

## *Press Release*

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FOR IMMEDIATE RELEASE  
30 October 2009

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### **US FDA Officials to Speak at RAPS Medical Device Workshop in Brussels**

**Rockville, MD, USA**—The Regulatory Affairs Professionals Society (RAPS), the leading international membership organization for regulatory professionals in the healthcare product sector, will bring together medical device industry experts and regulators from the US Food and Drug Administration (FDA) in Brussels for a workshop on US device submission and compliance. The two-day event, Medical Device Submission and Compliance Strategies for the US Market, will take place 9–10 November at the Sheraton Brussels Hotel.

The distinguished group of experts presenting at the RAPS workshop will include three FDA representatives: Stephen Rhodes, director, IDE/HDE Program, Office of Device Evaluation, Center for Devices and Radiological Health (CDRH); Heather Rosecrans, director, 510(k) staff, Office of Device Evaluation, CDRH; and Matthew Tarosky, PharmD, EJD, CCRP, deputy director, Division of Bioresearch Monitoring, Office of Compliance. Lead faculty for the workshop will be David Chadwick, regulatory scientist, Cook Inc.; and April Veoukas, director, regulatory affairs, Abbott Laboratories. Also presenting will be Roger Gray, vice president, quality and regulatory, Donawa Lifescience Consulting.

“It’s not every day that such an outstanding panel, including FDA regulators and top device industry leaders, come together in Europe to discuss strategies for the US market,” said RAPS Executive Director Sherry Keramidis, PhD, CAE. “This event is truly a unique opportunity for regulatory professionals in Europe to interact with FDA and discuss US market strategy close to home.”

This workshop will provide critical information on effective communication with FDA and explore case studies for unique insight into the perspectives of both FDA and industry. Speakers will also address needs and requirements outside the scope of FDA guidance. Emphasis will be placed on audit inspections and premarket and postmarket compliance. Participants will learn the ins and outs of device classification, explore required timeframes and learn how the device review and documentation process differs according to device classification. For more information, visit [www.RAPS.org/EUsubmission09](http://www.RAPS.org/EUsubmission09).

#### **About RAPS**

The Regulatory Affairs Professionals Society (RAPS) is an international membership organization of regulatory professionals in the rapidly growing medical device, pharmaceutical and biotechnology sectors. Regulatory professionals play vital roles in making better healthcare products possible. They work throughout the healthcare product lifecycle, ensuring these products are safe and effective, while driving organizational strategy and sound decision-making. RAPS supports these individuals and the regulatory profession by providing education and training, Regulatory Affairs Certification (RAC), professional standards, research, knowledge-sharing, publications, networking, career development opportunities and other valuable resources; and is committed to helping its members continually develop the knowledge and skills they need to excel. RAPS is headquartered near Washington, DC, with offices in Brussels and Tokyo. [RAPS.org](http://RAPS.org)

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