

4th ICH-M7/QSAR Workshop 開催のご案内

ICH-M7 QSAR/Expert Judgment Workshop - iGenotox Challenge Prediction –

2019年11月18–20日に東京で開催される第6回アジア変異原学会日本環境変異原学会第48回大会合同大会 (ACEM/JEMS2019) にて、19日に第4回 ICH-M7/QSAR ワークショップが開催されます。適切な理解をサポートするため同時通訳が付きまます。ワークショップでは、QSAR エキスパートジャッジと、不純物管理のためのパージファクターの利用について議論します。詳細は国立医薬品食品衛生研究所ホームページ <http://www.nihs.go.jp/dgm/M7QSAR.html>、参加申し込み等につきましては ACEM/JEMS2019 ホームページをご覧ください <http://www.acem-jems2019.jp/>.

Part I: QSAR prediction and expert judgment for Ames mutagenicity

Chairs: Kiyohiro Hashimoto, Masamitsu Honma

- 9:00- 9:05 Introduction: Kiyohiro Hashimoto (Takeda)
- 9:05- 9:25 Ames/QSAR International Challenge Project; Masamitsu Honma (NIHS)
- 9:25- 9:45 Actions of PhiAS-Contract research and consultation support of ICH M7/QSAR for pharmaceutical companies-: Tsukasa Kikuno (PhiAS)
- 9:45- 9:55 Overview of expert judgments with 20 substances: Masayuki Mishima (Chugai)
- 9:55-10:15 Case studies of the expert judgment: TBD
- 10:15-10:45 Undertaking expert review under the ICH M7 guidelines: Chris Barber (Lhasa)
- 10:45-11:15 Effective expert review strategy for ICH M7 assessments: Roustem Saiakhov (MultiCASE)
- 11:30-12:00 Handling out-of-domain and indeterminate results as part of ICH M7 recommended (Q)SAR analyses. A Leadscope perspective: Manuela Pavan (Innovatune)
- 12:00-12:10 Discussion and summary: Chris Barber (Lhasa)

Part II: Control of impurities in pharmaceuticals by purge factor

Chairs: Junichi Fukuchi, Masayuki Mishima

- 12:10-12:15 Introduction: Junichi Fukuchi (PMDA)
- 12:15-12:30 Control strategy for potential mutagenic impurities in the synthesis of drug substance, Sakuramil mock case study: Yusuke Nagato (FUJIFILM)
- 12:30-12:45 Case study, use of purge factor to evaluate regulatory starting material: Hiroshi Iwamura (Chugai)
- 12:45-13:15 Use of Mirabilis based purge calculations to understand MI related risk and control strategy options – case study examples (including management of N-Nitrosamines): Andrew Teasdale (Astrazeneca)

Closing: Masamitsu Honma (NIHS)

4th ICH-M7/QSAR ワークショップ世話人

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