact:** Masamitsu Honma, NIHS ([honma@nihs.go.jp](mailto:honma@nihs.go.jp))

**<Program>**

**\*Simultaneous interpretation between English and Japanese is available**

**10:00-10:05;** Opening Remarks Yoshifumi Uno (JEMS President)

**10:05-12:10; Session1; Assessment of Mutagenicity of Genotoxic Impurities**

Chair: Atushi Hakura (Eisai), Junichi Fukuchi (PMDA)

10:05-10:30; Progress of ICH-M7 (R1) Guideline

Tsuneo Hashizume (Takeda)

10:30-10:50; Progress of QSAR Models for Predicting Ames Mutagenicity

Masamitsu Honma (NIHS)

10:50-11:30; Expert Review under ICH-M7 using Derek Nexus and Sarah Nexus

Chris Barber (Lhasa)

11:30-12:10; Analysis of Alerts, Importance of Uncovered Features and Inconclusives in ICH-M7 Mutagenicity Assessments

Suman Chakravarti (MultiCASE)

<Lunch; 12:10-13:30>

**13:30-14:30; Invitation Lecture**

Chair: Masamitsu Honma (NIHS)

FDA Experience in the Interpretation of (Q)SAR data under ICH M7

Naomi Kruhlak (FDA, CDER)



**Naomi Kruhlak, Ph.D.**

Lead, Chemical Informatics Program, Center for Drug Evaluation and Research

Dr. Kruhlak develops and applies (quantitative) structure-activity relationship ((Q)SAR) models to support regulatory review decisions. She is currently the lead for the Division of Applied Regulatory Science's Chemical Informatics Program and is the principal investigator on three FDA/CDER Research Collaboration Agreements with commercial (Q)SAR software vendors. She has published 29 peer-reviewed articles describing data standardization, transformation, and classification for modeling purposes, as well as the creation and refinement of (Q)SAR models with chemical interpretability. She has extensive experience in the technical aspects of (Q)SAR modeling as well as their application in a regulatory context.

<Coffee Break; 14:30-14:45>

**14:45-16:55; Session 2; Expert Judgement in Case Studies**

Discussion Leaders; Masayuki Mishima (Chugai), Tsuneo Hashizume (Takeda)

\*Some volunteers challenge the expert judgement for assessing mutagenicity of the chemicals, which were appointed by organizers before the workshop.

**16:55-17:00; Closing Remarks**

Dr. Masayuki Kato (BMS President)