Attachment 2
MEDDEV 2.10-2 Rev 1
April 2001

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

9:45 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; IS014969 (draft); EN1441,

11:30 Session 1.5 **Workshop 1; Assessments in the Context of the Directives**;
"Whatabout 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: Workthoo, 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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