

Press Release

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RAPS Honors Walker, Michor, Hoffman and Matsumoto For Outstanding Contributions to Healthcare Product Regulatory Profession

Boston—The Regulatory Affairs Professionals Society (RAPS) today honored the recipients of several prestigious awards for outstanding contributions to the healthcare product regulatory profession. RAPS' Leonard Stauffer Award for mentoring and furthering regulatory professional education was bestowed upon independent consultant Kim Walker. RAPS' Global Leadership Award for contributions to worldwide development of the profession was awarded to Salma Michor, also an independent consultant. RAPS also honored the US Food and Drug Administration's Rita Hoffman and Kenichi Matsumoto of Sakura FineTec with Special Recognition Awards for their unique contributions. Awardees were honored during a presentation on the final day of the 2008 RAPS Annual Conference & Exhibition in Boston.

“These worthy award recipients are all leaders in the growing global regulatory field,” said RAPS Executive Director Sherry Keramidas, PhD, CAE. “The healthcare product regulatory profession is rapidly evolving and constantly being redefined by its leaders. Examining the many dimensions of leadership has been the focus of this conference so it is particularly fitting this year to honor this great group for their outstanding contributions that have helped further the profession and set the standard for other dedicated professionals to aspire to.”

Each year, RAPS' awards pay tribute to outstanding regulatory professionals who have made significant contributions to the profession and to RAPS. Award winners are recognized by their colleagues for their hard work, dedication, leadership, and accomplishments. The award recipients are nominated by their peers and selected by the RAPS Awards Committee.

Leonard Stauffer Award

The Leonard Stauffer Award recognizes exceptional contributions to mentoring and furthering regulatory professional education and development including special achievements related to RAC. The 2008 winner, Kim Walker, MS, RAC, is an independent global regulatory affairs and Quality Assurance consultant. Her work experience includes environmental chemistry, veterinary science, blood banking, microbiology, IVDs, biologics, pharmaceuticals, combination products and medical devices in both start-up and large company environments. She has served on the Orange County Regulatory Affairs (OCRA) Discussion Group Program Committee and has coordinated the OCRA RAC study group for the past five years. Additionally, she has served on the OCRA board of directors for the past four years and is the 2008-09 president. Walker has earned both the US and EU RAC certifications. She holds a BS in biomedical sciences from Auburn University and an MS in regulatory affairs from San Diego State University.

Global Leadership Award

Introduced last year, the Global Leadership Award recognizes professionals who exemplify leadership and contributions toward worldwide development of the regulatory profession and RAPS.

This year's recipient, Salma Michor, PhD, RAC, is an independent consultant to the pharmaceutical and medical device sectors, specializing in regulatory affairs, regulatory compliance, Quality

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Assurance, risk management and interim management. She also acts as a European Authorised Representative. Previously, she worked for Chiesi-Torrex, Wyeth Whitehall and, most recently, Croma Pharma, where she was director of supporting operations. Michor served as an independent expert for the European Commission evaluating and reviewing industrial research projects for small and medium enterprises and the Marie Curie Fellowships program for the 6th and 7th Framework programs. She teaches regulatory affairs and clinical strategies at the University of Krems in Austria. She holds a PhD in bioengineering and an MSc in food and biotechnology from the University of Applied Life Sciences in Vienna, and an MSc from King's College, University of London, in food technology. She is EU Regulatory Affairs Certified and is a member of RAPS Board of Editors for *Regulatory Focus* magazine.

Special Recognition Awards

The Special Recognition Award recognizes unique contributions and achievements of individuals and organizations that advance the quality of health and regulatory affairs. RAPS bestowed this honor today upon Rita Hoffman, the Recall Branch chief for the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), responsible for the oversight and review for all medical device recalls submitted for health risk classification. In more than 30 years with FDA, Hoffman has worked on many aspects of agency compliance and policy in the areas of drugs, devices and veterinary products. During her tenure with FDA, Hoffman has received a number of FDA awards including the Leveraging and Collaboration Award, the Commendable Service Award and Outstanding Recognition Awards. She has been a RAPS member for 25 years and has served as co-chair of RAPS' Baltimore/Washington Metropolitan Area Chapter for the past three years, working in collaboration with both chapter members and FDA to increase professional awareness of regulatory issues. Hoffman is Regulatory Affairs Certified and holds a BS in speech pathology and audiology from the University of Maryland.

An additional Special Recognition Award has been awarded to Kenichi Matsumoto for his exceptional support of in helping to establish the RAPS Japan Affiliate and to solidly build its stature and influence, as well as his long-term and distinguished commitment to advancing the international healthcare sector. Mr. Matsumoto's career in the healthcare industry spans more than 45 years. Currently, he serves as chairman and representative director, Sakura FineTec Japan K.K.; chairman and representative director, Sakura FineTec Europe BV; and chairman and representative director, Sakura Seiki K.K. Mr. Matsumoto is also advisor of International Committee, MHLW, People's Republic of China; advisor of China-Japan Friendship Hospital, MHLW, People's Republic of China; and chairman of the Japan Healthcare Industry Executive Association. In addition, he has received a number of distinguished awards, including the Conferment of Decoration, presented by the Emperor of Japan. Mr. Matsumoto was unable to attend the awards presentation.

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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