Joel M. Cohen, Sc.D., DABT

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Predictive Toxicology Approaches for Medical Device Compatibility Assessment

Comprehensive toxicological characterization of extractable/leachable substances is an essential component of a medical device biocompatibility assessment. Chemical analysis often identifies unique or complex extractable chemical structures that lack complete toxicological data packages. Best practices for using new approach methodology (NAM) predictive tools to evaluate these detected chemicals have yet to be formally established. This presentation will provide an overview of predictive toxicology tools currently available for evaluating risks to human health, along with a discussion of potential pitfalls and best practices. The ICH M7 Guideline provides a clear method for applying computational toxicology programs to predict mutagenic potential, which can then be applied to establish an appropriate Threshold of Toxicological Concern. However, such programs must not be used as a black box. Predictions should be evaluated using expert judgment to support a risk conclusion based solely on computational methods. Furthermore, computational toxicology predictions for other hazard endpoints (e.g., developmental or reproductive effects) are less well studied but are actively under development. Case studies will be presented to demonstrate the role of expert judgment when interpreting *in silico* hazard predictions for mutagenicity and skin sensitization endpoints. Read-across approaches relying on experimental data for chemicals sharing similar structural, physical, and chemical properties, along with a similar anticipated mechanism of action, may provide additional information for establishing appropriate safety limits for extractable compounds lacking data. Additional case studies will present approaches for justifying read-across for risk assessment of extractable compounds lacking toxicity data.