

## ***Foundation course in ISO 13485:2012***

### ***OVERVIEW***

*ISO 13485 shapes the Quality Management Systems for Medical Device Manufacturers . The standard applies to design, development , production ,installation and servicing of medical devices compliance to this standard by all categories of management and staff is crucial*

### ***CONTENTS***

- General overview of ISO 13485 2012
- CE marking issues
- 8 quality management principles of the standards
- Risk Management application
- CAPA management principles
- Labelling risks
- Internal Auditor approaches
- GMP requirements

### ***LEARNING OUTCOMES***

- On successful completion of the course participants will be able to
- Understand the structure of ISO 13485
- Understand the relationship between ISO 13485 and ISO 9001
- Understand the key issues within the standard that affects their organisations
- Be aware of what they can do to positively assist in compliance to the standard .
- Be better able to deal with external auditors
- be better internal Auditors as a result of the course
- Be able to give feed back to their respective organisations on possible gaps in the company's QMS system

### ***CASE STUDY***

- A interactive case study will be used as part of the course to assist participants in learning

### ***COURSE MATERIAL***

- Course manual and appropriate material will be provided for all participants

### ***WHO SHOULD ATTEND***

- Supervisors
- Team Leaders
- Internal auditors
- Operators who are involving in Quality activities