

Press Release

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Healthcare Product Regulatory Professionals to Convene in Boston for RAPS Annual Conference & Exhibition

Rockville, MD—Regulatory professionals from more than 25 countries will converge on Boston next week for the Regulatory Affairs Professionals Society's (RAPS) 2008 Annual Conference & Exhibition. The annual event is the largest of its kind exclusively for regulatory professionals in the healthcare product sector.

The regulatory profession encompasses a wide range of professional titles and job responsibilities related to ensuring that healthcare products in areas such as medical devices, biologics and pharmaceuticals are safe and effective and comply with all applicable government regulations. The **2008 RAPS Annual Conference & Exhibition**, the theme of which is "Leadership in Motion," will take place at Boston's **Hynes Convention Center, 14–17 September**.

"This is a very exciting time to be in the healthcare product regulatory profession as the profession continues to grow in its influence and recognition," said RAPS Executive Director Sherry Keramidias, PhD, CAE. "From research and development through clinical trials, marketing and product surveillance, regulatory professionals play important roles at every stage. With the rapid pace of new medical and healthcare technology, the changing global regulatory landscape and the increased attention to the role that regulatory concerns play throughout the healthcare product lifecycle, this year's RAPS Annual Conference & Exhibition promises to be an important one to watch for anyone concerned with developing and disseminating life-saving and life-enhancing products."

Among the topics to be examined at the conference are safety issues in clinical trials; the evolving regulatory environment in China, India, Southeast Asia and other emerging regions, and the impact on the global healthcare product market; postmarket clinical registries; drug anti-counterfeiting strategies; environmental regulations' impact on drug development; and pediatric drug development. The overarching theme of leadership will be discussed at sessions throughout the conference.

Senior officials from the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other top regulators will update attendees on the latest developments from their respective agencies. Attendees also will hear from prominent keynote speakers in medicine, media and business.

Following are some conference highlights. For more information and a complete listing of conference events, visit www.raps.org/ac2008.

Monday, 15 September
8:30–10:00 am

Keynote: Dr. Atul Gawande, practicing surgeon, writer and best-selling author

11:00 am–12:00 pm

Regulatory Hot Topics Overview: Asia

Overview of the diverse, rapidly evolving regulatory structure and processes of China, India and Southeast Asia.

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Tuesday, 16 September

8:30–10:00 am

Keynote: Dr. Joseph L. Bower, Baker Foundation Professor, Harvard Business School

11:00 am–12:00 pm

Seeking Balance: Regulation, Innovation and Cost-Containment of Orphan Biopharmaceuticals

Examination of the current regulatory landscape of orphan drugs from both US and EU perspectives.

1:30–3:00 pm

Postmarket Clinical Registries

Usage of clinical registries has increased, providing more information for postmarket surveillance and altering expectations for medical devices.

3:30–5:00 pm

Emerging Safety Issues in Clinical Trials

Recent drug recalls and media coverage of safety concerns have heightened the political climate in which regulators operate. What are the emerging safety issues in clinical trials?

Product Testing and China’s Regulatory Environment

Regulations for medical devices in China are evolving continuously. Speakers will discuss expected changes for product testing and their potential impact on the global marketplace.

Wednesday, 17 September

8:30–10:00 am

Food and Drug Administration Amendments Act of 2007: One Year Later

The Food and Drug Administration Amendments Act (FDAAA) of 2007 presented some of the biggest changes to US medical device and pharmaceutical regulation in perhaps 10 years. Speakers will review implementation accomplishments and expectations, nearly a year later, as well as discuss future challenges for *FDAAA*.

12:00–2:00 pm

Keynote: Dr. Holly Atkinson, prominent healthcare journalist

Members of the working media wishing to cover all or part of the 2008 RAPS Annual Conference & Exhibition should contact RAPS Communications Manager Zachary Brousseau at zbrousseau@raps.org or +1 301 770 2920, ext. 245. On-site registration also will be available and members of the media must bring valid press credentials or a letter from an assigning editor on company letterhead.

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. As regulatory professionals, RAPS members perform vital work in all areas of 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 as a whole by providing education and training, certification, professional standards, research, knowledge-sharing, publications, networking and career development opportunities and other valuable resources; and is committed to helping its members continually develop the knowledge and skills they need to excel. www.raps.org

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