

Stephanie A. Wilkins, PE, Lean Six Sigma Green Belt

President

PharmaConsult US, Inc



PharmaConsult Us

Education

Pennsylvania State
University Bachelor of
Architectural
Engineering

Registrations

Professional Engineer
Pennsylvania

Lean Six Sigma
Green Belt

Affiliations

Member ISPE

ISPE Committee
Chairperson of the
year in 2001.

Member of the
International Board of
Directors 2005 – 2009

Team Leader for the
ISPE Risk-MaPP
Baseline Guide©

Professional Experience

Stephanie has over 25 years of professional experience in project management, engineering, and validation solutions for the pharmaceutical industry. She has managed, designed and validated facilities and systems for research, development, pilot plants and manufacturing facilities for the pharmaceutical and biotech industries. Currently she is working with many global companies to implement Risk-MaPP principles with respect to managing the risk of cross contamination.

Stephanie provides project management to all projects carried out by PharmaConsult US as well as provides regulatory input to risk assessments for cross contamination. In addition, provides marketing and manages the operation of the company.

Stephanie keeps abreast of the regulations worldwide with respect to cross contamination and has a good working relationship with regulators worldwide in this area.

Published Material

The Use of Acceptable Daily Exposure (ADE's) for Managing the Risk of Cross Contamination in Pharmaceutical Manufacturing, Pharmaceutical Engineering, 2012

Risk-MaPP and Multi-Use Facilities; Managing cross-contamination risks, Contract Pharma, 2011

A Technical Review of Isolators, Pharmaceutical Engineering, 1998

ISPE Knowledge Brief *Risk Based Approaches to Cross Contamination* 2008

Seminars Given

Official instructor and developed the ISPE training session on the use of Risk-MaPP

Risk-MaPP seminars given in India, Japan, Canada, Ireland, Brussels, Singapore, Washington DC, St. Louis Missouri