



# RAPS YEAR IN REVIEW

## Together, We Accomplished a lot in 2016

2016 was a year of transition and reflection for RAPS, and also one of tremendous accomplishment. Together with you—our members, volunteers, partners and stakeholders—we achieved quite a bit. Let's review some of the year's milestones.

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## Transition in Leadership, Continuity of Purpose

When Sherry Keramidas stepped down as executive director in early 2016, it left RAPS searching for a new chief executive for the first time in nearly 20 years. Keramidas had served RAPS and its members during a critical period of change in healthcare, and her extensive work on behalf of the profession helped broaden the scope of the field and elevate the profile of regulatory professionals everywhere.

It was vitally important for the future of both RAPS and the profession to choose the right successor. After a thorough search, the board of directors unanimously selected Paul Brooks, a former RAPS board chairman and experienced regulatory professional as well as a long-time member, volunteer, leader and supporter of RAPS.

### Message From Executive Director Paul Brooks



These first few months as RAPS executive director have been very exciting for me. I am honored to be leading this great organization. I have been energized by my many conversations with RAPS members, volunteers, stakeholders and staff. This truly is an exciting time for regulatory. The profession has matured, but is still rapidly growing and developing. Looking back on RAPS' 40 years, it is astounding to see how far we have come, and looking ahead to the next 40 years and beyond, I believe we have great potential.

Having been a member of RAPS myself for more than 20 years, I have long valued the access to knowledge, networking, news and information, friendships and opportunities RAPS offers to keep us all informed and effective our daily work.

But there is more to RAPS than simply resources and networking. RAPS is the platform to promote and support our profession, ensuring we have a seat at the table and a voice in the important conversations. It is the community where those concerned with supporting and enhancing best regulatory practice come together to share, learn and grow, and it is our collective commitment to the pursuit of regulatory excellence at all levels.

We have only just begun to make our impact as a profession. I look forward to our work together, continuing to elevate and support the regulatory profession for years to come.

Paul Brooks  
RAPS Executive Director

## Celebrating 40 Years

In 2016, RAPS marked its 40<sup>th</sup> anniversary, and throughout the year we took the opportunity to reflect on four decades of leading and supporting our critically important profession. RAPS helped define the regulatory profession as a distinct discipline. When the organization was founded in 1976, regulatory was seen as more of a set of tasks than a respected profession. RAPS changed that.

Today, regulatory professionals are critical partners in helping to guide new life-saving and life-sustaining products to market for the benefit of millions of patients, and they help ensure those products are safe and effective. Regulatory expertise is recognized as an area of major strategic importance and a business-critical asset. And RAPS' mission—to *develop and sustain a competent global regulatory workforce that drives good regulatory practice and policy to advance public health*—is more important today than ever.



## Scope of Practice Survey: A Snapshot of the Profession

Every two years, RAPS conducts the most comprehensive study of regulatory professionals around the world, the Scope of Practice & Compensation Survey of the Regulatory Profession. The 2016 survey was fielded in March and April, and garnered more than 3,300 responses from respondents in 56 different countries. From these responses, we compiled a detailed snapshot of the regulatory profession.

**>88%**

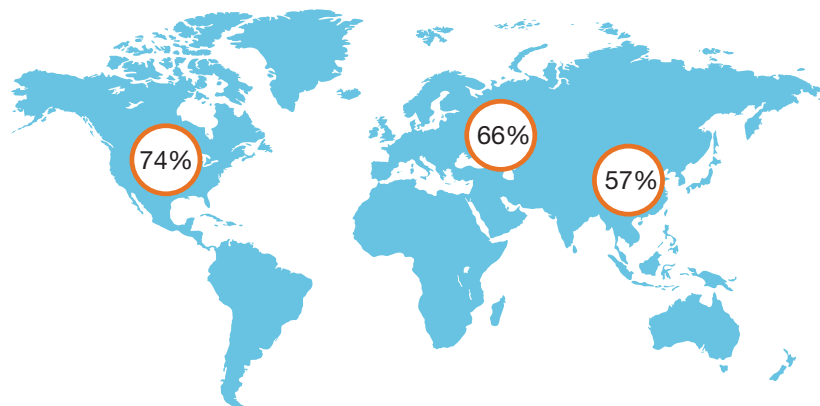
of regulatory professionals  
began their careers  
working in another field.

**↑15.9%**

Respondents reported an  
average base salary increase  
of 5.9% from 2014 to 2015.



RAC holders on  
average earn 11%  
more than non-RAC  
colleagues.



74% of professionals in North America, 66% in Europe and 57% in Asia report multiregional or worldwide responsibilities.

More survey results and analysis can be found in the *Scope of Practice & Compensation Report*, which can be downloaded at [RAPS.org/sop](http://RAPS.org/sop).

## A Framework for Regulatory Competency



In April, we released RAPS' Regulatory Competency Framework, a one-of-a-kind tool to help individuals and organizations design training and map professional and career development plans for regulatory professionals.

It outlines a shared set of competencies for the profession, including knowledge and the necessary skills to apply it. Applicable across the globe, the Framework describes the essential elements of what is required of regulatory professionals at four major career and professional levels, and breaks the basic competencies down into clear, easy-to-understand statements, providing a foundation for individuals and organizations to customize their plans.

Information about the Framework is available at [RAPS.org/rcf](http://RAPS.org/rcf).

## Members: The Heart of RAPS' Global Community



RAPS members and volunteers remain the core of our global community of regulatory professionals. As the regulatory profession continues to grow and employers increasingly value highly competent, well-trained regulatory staff, the need for RAPS and its resources also has grown. In 2016, RAPS' total membership grew to nearly 15,000 individuals. We also added 19 new Enterprise members, our organizational membership

category that allows all of a company's regulatory staff to enjoy the benefits of RAPS membership. The total number of enterprise members now stands at 54.

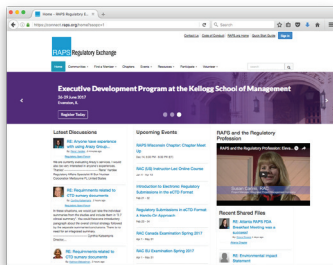
**15,000**

individuals are RAPS members

**54**

companies are Enterprise members of RAPS

## Regulatory Exchange: RAPS Members Connect Online



RegEx was named one of three Most Successful Community award winners of 2016 by Higher Logic.

RAPS' award-winning members-only online community, Regulatory Exchange or "RegEx" as it is often called, has continued to grow since its launch five years ago, and in 2016, it really hit its stride. Members engaged one another in discussion at an unprecedented rate, posting around 4,000 total messages for the year. When we asked members to name things that they thought RAPS is "doing right," RegEx was cited near the top of the list.

## Chapters and Networking: The Local Connection

RAPS currently has 16 local chapters and five Local Networking Groups. Most are in North America, but there are active chapters and groups in Europe and Asia, as well. Collectively, RAPS chapters conducted more than 50 local events and activities in 2016, involving nearly 2,300 professionals around the world.

**↑36%**

Chapter engagement increased 36% in 2016.



In February, the RAPS Taiwan Chapter was endorsed by the Asia-Pacific Economic Cooperation (APEC), a regional economic forum, as a Center of Excellence for its work promoting Good Registration Management (GRM). In November, the chapter hosted an APEC pilot GRM workshop in Taipei, with 58 industry and regulatory trainees attending from 15 countries.

## Volunteering Made Easier

In May, we launched the [Volunteer Module](#) on RegEx, making it easier for members to find RAPS volunteer opportunities that leverage their areas of expertise. There currently are more than 750 professionals in RAPS' volunteer database, and they have completed 357 volunteer tasks, and contributed 542 hours to the organization.



750 professionals in RAPS' volunteer database



357 volunteer tasks completed



542 hours contributed to the organization

## Regulatory Knowledge and Education

In June, we launched a new online [Member Knowledge Center](#), where RAPS members can access a library of free content, including e-books, recorded webcasts and session recordings from RAPS' Regulatory Convergence. Its content is reviewed quarterly and updated based on the availability of new products as well as the results of user ratings and feedback.



9,000 e-learning enrollments in 2016

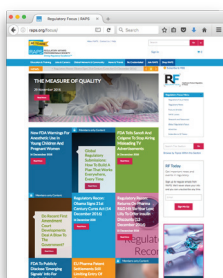
Enrollments in RAPS' [e-learning](#) opportunities, including RAPS Online University and webcasts, climbed to nearly 9,000 in 2016. This was an increase of 18% over the previous year.

RAPS' partnership with the National University of Singapore continued its blended-learning Medical Device Regulatory Affairs Graduate Certificate Program in 2016, welcoming its third intake of students and bringing total number who have participated to 75.



## Keeping You Updated in Multiple Ways

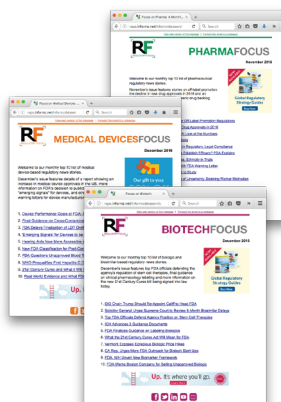
RAPS' flagship online publication, *Regulatory Focus*, has seen continued growth over the past three years, and continues to be cited by RAPS members, others in the media and experts as one of our most useful resources. *Focus* is read online by nearly 100,000 unique visitors each month and was cited as a source by other publications—including *FiercePharma*, *STAT*, *Politico* and *MedCity News*—more than 200 times in 2016.



*Regulatory Focus* is a must-read for regulatory professionals.

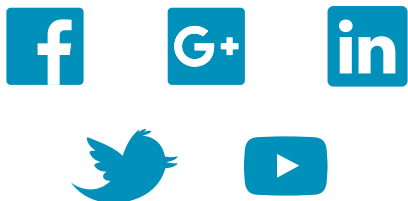


More subscribers than ever turn to the *RF Today* e-newsletter on a daily basis.



In September, *Focus* launched three new monthly newsletters dedicated to the month's top news from the worlds of pharmaceuticals, medical devices and biotech, respectively.

Sign up at the [Focus subscribe](#) page.



RAPS' Twitter, Facebook, LinkedIn and Google+ accounts collectively reach more than 30,000 followers, and are constantly updated and provide a convenient way to keep up with the latest regulatory and RAPS news.



RAPS members also stay updated on news and the latest from RAPS via two other e-newsletters, *RAPS Weekly Update* and *UnderRAPS*, a new-in-2016 monthly with expanded stories about RAPS members and volunteers, and more.

## Publications

RAPS released nine new publications in 2016. All are available online from the [RAPS Store](#).

- *Regulatory Intelligence 101, Second Edition*
- *Eclectic Science and Regulatory Compliance: Stories for the Curious*
- *US Regulatory Acronyms and Definitions*
- *EU Regulatory Acronyms and Definitions*
- *International Regulatory Acronyms and Definitions*
- *Canadian Regulatory Acronyms and Definitions*
- *Global Medical Device Regulatory Strategy*
- *Global Pharmaceutical and Biologics Regulatory Strategy*
- *Fundamentals of Japanese Regulatory Affairs, Second Edition* (in Japanese)



## The Regulatory Convergence: Where it all Comes Together

In September, RAPS' signature annual event, the Regulatory Convergence, was held in the heart of Silicon Valley—San Jose, CA. The Convergence is the largest annual conference anywhere in the world for regulatory professionals working in the healthcare product space. More than 2,000 attendees, speakers and exhibitors gathered in San Jose for 2016 Convergence.



The opening keynote presentation from leading tech analyst and author R “Ray” Wang covered disruptive technology, new business models and how regulatory can keep up.



Attendees heard a panel discussion on innovation and technology featuring top regulatory professionals from industry and FDA's associate director for digital health.



Regulators from authorities around the world participated as session speakers and panelists, including for the first time ever, the head of Cuba's National Regulatory Agency.



Closing keynote speaker, Lori Hartwell, founder of the Renal Support Network, wrapped things up sharing her perspective as a patient and passionate patient advocate.



The highlight of the Convergence is the chance to connect and reconnect with regulatory peers, colleagues and friends.

“

If someone is serious about regulatory affairs, Convergence is a great place to learn more about the new things that are happening at FDA and ministries of health around the world. It's a great place to network and to meet other people who enjoy learning the same thing as you.

– Grace Hong, senior regulatory specialist, Medtronic Inc.

“

I've been with RAPS for 20 years. I come every year to Convergence to meet friends, to learn new knowledge and to continue my RAC certification credits.

– Penny Northcutt, FRAPS, RAC, CQA, CEO, president, REGSolutions LLC, RAPS Atlanta Chapter Chair

### Six RAPS Fellows Honored

During the Convergence, RAPS honored six regulatory experts as the newest RAPS Fellows. The RAPS Fellows program recognizes senior regulatory professionals for their continued contributions and leadership toward the advancement of the profession and the professional. The 2016 RAPS Fellows are:

- Ayse Baker, FRAPS, global regulatory affairs head, GE Healthcare
- Meredith Brown-Tuttle, RAC, FRAPS, vice president, regulatory and quality, Lyric Pharmaceuticals Inc.; CEO, Regulatorium
- Nicole Landreville, RAC, FRAPS, regulatory affairs program manager, GE Healthcare
- Erin Oliver, RAC, FRAPS, global regulatory lead, Rx-to-OTC switch, GSK Consumer Healthcare
- Debra Rasmussen, RAC, FRAPS, global regulatory affairs diagnostic leader/senior director, Janssen Pharmaceutical
- Kimberly Walker, RAC, FRAPS, global RA and QA consultant, Kim Walker Consulting



### 472 Individuals Earned RAC



In 2016, 472 regulatory professionals joined the ranks of those who have earned Regulatory Affairs Certification (RAC). In February, RAPS announced the names of 256 who passed one or more RAC exams in the previous autumn, and in June, we congratulated another 219 professionals who earned the RAC in spring 2016. There are more than 4,000 RAC-credentialed professionals around the world.

## 2016 Board of Directors

RAPS' success would not be possible without the commitment and dedication of our board of directors. We thank them all for their invaluable guidance, including a special thank you to outgoing chairman, Martha A. Brumfield and outgoing director, Robert Yocher. We also wish to welcome two new members joining to board for 2017, Gert Bos and Michael Morton.

### Chairman of the Board

Martha A. Brumfield, PhD, president and chief executive officer, Critical Path Institute

### President

Todd Chermak, RPh, PhD, divisional vice president of Innovation & Development, Abbott Established Pharmaceuticals

### President-Elect

Susumu Nozawa, RAC, FRAPS, director of corporate regulatory affairs for the Japan region, BD

### Treasurer

Salma Michor, PhD, MSc, MBA, CMgr, RAC, founder and CEO of Michor Consulting e.U

### Directors

Don Boyer, BSc, RAC, FRAPS, former director, establishment licensing, billing and invoicing unit of the Health Products and Food Branch Inspectorate, Health Canada

Paul Brooks, executive director, RAPS

Glenn N. Byrd, MBA, RAC, senior director, promotional regulatory affairs, AstraZeneca

David E. Chadwick, PhD, RAC, FRAPS, director of regulatory affairs and regulatory science for Cook Inc.

Raina Dauria, MS, RAC, vice president of regulatory affairs, Ethicon Biosurgery

Jethro Ekuta, DVM, PhD, RAC, FRAPS, is vice president and head of regulatory affairs North America, Johnson & Johnson Consumer Inc.

Laila Gurney, MSc, RAC, executive, regulatory affairs, GE Healthcare

Judith Smith, MS, MT (ASCP), vice president of in vitro diagnostics and quality within Precision for Medicine's translational and regulatory sciences practice

Edward Tabor, MD, vice president, regulatory affairs North America, Fresenius Kabi

Robert Yocher, MS, RAC, CQA, FRAPS, senior vice president, regulatory affairs and quality assurance, HeartWare Inc.

## Looking Ahead

2017

Having paused to look back on an eventful 2016, let's take a brief moment to also look ahead. We will continue to lead the profession and support the professional in numerous ways. Plans already are in motion for new products, new initiatives and continuous improvements to serve you better and more effectively. Following are just a few things to watch for in 2017:

- Executive Development Program at the Kellogg School of Management, 26–29 June, Evanston, IL
- 2017 Regulatory Convergence, 9–12 September, National Harbor, MD
- Improved RAPS.org and *Regulatory Focus* user experience
- 2017 RAC exam registration deadlines—Spring: 1 March; Autumn: 1 September
- *Fundamentals of International Regulatory Affairs, Third Edition*
- *Fundamentals of US Regulatory Affairs, 10th Edition*
- *Fundamentals of EU Regulatory Affairs, Eighth Edition*
- New RAC prep tools and courses
- Improvements to RAPS Online University
- Continued outreach to better to serve and understand the regulatory community



5635 Fishers Lane  
Suite 550  
Rockville, MD 20852  
USA

[RAPS.org](http://RAPS.org)