



## *Press Release*

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### **Regulatory Affairs Professionals Society Announces Plans to Create Japanese Affiliate At its Annual Conference & Exhibition**

#### ***RAPS Also Announces New Board Members and 2005 Service Award Winners***

**Rockville, MD**—The Regulatory Affairs Professionals Society (RAPS) announced at its recent Annual Conference & Exhibition that it has begun the process of creating a RAPS affiliate in Japan. RAPS executive director Sherry Keramidas, PhD, CAE made the announcement at the conference—held in Baltimore, MD, US—with chief executive Akira Miyajima and other senior staff of Japan’s Pharmaceutical and Medical Device Agency (PMDA) in attendance. Also in attendance were senior staff members from Japan’s Ministry of Health, Labour and Welfare (MHLW).

In 2004, RAPS held several exploratory meetings to look at the need for and potential role of RAPS in advancing the regulatory profession in industry and government in Japan. Noting that industry professionals and key staff of both MHLW and PMDA have been engaged in the process of developing a Japanese RAPS affiliate, Dr. Keramidas explained that, “RAPS will serve an important role in Japan as a professional association representing the regulatory affairs profession and as a non-lobbying, neutral facilitator of discussions on regulatory directions.”

In other news from RAPS’ 2005 Annual Conference and Exhibition, RAPS announced the election of several new members of its Board of Directors and the winners of RAPS’ 2005 Service Awards.

Joining the RAPS Board of Directors for the first time in January 2006 will be (President-Elect) Bogdan Dziurzynski, DPA, RAC, a regulatory management consultant, a member of Dendreon’s Board of Directors and past Senior Vice President of Regulatory Affairs for MedImmune; (Secretary/Treasurer) Leigh Vaughan, MBA, PharmD, RAC; (Director) Donald Middlebrook, Vice President, Regulatory Affairs & Quality Assurance for Thoratec Corp.; (Director) Susan James, Vice President, Regulatory Affairs, Compliance & Quality for GlaxoSmithKline; and (Director) Zorina Pitkin, PhD, RAC, Vice President, Regulatory Affairs & Quality Systems for RenaMed Biologics.

RAPS President Bob O’Holla, Vice President, Regulatory Affairs for Johnson & Johnson Inc. will become Chair of the RAPS Board, while RAPS President-Elect Susan Alpert, PhD, MD, Vice President, Chief Quality & Regulatory Officer for Medtronic Inc. will assume the role of RAPS President. Linda Horton, JD, LLM, Partner at Hogan & Hartson LLP;

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Maria E. Donawa, MD, President of Donawa & Associates Ltd.; and Cal Bowman, JD, RAC, Vice President, Regulatory Affairs for Eisai Medical Research Inc., will continue as directors on the RAPS board.

RAPS also presented its 2005 service awards to three individuals who helped advance RAPS and the regulatory affairs profession through their professionalism, creativity and dedication.

Shoshana Friedman, RAC, Corporate Vice President of Regulatory & Medical Affairs for Given Imaging Ltd. in Yoqneam, Israel, took home the highest honor bestowed by RAPS—the Richard E. Greco Award. The Richard E. Greco Award recognizes professionals who have made superior contributions both to the regulatory affairs profession and to RAPS.

Ann Tanner, RPh, MPH, RAC—Senior Director in the Regulatory Consultants Group for Quintiles Transnational—was recognized as the winner of the 2005 Leonard Stauffer Award. This award recognizes contributions to mentoring and educational development in regulatory affairs, including special achievements related to Regulatory Affairs Certification (RAC). Meanwhile, Philipp Novales-Li, DMedSc, PhD, DPhil (Oxon), RAC, Director of Scientific and Regulatory Affairs for BioGenex Laboratories Inc., won the 2005 New Professional Award. RAPS' New Professional Award recognizes individuals early in their careers for their exceptional service to the profession and to RAPS.

#### **About RAPS®**

The Regulatory Affairs Professionals Society (RAPS) is the foremost worldwide member organization creating and upholding standards of ethics, credentialing and education for the regulatory affairs (RA) profession within the health product sector. Founded in 1976, RAPS represents nearly 10,000 individuals worldwide, working in government, corporations, academia, research and nonprofit organizations.

As the global source for Regulatory Affairs Certification (RAC), the [RA Code of Ethics](#), proprietary research and educational products, international conferences and the leading professional magazine, *Regulatory Affairs Focus*, RAPS establishes industry standards for professionalism, knowledge and achievement. Through expert education and resources, RAPS provides regulatory affairs professionals with the tools necessary to create strategic value for their organizations. The RA profession is vital to the development, approval and provision of health products, including pharmaceuticals, biologics and biotechnology, medical devices, cosmetics, veterinary products and nutritional supplements.

RAPS is a nonprofit educational/scientific organization with headquarters in Rockville, MD, and members in 45 countries in Asia, Europe, Latin America, the Middle East, North America and the Pacific Rim. RAPS is located at 11300 Rockville Pike, Suite 1000, Rockville, MD 20852; Phone: 301.770.2920; Web: [www.raps.org](http://www.raps.org)

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