Risk Management

This seminar teaches Risk Management as outlined in ISO 14971 and ICH Q9 Quality Risk Management. Students will learn how to design a risk management system. They will learn how planning and risk management can be integrated into existing business processes to reduce costs and timelines. It emphasizes the need for a clearly documented system for following the company's risk management process. The participants then learn how to write Risk Management reports that will withstand regulatory scrutiny. The class ends with a discussion of systems necessary to collect and process production and post-production information.

Who Should Attend: Medical Device, Pharmaceutical and Bio industry: Project managers, engineers, quality & production team members and business managers who need to implement risk management systems.

Class Length: Half day

Maximum Class Size: 20

Course Prerequisites: Participants must have a working knowledge of cGMP's.

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The Regulatory Requirements and draft guidelines that apply to Risk Management
- The business case for Risk Management systems
- What is Risk Management?
- Identification of hazards
    - The tools for identifying hazards
    - Fault and no-fault hazards
    - The two types of fault based hazards
- Estimating and evaluating associated risks,
- Analyzing risk control options
- Implementing risk control
- Evaluating residual risk
- Analyzing risk / benefit
- Analyzing risks arising from risk control
- Assessing effectiveness
- Controlling these risks, and
- Assessing the effectiveness of the control.
- What must be included in a Risk Management Report?
- Production and post-production information