

NCMD Opportunity Update – July 21, 2005

Medical Device Companies Speaking in Charlotte

NCMD is hosting a Medical Device Snapshot at this year's *Charlotte's Emerging Role in Biotechnology* conference at UNC Charlotte's Barnhardt Activity Center on Monday, September 26, 2005. The one-day conference will highlight the rapidly expanding biotechnology infrastructure in Charlotte, cutting-edge research projects, new & innovative statewide partnerships, and market insights.

To learn more about the conference and to register, please visit www.ott.uncc.edu/biotech. **NCMD members**, please ask about your **discounted rate** when registering for this event.

Be Part of the NCMD Industry Directory

NCMD is producing an industry directory to enhance networking and business in North Carolina. **Please help build the directory by filling out the Industry Directory Questionnaire** on the www.NCMedicalDevice.org site.

Initial production of the directory will be in electronic format that is password accessible and regularly updated. The directory is planned for release in January of 2006.

NCMD Members will receive a free listing in, and copy of the directory.

A general listing in the directory is free for all non-members that are primarily engaged in manufacturing, research, or development of medical devices and/or technologies, and that have a principal place of business or facility in NC.

NC State training opportunity for the Medical Device Industry

NC State is offering ISO 13485 training specifically for the Medical device Industry on August 23, 2005, on the NCSU Centennial Campus.

What does each standard mean?

ISO 9001 is a quality system standard applicable to many industries. ISO 13485/13488 are standards specific to medical device quality systems that supplement the ISO 9001 standard. Some of the additional requirements relate to design controls, process controls (including environmental controls), special processes, traceability, record retention, and regulatory actions, which are more critical for the medical device industry. ISO 13485/13488 are very similar to the European Standards EN 46001/46002, but do contain some additional requirements.

ISO 9001 / ISO 13485 - Who is certified to these standards?

- Companies who currently manufacture private label medical devices, but want to eventually place these devices under their name on the market in the European Union
- Consultants that design, manufacture, and assemble medical and in vitro diagnostic medical devices
- Medical component manufacturers
- Manufacturers of In Vitro Diagnostic Medical Devices that want to distinguish themselves, and prepare for future IVD regulatory obligations to enter the EU

See course description and register at www.ies.ncsu.edu/library/includes/CourseDetail.cfm?CourseID=706&CP=3

NC State Biomedical Engineering Project Participation Opportunity

Your guidance and participation is needed and welcomed in sponsoring engineering design projects and in supplying small items or parts for a reverse engineering exercise for the coming academic year for the seniors in the undergraduate Biomedical Engineering program at NC State.

To learn more about the Engineering Design Projects and Reverse Engineering Projects, please take a look at:

www.bae.ncsu.edu/topic/academic/BME/SolicitSrDesignProjects.htm

Classes begin in Mid-August, so if you are interested in participating, please provide your project descriptions as soon as possible. For additional questions or information, please contact Professor Frank Abrams at frank_abrams@ncsu.edu.