The RAPS Awards Program provides an opportunity to pay tribute to colleagues in regulatory affairs who have made significant contributions to our profession and society. The program began in 1979 with the first honor going to Richard E. Greco, the founder of RAPS. The tradition continues today with awards presented each year to recipients at the RAPS Annual Conference and Exhibition. The Awards Program provides RAPS members with a process for not only demonstrating appreciation for outstanding and sustained service in the regulatory affairs field, but also recognizing professionals with exceptional promise who may be new to the profession.

The New Professional Award celebrates both past accomplishments and recognizes future potential in the field. This award, first presented in 2000, recognizes individuals early in their professional careers for exceptional service or special accomplishments in the RA profession and RAPS. Each year, the winner of the New Professional Award is viewed as a promising future leader within the RA profession.

Hutch Humphreys, BSCE, MBS, RAC, was the 2006 New Professional Award recipient for his exceptional accomplishments and aspirations after being in the profession for only a short time. As a Senior Regulatory Affairs Associate at Amylin Pharmaceuticals in San Diego, Hutch had been in the pharmaceutical industry for just under three years when he received the RAPS award. He is part of the regulatory team at Amylin, responsible for developing regulatory strategy, preparing major submissions, providing oversight for compliance with clinical trial public disclosure requirements, and expediting adverse event reporting.

Hutch has a unique academic and professional background that contributed to his early success in the regulatory field. He holds a BS in chemical engineering from the University of Kansas and an MS in bioscience degree from Keck Graduate Institute, a division of Claremont Colleges in Claremont, CA. Prior to joining the pharmaceutical industry, Hutch served for five years in the US Navy as a submarine officer on the USS Helena (SSN725) while being stationed in Pearl Harbor, HI, Portsmouth, NH, and San Diego, CA. He is an active member of his local RAPS Chapter in San Diego.

Hutch is grateful for the recognition he received as an award recipient and agreed to share some of his thoughts regarding his involvement in the regulatory affairs profession and his receipt of the New Professional Award.

RAPS: Why did you decide to join the regulatory profession?
Hutch: Near graduation from KGI, I was looking at a few different functional areas within the pharmaceutical industry. I knew from my submarine experience that I was more of a generalist than a specifics/detail person and I wanted to be involved with as many different areas of the drug development pipeline as possible. Through reading and talking to some people in the industry, I determined that regulatory affairs was the area that would allow me to foster my generalist bent and directly interact with almost every department in the company. The two-year program at KGI provided a 70% focus on science and a 30% focus on business. This ratio is very important for RA professionals entering the field today. They need to understand that as they progress through the profession they will deal more and more with the business aspects of product development and regulatory affairs.

RAPS: What interested you most about regulatory affairs?
Hutch: There are a number of things that piqued my interest. Differences between the US and EU approaches to regulation and requirements set forth by the respective regulatory agencies (e.g., placebo vs. comparator controlled trials), exposure to the drug industry and regulation in many different countries, FDA efforts to modernize drug development through the Critical Path Initiative, public policy aspects of regulatory affairs (e.g.,
clinical trial registries and results disclosure), and the politics involved in what is supposed to be essentially a science-driven endeavor. Another interesting aspect is the overall strategy of interaction with FDA: trying to anticipate the data and context FDA will need to make an appropriate decision on your product’s approvability (looking several years ahead).

In 2007, RAPS is introducing a new Global Leadership Award. This award showcases the critical role of regulatory affairs in worldwide product development and regulation.

**Professional Award?
Hutch:** I first read about it in one of the RAPS weekly updates. At first glance, I really didn’t think too much about it, but later learned that the awards are for any RAPS members, early to the profession or seasoned. Fortunately, my supervisors also saw the advertisements and were proactive about nominating me for the award.

**RAPS: How have your background and training contributed to your success in regulatory affairs?**

**Hutch:** It is interesting how my military experience relates to the regulatory field. I worked as the Quality Assurance Officer on the sub, having the responsibility of making sure that all maintenance performed on the sub complied with regulatory requirements. I gained valuable experience in interpreting regulations from a government agency (Department of Defense) and learning how to apply the regulations to achieve compliance, even when circumstances were not ideal. Learning FDA regulations is not much different. Also, my Keck Graduate Institute training provided both a broad overview of cutting-edge science and principles of pharmaceutical business models, allowing me to hit the ground running in regulatory affairs. It was also coincidental that my studies prepared me well for initial interviews with Amylin, because the company’s science and business model happened to be one we studied extensively in class.

**RAPS: Did you have a mentor or work associate who helped guide your first three years in regulatory affairs?**

**Hutch:** Yes. Although Amylin doesn’t have a formal mentoring process, I had great mentors in my boss and other senior people in the department. Over my first three years, I was exposed to many different aspects of a development project. I was given many opportunities for growth. I was well-trusted, but never put in a “sink or swim” scenario on my own.

**RAPS: How did you first hear about the New Professional Award?**

**Hutch:** I first read about it in one of the RAPS weekly updates. At first glance, I really didn’t think too much about it, but later learned that the awards are for any RAPS members, early to the profession or seasoned. Fortunately, my supervisors also saw the advertisements and were proactive about nominating me for the award.

**RAPS: What did it mean to you to win the New Professional Award?**

**Hutch:** First, it was a great affirmation that I made a reasonable career move. It truly is a tribute to the mentoring I have received at Amylin and the broad education received at KGI, and a positive sign that those programs that provide exposure to both the scientific and business aspects are extremely useful to RA professionals. The exposure also gave me a few unexpected benefits. For one, I was able to re-establish a connection with a former submarine colleague who is now in the regulatory profession. I also heard from other former Navy people who have since transitioned into regulatory affairs.

**RAPS: What is next for you?**

**Hutch:** At this point in my career, I have been exposed to many of the pieces of a drug development puzzle; now I need to manage a whole puzzle from beginning to end (IND to NDA). I’d also like to work on developing my personnel management skills.

**RAPS: What advice would you give aspiring new RA professionals looking to make a difference in the field?**

**Hutch:** Your first step should be to determine a few things about yourself. Are you a generalist or a specifics/details person? Would you rather be in a large or small company environment? Are you comfortable managing ambiguity and shades of gray, because that is much of what regulatory is. Next, I would advise working to develop a reputation as willing to take on challenges. Volunteer for any professional opportunity that arises, especially those that others are reluctant to take on. Get
involved in the regulatory community outside your company, at your local RAPS chapter or a local college that is offering regulatory courses; get involved as a student or a teacher, especially if you have experience from another function within the company prior to moving to regulatory.

**RAPS: How might the award benefit new regulatory professionals?**

**Hutch:** It can certainly help to open some doors and make connections as I described above, and can provide a great deal of credibility for new, aspiring professionals in the field.

In 2007, RAPS is introducing a new Global Leadership Award. This award showcases the critical role of regulatory affairs in worldwide product development and regulation. The new award will recognize professionals who exemplify leadership and contributions to regulatory affairs on a global scale.

Recognition of outstanding colleagues is an important responsibility of RAPS members. Please take a moment to review the description of awards and consider nominating a colleague who has made a difference in regulatory affairs. Your recognition and support will mean a great deal to them, and to our profession.

The process for submitting a nomination is outlined on the RAPS website at www.raps.org/awards. For more information or questions, please contact Alison Crawford at 301.770.2920, ext. 282, or at awards@raps.org.