



## Risk-based Approach to Inspecting Quality Systems (New!)

**Course Objective:** The objective of this course is to understand the Quality Systems concept used by regulatory agencies and the characteristics of the subsystems involved. It covers six types of systems as well as its elements, characteristics and features of the various sub-systems that constitute this system and their inspections. In addition, participants will get the understand of the impact of the QS on Quality Assurance.

**Course Description:** Regulatory agencies are a using systems approach for both domestic and foreign inspections. The approach consist of classifying a firm's operation into six types of systems. The systems inspected depend on upon the purpose of the inspection and agencies prior experience with the firm but always includes the Quality System for which compliance is mandatory.

This course will cover what these systems are, with an emphasis on the need for integrating the design, operation and responsibilities for each of the systems and sub-systems .

**Course Outline:**

- The Quality Systems
- Materials System
- Production System
- Packaging and Labeling System
- Laboratory Control System
- Importance of each of the Quality System's components
- Regulatory Requirements and industry practices for:
  - SOPs, records and report requirements
  - Product Release,
  - Validation,
  - Reprocessing
  - Rework,
  - Returned and Salvaged Goods,
  - Product Complains,
  - Annual Product Reviews
- Other quality system components:
  - training,

- preventive activities
- product improvement
- Roles and Responsibilities for the Quality System Components:
  - Departmental rules and responsibilities including QA
- Impact of other systems on QA:
- Regulatory requirements,
- Current practices