

## *Press Release*

Contact: Eric M. McKeeby  
Communications & Public Relations Manager  
+1 301 770 2920, ext. 245; [emckeeby@raps.org](mailto:emckeeby@raps.org)

FOR IMMEDIATE RELEASE  
1 October 2007

---

### **New RAPS White Paper Details Career Development of Healthcare Products Regulatory Professionals**

**Boston**—The Regulatory Affairs Professionals Society (RAPS), the leading organization devoted to the global healthcare products regulatory profession, announced at their annual conference here last week the release of “Regulatory Affairs Professional Development Framework: An Overview,” a new white paper describing the knowledge, skills and abilities of regulatory professionals.

The white paper, introduced by RAPS’ Executive Director, Sherry Keramidas, PhD, CAE, during a Tuesday morning keynote session at RAPS 2007 Annual Conference & Exhibition, builds on several years of research conducted by occupational analysts and by experts in the regulatory field. This marks the first time descriptions of regulatory affairs career levels, including major responsibilities with associated knowledge and skills in related areas, have been consolidated in a report.

RAPS has defined and shaped the profession since RAPS’ founding in 1976. While research and analyses of the regulatory profession have always been a hallmark of RAPS, the release of the paper is a significant achievement for the organization

“This white paper represents a milestone for RAPS and for the regulatory profession,” said RAPS’ Executive Director, Sherry Keramidas, PhD, CAE. “The framework and report are important building blocks in RAPS’ efforts to research and create a comprehensive description of the regulatory affairs professional.”

As explained in the white paper, the Regulatory Affairs Professional Development Framework describes the knowledge, skills and abilities required at four different stages of professional development throughout the product lifecycle. The framework defines the profession in terms of

*-more-*

career levels. Within each career level, it describes domains or steps in the healthcare product lifecycle, responsibilities and tasks of the RA professional at each level, and associated knowledge and skills.

Keramidas said the framework offers a model for describing this body of knowledge across product lines, geographic locations and employer types.

“The framework and the white paper will be used to establish new pieces in the knowledgebase of the profession. With this report’s completion comes the reality that our research has really just begun,” Keramidas added.

RAPS conducts and publishes studies on various aspects of the global healthcare products regulatory profession, including Compensation/Scope of Practice Studies conducted in Europe and in North America.

RAPS collaborated with the RAPS Foundation, the research and special study entity of the regulatory profession, on the creation and release of the white paper.

The 19-page white paper includes charts, illustrations and a discussion on the methodology and process of developing the framework. To download the white paper at no charge, go to: [www.raps.org/pdFramework/WhitePaper](http://www.raps.org/pdFramework/WhitePaper)

For more information about RAPS 2007 Annual Conference & Exhibition, visit [www.raps.org/ac](http://www.raps.org/ac).

### **About RAPS**

The Regulatory Affairs Professionals Society (RAPS) guides and supports individuals—from industry, government, academia, research and clinical organizations—to bring life-saving and life-enhancing products to the global marketplace quickly and safely.

Founded in 1976 and operating outside the political arena, RAPS provides a neutral forum on emerging science and global regulatory challenges, offering personal and professional resources to help RA professionals continuously improve and work smarter, faster and in compliance with regulatory models.

RAPS established the regulatory profession worldwide and brings knowledge and progress to it. By identifying scope of practice, defining core competencies, upholding professional standards, developing professional certification, and providing educational and networking opportunities, RAPS supports professionals throughout the healthcare product lifecycle. [www.raps.org](http://www.raps.org)

###