Program

Day 1

07:45 Registration.

08:00 Session 1.1 Welcome & Introductions
   Aims & Objectives of the Course

08:30 Session 1.2 Development of Directives & Quality Management Systems
   - Directives
   - Consumer Protection
   - Medical Device Directives
   - Regulatory Systems
   - Quality Systems & Global Harmonisation
   - Medical Device Directive Overview

09:45 Session 1.3 Role of Product and System Standards (Hierarchy of ‘Horizontal’ & ‘Vertical’ Standards)
   Harmonisation of Standards

10:15 Session 1.4 Duality System R 1 Requirements
   - ISO 9001/2, EN 46001/2, ISO 13485/8
   - FDAcGMP (QSR)
   - ISO 9000-2; EN 50103; EN 724, EN 928;
   - ISO14969 (draft); EN1441,

11:30 Session 1.5 Workshop 1; Assessments in the Context of the Directives:
   “What about Class 1 devices?”
   (Team Exercise)

12:00 Session 1.6 Workshop 1: Report back

12:15 Session 1.7 Risk Analysis.

2:00 Session 1.8 Case Study: Workshop 2, Risk Analysis

3:00 Session 1.9 Case Study: Workshop 2: Report back.

3:30 Session 1.10 Practical Applications, 1
   - Regulatory Structures
   - Competent Authorities 1 Notified Bodies

4:00 CLOSE
Day 2

8:00  Session 2.1  Practical Applications 2

  - Classification
  - Conformity Assessment Routes

9:00  Session 2.2  Practical Applications 3

  - Design Control for Existing Products
  - "Private" Labeling

9:45  Session 2.3  Case Study: Workshop 3

  - "Technical Documentation” and Essential Requirements (Team Exercise)

11:00 Session 2.4  Case Study: Workshop 3: Report Back

12:30 Session 2.5  Tech. Documentation, Design Dossier

  Declaration of Conformity

1:00  Session 2.6  Essential Requirements & Administrative Issues

1:30 Session 2.7  Clinical Evaluation/investigation

  - EN540, & Annex X
  - Post Market Surveillance and Vigilance

2:15  Session 2.8  Labelling and 'Instructions for Use'

3:15 Session 2.9  Compliance with the Directive and National Requirements

4:00  CLOSE
Day 3

8:00  Session 3.1  New Provisions of MDD in Article 21 of IVDD (98/79/EEC)

8:30  Session 3.2  Process Validation - Sterilization as an Example

9:45  Session 3.3  Workshop 5: Course Review/Delegate Issues

10:15 Session 3.4  Examination (optional)

1:00  END OF COURSE

(At the delegates' request Day 3 can be started at 7:30 am and the programme advanced by a 1/2 hour to enable an earlier finish)

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