Method Validation 101:
One Critical Part of an Analytical Method Lifecycle

July 31, 2017
1:00-5:15 PM
Fluno Center, Madison, WI

Goals and Objectives:

Analytical method validation is a key element of any pharmaceutical development program. Validation is vital, since both NDA and ANDA must include the analytical procedures necessary to ensure the identity, strength, quality, purity, and potency of the drug substance and drug product. Data must be available to establish that the analytical procedures used in testing meet proper standards of accuracy, sensitivity, and reproducibility and are suitable for their intended purpose. Regulatory agencies require method validation at certain stages of the drug approval process. It may not always be required for early development and GLP requirements, but is required and essential for GMP associated with Phase I-IV product development. This course will examine the role of method validation with respect to the lifecycle of the method and the continuous improvement process. Upon completion of the course, the learner should be able to:

1) discuss method validation and requirements for successful validation of a method;
2) describe the appropriate types of method validation studies for given regulatory requirements;
3) identify and apply the statistics required during method validation;
4) discuss the mean of system suitability and its role in method validation; and
5) identify required protocols and reports that are part of a method validation.

Who should attend:

This course is intended for individuals needing a practical overview of the procedures and requirements associated with validating an analytical method. It is intended for those scientists responsible for creating or implementing methods for APIs or finished pharmaceutical dosage forms. It will benefit those in research and development, quality control, quality assurance, technical operations and regulatory affairs.

Contents:

12:30 pm Registration

1:00 pm **Basics of Method Validation**
Definitions and Pre-requisites.

1:40 pm Break

1:55 pm **Reasons for Validating a Method and Timing**
Regulatory expectations and guidance for industry.
Validation and phases of development.

2:35 pm Break

2:50 pm **Elements of Method Validation**
Specificity, accuracy, precision, linearity, range, DL/QL, robustness, stability-indicating assays.

3:30 pm **Establishing Method Controls after Validation**
System suitability criteria.

4:10 pm Break

4:25 pm **Method Validation Documentation Requirements**
Protocols and reports.

5:00 pm Open Discussion

5:15 pm Adjourn Pre-Conference Workshop

Instructor: Ivelisse Colón-Rivera, Ph.D.
Senior Director, Technical Operations
Vertex Pharmaceuticals, Boston, MA

Fee: $175

Register: https://ce.pharmacy.wisc.edu/pd/pharmaceuticalanalysisconf/