

## Developing new approaches to the health hazard assessment of potent pharmaceuticals

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The current approach to setting “safe” levels of exposure to potent pharmaceutical compounds has remained fundamentally unchanged for over 50 years. This approach has been applied to both worker setting (through the setting of Occupational Exposure Limits) and, more recently, patient and/or product safety (through the setting of Permitted Daily Exposures). New developments in pharmaceutical technology (i.e., antibody-drug conjugates, nanodrugs, viral vectors and other biologicals, and emerging immunotherapy targets) have combined with ever-increasing drug potency present challenges to the paradigm of hazard assessment, and have spurred advances and adaptations by which robust evaluations of these compounds can be performed. The purpose of this presentation is to deliver an overview of the hazard assessment process and its applicability to both work and patient/product safety, which will include a description of what constitutes a “potent” pharmaceutical

agent. Application of hazard assessment methodologies to novel drug candidates and drug delivery technologies, which stretch the boundaries of established approaches to hazard assessment, will then be discussed.

### Speaker Biography

Tracy A Kimmel has received her PhD in Environmental Health Sciences from New York University, and is a Diplomate of the American Board of Toxicology. She has almost 25 years' experience in the pharmaceuticals industry, including 12 years working with Corporate EH&S groups. She is currently Senior Manager of Toxicology at SafeBridge Consultants, Inc. Her primary responsibilities include performing health hazard assessments of pharmaceutical and industrial compounds, predicting the toxicity of compounds using computational modeling software and qualitative analyses, evaluation of pharmaceutical impurities and synthetic intermediates, and assisting with environmental risk assessments. She is a former Chair of the Occupational Alliance for Risk Science (OARS) Workplace Environmental Exposure Level (WEEL) Committee, and now serves on the ACGIH Threshold Limit Value (TLV®) Committee. She has contributed to peer-reviewed journal articles and publications, has prepared white papers on occupational hazard assessment, and has delivered presentations and workshops at worldwide locations.

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