



Medical Devices Clinical Study Day

Thursday 15th January 2009

Roger Feneley Seminar Room, Bristol Urological Institute, Southmead Hospital,
Bristol, BS10 5NB

The **Aim** of the Course is to lead delegates through the regulatory and clinical aspects of conducting device studies with particular emphasis on the difference between device and drug studies

Who will benefit?

Anyone involved or interested in the development, evaluation and adoption of medical devices; including clinical research professionals, NHS R&D staff, NHS Innovations hubs, university researchers, medical device company representatives and product development staff.

Key areas that will be covered include:

- How devices are classified
- The process involved for CE marking
- The new model clinical trial agreement for device trials and guidance on its use
- Identify how device development differs to drug development
- The Role of the Competent Authority and the Notified Body
- The international standard for conducting device studies
- Randomisation and statistics
- Adverse Events and Device Vigilance, Monitoring
- Obtaining approvals (CA and REC)

Tuition will be provided by the Institute of Clinical Research, who through a blend of trainer input, group exercise and practical workshops will guide delegates through the fascinating world of medical devices.

Additional Benefits

All delegates will receive a comprehensive workbook and the course is accredited for Continuing Professional Development (ICR)

Date: Thursday January 15th 2009

Venue: Roger Feneley Seminar Room, Bristol Urological Institute, Southmead Hospital, Bristol, BS10 5NB

Timings: 9.00am to 5.00 pm. Lunch and refreshments throughout the day will be provided

Cost: No fee applicable to all NBT-based Staff.
£150 per person for NHS organisations
£200 for non-NHS organisations
Please note: Places are limited to 25

For further information please e-mail andrea.moore@nbt.nhs.uk or phone 0117 959 5188

Booking forms can be downloaded via the website

<http://www.biomedhtc.org.uk/MedicalDevicesRegistrationForm.doc> or by phoning Nick Urch on 0117 959 5690