## REGISTER NOW!!! 2 PDH credits: Engineering Quality by Design (QbD): A Systematic Approach to Optimized Operations and Experimental Design by Dr. Zenaida Otero Gephardt

**Venue**: Jacobs Engineering, Three Tower Bridge, 2 Ash St. Conshohocken, 19428 PA | 3<sup>rd</sup> Floor Main Conference Room

**Time**: 5.30pm – 7.30pm Wednesday December 19, 2012

Dinner will be included with registration

**Registration Fee:** \$35 (Non-Members), \$30 (AICHE Members), \$10 (Students)

## Engineering Quality by Design (QbD): A Systematic Approach to Optimized Operations and Experimental Design

Quality by Design (QbD) is a methodology for building quality in every aspect of operations. QbD offers a systematic approach for the identification of critical variables in an operation and their impact on product or system characteristics. The pharmaceutical industry, in particular, has embraced the QbD paradigm for its potential in streamlining regulatory operations. Pilot projects with the FDA offer the promise of streamlined regulatory oversight in exchange for QbD analysis of operations, and implementation resulting in robust development of a design space based on engineering statistical methods. The design space is the multidimensional combination of significant variables in an operation. Models that can be used to predict process behavior within an established design space (variable ranges) yield enhanced understanding of process and product characteristics and are critical for optimization. QbD can enhance productivity and build quality in all aspects and all scales of manufacturing and laboratory operations. Building quality in all aspects and phases of processing results in better decisions and more efficient and cost-effective operations. The background and basic principles of QbD will be discussed with a focus on experimental design methodology.

## Zenaida Otero Gephardt, PhD, PE

Zenaida Otero Gephardt is Associate Professor of Chemical Engineering at Rowan University where she has served as Director and Assistant Dean of Engineering. Her major interests are in experimental design, data analysis and high pressure and multi-phase systems. She teaches fluid mechanics, unit operations and process dynamics and control. Dr. Gephardt is Chair-elect of the AIChE Societal Impact Operating Council (SIOC) and is Vice President in charge of Accreditation of the Latin American and Caribbean Consortium of Engineering Institutions (LACCEI). She also serves on the board of the AIChE-DVS and is immediate past president of Delaware Girls Inc. Dr. Gephardt has PhD and MS degrees in chemical engineering from the University of Delaware and a BS in chemical engineering from Northwestern University. She is a registered professional engineer in the State of Delaware and conducts workshops and consults in the areas of experimental design and data management for the chemical and pharmaceutical industries.