

MichBio Joins in Announcing Formation of Medical Device Innovation Consortium

The Associated Press

ANN ARBOR, Mich.--(BUSINESS WIRE)--Dec 4, 2012--MichBio, the biosciences industry association in Michigan, joined U.S. Food & Drug Administration (FDA) Commissioner Dr. Margaret Hamburg, FDA Center for Medical Device & Radiologic Health (CDRH) Director Dr. Jeff Shuren, LifeScience Alley CEO Dale Wahlstrom, key elected and government officials, medical device industry representatives, and other VIPs, in Washington, DC, to announce the formation of the Medical Device Innovation Consortium (MDIC). Dr. Stephen Rapundalo, President and CEO of MichBio, was present for the announcement in his capacity both as Chair of the State Medical Technology Alliance (a network of regional medical device groups working under the auspices of AdvaMed, the national medical technology trade association) and a partner to the new MDIC initiative.

The Consortium is a national public-private partnership with the FDA's CDRH and will be administered through a new non-profit organization. Its overarching mission is to bring leaders of industry, academia and government agencies together to advance medical device regulatory science technologies in a collaborative manner. LifeScience Alley (MichBio's sister organization in Minnesota) provided the leadership and support to the initial development phase of the MDIC that is now transitioning to an independent organization.

"The establishment of the Medical Device Innovation Consortium is sure to be a valuable approach towards advancing medical device regulatory science," said Dr. Rapundalo. "I applaud LifeScience Alley and the FDA for spearheading this initiative. MichBio is excited to partner with them and other medical device industry stakeholders to achieve the MDIC's mission. I encourage Michigan's medical device companies large and small, as well as others across the U.S., to get involved with the MDIC and contribute to solving pre-competitive technical issues on behalf of nation's medtech industry." Dr. Maura Donovan will serve as interim executive director of the MDIC. Most recently, Dr. Donovan served as vice president of therapy research and development at Medtronic, Inc. As interim executive director, Dr. Donovan will be leading efforts to recruit the inaugural Board of Directors made up of national industry executives and government leaders, build the organization's membership and initiate the first subcommittee teams to identify and lead specific projects.

The Medical Device Innovation Consortium will function in the pre-competitive medical device research space and focus on developing scientific and engineering tools/methods to assist stakeholders in assessing the safety and effectiveness of new medical device products. Medtech companies of all sizes and business stages can become members of the Consortium. MDIC members will help develop technology priorities, as well as regulatory methods and tools that can be adopted

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by the medical device community and FDA. In addition, the MDIC will provide a forum for medical device stakeholders to securely share proprietary pre-competitive data. Such public-private collaborative efforts will serve to validate and make regulatory standards more transparent, enhance the quality and performance of medical devices, and make products more accessible to patients.

Those interested in learning more about the Medical Device Innovation Consortium are encouraged to visit www.deviceconsortium.org.

About MichBio MichBio, is the non-profit, statewide biosciences industry association in Michigan. The Association's mission is to drive bioscience business growth through education and informative communications, influencing state and federal public policy, supporting technology innovation and entrepreneurship with resources and programming, and enabling bio-industry networks. Members of MichBio include bioscience companies across multiple sectors (ag/food, industrial/bio-based, medical technology, pharmaceuticals, bio-tools and diagnostics, and health IT), academic and clinical research institutions, bioscience service providers and related organizations. MichBio partners with many national, regional and state organizations, as it serves to strengthen Michigan's economy by assisting in the growth of established and emerging companies, and in the recruitment and retention of new enterprises, talent and capital. www.michbio.org.

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