DSc 2005 Congress

1st April 2005

MDD and ISO13485:2003 Compliance
- An Integrated Approach

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Standards

- ISO9001:2000
  - Quality Management
    - Customer satisfaction
    - Process driven
    - Continual Improvement
    - Limited procedure requirements (six)
    - Now 8 sections vs. 20 clauses

- ISO13485:2003
  - Medical devices
    - ISO9001:2000 structure with significant differences
    - Stand alone
    - Additional requirements for medical devices

- ISO14971:2001
  - Risk Management
SSD Standards

ISO14971: 2001

MDD: 93/42/EEC

ISO9001: 2000

ISO13485: 2003
Performance Building Blocks

- Strategy
- Objectives
- Indicators
- People
- Processes
- Reference Criteria - ISO9001, ISO13485, Business Excellence, etc

Communication
Case Study
BMI Sterile Services (Glasgow)

Demonstration
**Design Principles**
- ISO specific
- Easy to use technology
- Time efficient
- Visible
- Management control
- Scalable and flexible
- Flexible data import

**Business fit**
- Tailored & bespoke
- Supported
- Not complex or costly
- Business case proven

**Benefits**
- One stop shop
- Eases assessment
- Flexibility
- Integration
- Brings ISO & processes to life
- Reduced maintenance

**Deliverables**
Multiple Applications

- ISO9001:2000
- Medical Devices
- Environmental
- Health & Safety
- Business Excellence Model (EFQM)
- Balanced Scorecard
- All of the above!!!
- Etc, etc
UKAS Requirements
(of 23/05/2002)

- QMS to be fully integrated into normal business operations
- Emphasis on measurement, analysis and results not compliance with procedures
- Top Management must demonstrate that the QMS works for them and how they meet customer requirements & expectations on a continuing basis
- External auditors to establish that QMS is actually effective and that all processes and interfaces have been assessed
- External audit records gained from a transition implementation over a period of time should collectively contain the same information as if it were a new assessment