MEDICAL DEVICE INNOVATION CONSORTIUM

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Medical Device Innovation Consortium (MDIC)
Chairman Bill Hawkins presents at RAPS 2013: The Regulatory Convergence

"***FDA and Industry working together on Regulatory Science***" was the title of a program session delivered by MDIC Board Chairman Bill Hawkins on Tuesday, October 1 at The Regulatory Convergence, hosted by the Regulatory Affairs Professional Society (RAPS) in Boston, MA. Moderated by Susan Alpert, Ph.D., M.D., this Medical Device and In Vitro Diagnostics session highlighted the MDIC's latest efforts as a Public-Private Partnership to speed patient access to new medical device technologies.

Regulatory Focus (RF), flagship publication of RAPS, covered the presentation and cited Hawkins as saying, "There's a real need for industry, FDA and academia to work together to find alignment and agreement on the best methods or tools to be using to evaluate risk and performance and get those understood before industry goes to FDA." (http://www.raps.org/focus-online/news/news-article-view/article/4144)

This RF article also commented on FDA's engagement with MDIC, writing:

> *FDA, for its part, has thrown its support firmly behind the MDIC from the start. When the initiative launched in the waning months of 2012, Jeff Shuren, director of CDRH, tied it to the future of healthcare product regulation in the US.*
>
> *"If the US wants to remain the leader in medical device innovation, we also must be the leader in regulatory science," (Shuren) said in a January 2012 meeting before members of the medical device industry.*

Additionally, Hawkins' presentation provided an in-depth description on the progress of one of MDIC's initial project initiatives: *Computational Modeling and Simulation.* He also highlighted the unique opportunity for industry to leverage resources through projects that share research inside the MDIC's Public-Private Partnership collaborative environment.

About the Medical Device Innovation Consortium
Founded in 2012, MDIC is the first public-private partnership created with the sole objective of advancing medical device regulatory science in an effort to improve product safety and performance while reducing cost and time to market. The MDIC functions in the pre-competitive medical device space, providing a forum for collaboration to leverage resources and share critical information. MDIC's mission is to promote public health through science and technology, to solve issues facing the industry while enhancing safe and effective product performance through the total product lifecycle of commercialized medical devices, and to enhance trust and confidence among stakeholders. Visit www.MDIC.org for more information.

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