



Biomedical Engineering Department Seminar

Friday, January 26, 2007

Location: Cullimore Hall, Lecture Hall 3

Time: 12:00 - 1:00 PM

Risk Management for Medical Devices.

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"Risk Management is a required critical process for developing and marketing medical devices. It is a Regulatory requirement for devices marketed in the US, Europe, Canada, Japan, and Australia. Risk Management is used to identify and manage potential safety hazards associated with devices and assures that appropriate risk controls are implemented. The relationship between hazards, harm, and risk will be discussed. The concepts of Risk Analysis and Risk Benefit Analysis as an element of Risk Management will be discussed. Other applications for the concepts of risk management, such as computer systems and business decision making will be covered.

The presentation is a general overview of the concepts with reference to specific tools available to manage risk. Specific tools for conducting risk analysis will be referenced."

Refreshments will be served.