

NEWS RELEASE

FDA Speakers to Discuss Medical Device and Combination Product Regulatory Submission Best Practices

N.C. Medical Device Organization Hosts May 16th Forum at the N.C. Biotechnology Center

RESEARCH TRIANGLE PARK, N.C. (April 21, 2005) – The North Carolina Medical Device Organization (NCMD) is hosting three U.S. Food and Drug Administration (FDA) speakers who will discuss issues such as submission best practices, new guidance, and dispute resolution. The forum, “FDA Regulatory Update,” will be held May 16 from 4:30 p.m. to 8:00 p.m. at the North Carolina Biotechnology Center. The panel will also include a regulatory submission perspective from a local medical device firm.

NCMD Executive Director Andrew DiMeo said the May Medical Device Forum will serve as a great refresher for experienced professionals as well as an introduction for those who are new to medical device and combination product regulatory issues.

“North Carolina and the Research Triangle community are generally familiar with the issues and challenges associated with biologic and drug submissions. This event will give our community a good opportunity to focus on the unique regulatory requirements of the medical device industry, as well as the intersection of all three sectors in the combination product segment,” said DiMeo. “NCMD’s forum promises to be a great opportunity for members of the medical device and diagnostic sector to interact in a social setting. We are looking for active audience participation during the panel discussion along with a strategic networking opportunity.”

Panelists at the NCMD Medical Device Forum include the following:

- **Patricia Love**, Associate Director, FDA, Office of Combination Products
- **Heather Rosecrans**, Director of 510(k) Staff, FDA, Center for Devices and Radiological Health
- **Les Weinstein**, CDRH Ombudsman, FDA, Center for Devices and Radiological Health
- **Tammy Carrea**, Director, Regulatory Affairs, Sichel Technologies
- **Dan Pelak** (moderator), President and CEO, Closure Medical

Pre-registration for the May Medical Device Forum is open until Thursday, May 12, at 5:00 p.m. On-site registration will be available at the North Carolina Biotechnology Center. For general registration details, visit the NCMD events page (www.NCMedicalDevice.org/events.html).

About NCMD

NCMD is a nonprofit cluster organization with a mission to make North Carolina’s medical device and diagnostic industry a research, development, and production world leader. NCMD serves a broad sector of the industry, including research, development, and manufacturing firms, suppliers, service companies, hospitals, clinics, and educational institutions. NCMD is primarily focused on the medical device industry, including combination products, diagnostics, and medical information systems.

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