



国立医薬品食品衛生 研究所・特別講演会

日時

2024年7月9日（火） 14:00–15:00

場所

国立医薬品食品衛生研究所2階【共用会議室】
神奈川県川崎市川崎区殿町3-25-26

講師

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(Vice President, Institute for In Vitro Sciences, USA)



題目

Learning by Doing: Gaining confidence in new approaches for regulatory decision-making and risk assessment

要旨

The use of toxicological test methods that do not use animals, but rather rely on computational predictions or in vitro methods (New Approach Methods, NAMs) is becoming more common worldwide. The Institute for In Vitro Sciences has collaborated with companies, government agencies, and other stakeholders to validate and apply NAMs in the United States and, via the Organization for Cooperation and Development (OECD), worldwide. Currently, NAMs are available and accepted by regulatory agencies for many endpoints, including skin and eye irritation and skin sensitization. However, many more tools are available, including high-content and high-throughput assay batteries, assessment of absorption, distribution, metabolism, and excretion (ADME) behavior, physiologically-based kinetic modeling, mechanistically-driven testing strategies, and similar Integrated Approaches to Testing and Assessment (IATA). These approaches can be used within a Next-Generation Risk Assessment (NGRA) framework to assess the potential risks for systemic toxicity from chemicals and products.

This presentation will discuss efforts in systemic toxicity, skin and respiratory sensitization, and genotoxicity to implement modern NAM tools into chemical risk assessment through case studies, validation, and good practices.

お問い合わせ

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