Pharmaceutical Inspectorate Curriculum

<u>Module 1</u> – Regulating Pharmaceutical Quality and the Relationship to FDA's Mission

Objective – Accurately explain the philosophy behind why we regulate pharmaceutical quality and how pharmaceutical quality relates to FDA's mission.

<u>Module 2</u> – Risk Management

Objectives

- Identify current concepts of risk management as they relate to product quality and discuss the relationship between this knowledge and how it would be applied during inspections.
- Conduct critical evaluation of GMP violations to determine level of their impact and their affect on the firm's state of control.
- Discuss how Investigators should strategize to determine product risk as it applies to inspectional approach and case development.

<u>Module 3</u> – Advanced Quality Systems

Objective – Accurately explain advanced modern quality management techniques, including implementation of quality systems approaches to all aspects of pharmaceutical production and quality assurance and how this would enhance the quality of inspections of pharmaceutical facilities.

<u>Module 4</u> – Pharmaceutical Science

Objectives

- Describe the science underlying the approaches to both controlling product quality and causes of variability and explain how this would enhance the quality of inspections of pharmaceutical facilities.
- Demonstrate a comprehension of the concerns those Center reviewers and Center case managers have in their review of applications/cases, according to pre-determined expectations provided by the Center divisions.

<u>Module 5</u> – Current Regulatory Programs and Procedures

Objectives

- Describe the integration of the review program and inspectional program as they relate to each other regarding product quality.
- Through a case study, demonstrate effective use of "critical thinking" and "inspectional discretion" in the evaluation of GMP violations to determine the level of impact.
- Through a case study, demonstrate effective communication of complex product quality issues to an agency/industry audience.

Module 6 – Technology

Objectives

- Demonstrate a comprehension of science and technology advances used in pharmaceutical manufacturing processes.
- Explain the value of the science and technology advances and how these advances would enhance the quality of inspections of pharmaceutical facilities.
- Explain why knowledge of science and technology advances used in pharmaceutical manufacturing processes will result in inspections being conducted in a highly effective and consistent manner.
- Explain how exposure to a 'new' advanced science or technology (un-encountered prior to that inspection) could/should alter the investigator's inspectional approach.
- Discuss the best practices and compliance issues.
- Explain common and unique problems that may occur using the technology.
- Identify technological developments that may impact future production decisions.

Module 7 – Investigational

Objectives

- Identify situation(s) when the investigator would determine that he/she needs to learn more about a particular topic .
- Provide a list of possible sources where the investigator could seek necessary training on a topic for which he/she is not knowledgeable.
- Identify inspectional technique differences between inspections of firms that manufacture CDER, CVM, and CBER regulated drug products.