Highlights / Overview of New Regulatory Guidelines

- **EMEA Guideline on "The use of Near Infrared Spectroscopy by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations"**
  - Compilation of requirements,
  - Very detailed document…too detailed?
  - No comments on the validation of on-line methods
  - Added value to the USP/EP requirements?
  - NIR treated differently than other analytical methods

- FDA Guidance on Process Validation:

Background

- Completed under auspices of GMPs for the 21st Century initiative that commenced in 2004
  - foster innovation and advance the science of the pharmaceutical manufacturing.
- Aligns Process Validation activities with the product lifecycle
- Approach aligns with Quality by Design (QbD) initiative
- Builds on the concepts delineated in the 1987 Guideline

Lifecycle Approach

- Lifecycle
  - Overall validation is not “completed” but ongoing
  - Necessitates comprehensive process design to understand sources of variability and achieve process understanding
  - Incorporates risk management
  - Recognizes that more knowledge will be gained during commercialization

Process Lifecycle Stages

Stage 1, Process Design:

- Lab, pilot, small scale and commercial scale studies to establish process

Stage 2, Process Qualification:

- Facility, utilities and equipment
- Performance Qualification (Confirm commercial process design)

Stage 3, Continued Process Verification:

- Monitor, collect information, assess during commercialization
- Maintenance, continuous verification, process improvement.