

Assessment Strategies to Meet the Requirements: To Test or Not To Test
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The presentation will highlight translating permitted daily exposure (PDE) values in the guidance to finished product levels, and provide a toxicological perspective on what the calculations reveal from a finished product manufacturer. A brief explanation of how PDE and other similar thresholds are derived will identify similarities in other medical products, and "real life" examples of calculations will be used to provide insight into the process. The presentation will focus on injectable products (e.g., LVP or SVP products) and how to use product-specific dosing information to transform PDE levels in mass per day or ppm to product threshold levels.

The concepts presented can also be applied to other dosage forms. Information from suppliers on individual raw materials used in the product formulation is an obvious key component in the translation calculations, as described in the guidance, but other sources of information may be useful too and will be discussed. Residual solvent testing of the drug product is recommended under the guidance when calculated levels of the residual solvent (by the cumulative method) in a finished product exceed the PDE. The presentation will also address several potential health-based risk assessment options to consider if analytical testing indicates that actual product levels exceed the PDE, especially for currently marketed product.