



## Medical Device Regulatory Audits: Are You Ready?

**Course Objective:** To provide an understanding of the Medical Device Regulations and quality system requirements pertaining to medical device companies.

**Course Description:** This course will help students determine how the quality system requirements and medical device regulations apply to their operations. This course will cover the Food and Drugs Act and Medical Device Regulations, CMDCAS, Establishment and product licensing, and quality system concepts. The presentation will focus on the practical interpretations of regulations to achieve compliance. In addition, practical advice on preparing for and handling regulatory inspections will be discussed.

**Course Outline:**

- Overview of the Food and Drugs Act and Medical Device Regulations
- Overview of Health Canada Inspection Program
- Medical Device Licensing
- Safety and Effectiveness requirements
- Quality System Requirements – ISO 13485- CMDCAS
- Establishment Licensing requirements
- Regulatory SOPs
  - complaints,
  - recalls,
  - mandatory problem reports,
  - distribution records
- Handling, storage, delivery, installation
- Custom-made and Special Access process