

**Assessment Strategies to Meet the Requirements
Supplier Qualification, Audits, and Acceptance by COA**
Susan J. Schniepp
Hospira, Inc.

This session will explore a risk-based approach to determining the testing requirement of residual solvents in APIs, excipients, and dosage forms.

Decisions should be based on knowledge of the manufacturer's process, quality history with the supplier, the use of the final product (chronic or short term therapy) and other key parameters that could impact the decision of whether or not testing is warranted.