

Press Release

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FDA Commissioner Margaret Hamburg, Bestselling Author Jim Collins To Keynote RAPS Annual Conference in Philadelphia

Conference to Examine Latest in Healthcare Product Regulation, Trends, Technology

Rockville, MD—Professionals concerned with developing and bringing safe and effective drugs, medical devices, biotechnology and other healthcare products to the worldwide market will convene in Philadelphia next month for the Regulatory Affairs Professionals Society's (RAPS) 2009 Annual Conference & Exhibition. Attendees will come from around the world for what is the largest annual event of its kind exclusively for regulatory professionals in the healthcare product sector.

New US Food and Drug Administration (FDA) Commissioner Margaret Hamburg, MD, who has gained attention since taking office for her public statements about refocusing FDA on its public health mission, will address attendees as this year's closing keynote speaker. The **2009 RAPS Annual Conference & Exhibition**, the theme of which is "Succeed in the New Regulatory Landscape," will take place at Philadelphia's **Pennsylvania Convention Center, 13–16 September**. Bestselling business author Jim Collins of *Good to Great* fame will open the conference's first official day of sessions with a keynote address on Monday, 14 September. For more information and a complete listing of conference sessions and events, visit www.raps.org/ac2009. Follow conference updates on Twitter at [@RAPSAnnualConf](https://twitter.com/RAPSAnnualConf).

"Regulatory professionals play a vital role in ensuring access to safe and effective medicines, medical devices and myriad other healthcare products by the patients and healthcare professionals who need them every day," said RAPS Executive Director Sherry Keramidias, PhD, CAE. "It may not be thoroughly understood by the typical consumer, but these dedicated professionals are involved at every stage of healthcare product development and marketing. This conference is the premier event for regulatory professionals to gather, learn, network and hear from high-profile speakers like Dr. Hamburg and Jim Collins."

In addition to the keynote speakers, the conference will feature more than 25 additional senior FDA officials presenting at various sessions and briefings, as well as representatives from Japan's Ministry of Health Labor and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), the Drugs Controller General of India (DCGI) and the Dutch Healthcare Inspectorate as well as many other healthcare and regulatory experts from around the world.

Among the topics to be examined at the conference are regulation of biosimilars; considerations for clinical trials of stem cell products; regulations governing counter-bioterrorism agents; health technology assessment and its relationship to comparative effectiveness research; global clinical trials; international regulatory considerations for drugs, devices, biotechnology and combination products; regulatory challenges in emerging markets; advertising and promotion; postmarket surveillance and more. Attendees also will receive briefings from representatives of FDA's Center for Devices and Radiological Health (CDRH) and Center for Drug Evaluation and Research (CDER), the European Medicines Agency (EMA) and Health Canada.

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Members of the working media wishing to cover all or part of the 2009 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.

Conference sponsors include: Anson Group, BSI Healthcare, Crimson/Transperfect, Elsevier Business Intelligence, GE Healthcare, Kendle, Prolifiq Software, Stericycle and Tarius.

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

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