

NCMD Update – June 2005

Medical Device Forum Recap

On May 16th, NCMD hosted three FDA speakers along with one local regulatory affairs director at the North Carolina Biotechnology Center. The forum was attended by well over 150 participants and received very favorable reviews in our follow-up survey. For those of you who missed the presentations, or for those participants who want a refresher, the speaker presentations are available at the www.NCMedicalDevice.org site.

The panel, which was lead by Closure Medical CEO Dan Pelak, began with an overview of the FDA's Office of Combination Products by its Associate Director, Patricia Love. Additional speakers included Heather Rosecrans, Director of the 510(k) staff; Les Weinstein, the FDA's CDRH Ombudsman; and Tammy Carrea, Director of Regulatory Affairs at Sidel Technologies.

NCMD thanks all who participated in the event resulting in such a good turnout. On that note, Heather Rosecrans remarked that she has, "spoken to other such organizations and often only have 50-75 people in attendance." This comment really says a great deal about how vibrant our medical device community is in North Carolina.

All three speakers gave an open invitation to invite the FDA to come again. Please let NCMD know if you are interested in an in-depth follow up on any of the topics covered on May 16th, or to provide any topic ideas, send a note to Events@NCMedicalDevice.org.

Be Part of the NCMD MedTech 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 MedTech 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. Hardcopy editions are planned for release once yearly. The first electronic copy is planned for release in January of 2006.

NCMD Members will receive a free listing in the directory and will receive free copies of both the electronic and hardcopy editions, all as a benefit of membership.

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

NCMD is North Carolina's Link to AdvaMed

In addition to partnering with the North Carolina Biosciences Organization (NCBIO) to address the public policy needs of our members, NCMD's relationship with the Advanced Medical Technology Association (AdvaMed) is strategically positioned to benefit North Carolina. NCBIO and NCMD are working together to act as a conduit between AdvaMed and our local congress.

This month NCMD will be present at AdvaMed's Emerging Growth Company Conference at Medtronic World Headquarters in Minneapolis. Topics at the conference will include:

- Important Changes with Clinical Trials and Post-Market Surveillance
- Perspectives from an FDA Biomedical Engineer/Compliance Officer
- Working effectively within the Code of Ethics
- Keys to early reimbursement planning
- Convergence in the medical technology industry
- Securing NIH/SBIR grants

Look for a report on this event in the next *NCMD Update*. To learn more about AdvaMed, go to www.AdvaMed.org.

Join the NCMD Events Planning Committee

NCMD Members are invited to join the Events Planning Committee, which will start meeting this summer. If you are a member, or are planning on joining, please let NCMD know about your interest in being on the committee.