

Scott McDonald, Lhasa Limited, gave this presentation at the "Streamlining Drug Discovery" symposia held in Shanghai, China on 31 May 2018 and Tokyo, Japan on 5 June 2018.

Abstract

Expert assessment is a fundamental part of the assessment of the mutagenic potential of impurities under the ICH M7 guideline and it makes a specific provision for the application of expert knowledge to support or overturn an *in silico* prediction. Whilst expert assessment has been successfully applied in this context, there remains some uncertainty as to what constitutes expert analysis.

This presentation will outline a framework to more clearly understand the process of expert assessment under ICH M7 and the role that both *in silico* prediction methodologies and supporting data play. The use of such a framework can assist in dealing with relatively straightforward situations where the two required

in silico

methodologies agree to more complicated cases of model disagreement or “indeterminate” or “out-of-domain” predictions.

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