2018 RAPS YEAR IN REVIEW

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A MESSAGE FROM EXECUTIVE DIRECTOR PAUL BROOKS



Over the past decade, we have witnessed big changes in the global regulatory landscape, and 2018 was no exception. In the device sector, much attention has been focused on preparations for the EU's new *Medical Device Regulation* and *IVD Regulation* as their effective dates draw nearer. Unique device identification, software and cybersecurity for connected devices also were among the year's important themes. On the pharma side, innovations in adaptive clinical trial design, personalized medicine, gene editing and other biotech breakthroughs challenged

regulators and industry alike. Patient involvement and real-world evidence are gaining in importance across sectors, and the coming Brexit deadline looms large over the uncertain future of the EU and UK markets.

Against this backdrop, regulatory professionals are called upon to provide clarity even when the waters are murky. We can't wait until we have all the answers. We must provide expert input and develop sound regulatory strategies to navigate through the uncertainty. Advancing the development and delivery of better, safer healthcare products is much too important. I would argue that regulatory expertise is more critical than ever.

Looking back over the past year, I am very proud of RAPS and of our dedicated community of professionals who are so incredibly supportive of one another in pursuit of regulatory excellence. I witness this community spirit all the time in helpful online discussions, informal hallway conversations at RAPS events, enthusiastic volunteers at all levels, and the overall emphasis on sharing expertise, ideas and the wisdom of experience.

I believe strongly that this community spirit is a major factor in RAPS' continued success. Membership has grown to more than 20,000. Volunteerism and engagement are up. More people are reading and consuming RAPS content. It was a busy year on many fronts. We released the results of the latest Compensation & Scope of Practice Survey. We launched two new, sector-specific Regulatory Affairs Certifications. We launched a redesigned website. And we held a very successful Regulatory Convergence in Vancouver, bringing the conference to Canada for the first time.

Having been a member for a long time before becoming executive director, I know firsthand that RAPS is more than just an association, it truly is a community, one based on strong human relationships. We are focused on supporting and leading this profession forward, driven by regulatory professionals for regulatory professionals.

Thank you for being a part of our community. Whether you are a member, a volunteer, RAPS staff, a sponsor or some other stakeholder, you are a key element in our success.

I can't wait to see what we accomplish together in 2019.

Paul Brooks

Executive Director, RAPS

THE REGULATORY COMMUNITY

MEMBERSHIP CONTINUES TO GROW

RAPS is the heart of the global regulatory professional community, and the community is thriving. RAPS membership continued to grow in 2018, climbing to more than 20,000 individuals in more than 80 countries. More than 90 companies are now Enterprise members.





MEMBERS AND STAKEHOLDERS: ACTIVE AND ENGAGED

In addition to the growth in overall numbers, RAPS members are more active and engaged than ever. They are using member-exclusive resources like the Member Knowledge Center and the Regulatory Exchange—"RegEx"—online community in record numbers. More than 6,400 individual messages were posted on RegEx discussion forums. Quarterly "ask me anything" discussion threads, with subject matter experts fielding questions, proved to be among the most popular. Volunteerism remains strong with more than 2,500 individuals stepping up to serve as volunteers.



3,900+
Member Knowledge
Center Enrollments



7,000+ views of RegEx library content



6,400+ messages posted on RegEx



THE REGULATORY COMMUNITY

LOCAL MATTERS

Volunteers and participants involved with RAPS chapters and local networks are among the most active and committed members of our global community. And in 2018, they certainly were active, hosting some 60 programs, involving more than 2,700 participants. The number of local networking groups also grew, and one group launched as an official chapter-the RAPS Utah Chapter.



RAPS chapters



local networking groups



events



2,700+participants









THE SOCIAL NETWORK

Members and nonmembers alike continue to engage with RAPS on social media. In 2018, the number of people following RAPS on LinkedIn, Twitter and Facebook rose 32% to more than 53,000.









32% increase in social followers



53,000+ total followers

COMPENSATION & SCOPE OF PRACTICE SURVEY RESULTS

As we have every other year for more than two decades, in 2018, we surveyed regulatory professionals in countries around the world and released the results in RAPS' 2018 Global Compensation & Scope of Practice Report for the Regulatory Profession. The report offers a detailed look at how much regulatory professionals earn, the product areas in which they work, what their work entails, and how their roles within their organizations have evolved. Key findings include:





4.7% average base salary increase in 2017



17.6% average earnings increase for US-based RAC holders



31.6% of organizations increased regulatory staff in 2017



86% average percentage of time spent working on primary product area



82.3% help shape key strategic and/ or business decisions

THE RACE TO EU MDR COMPLIANCE



With the 2020 deadline looming for implementation of the EU's *Medical Device Regulation*, RAPS partnered with KPMG to survey 220 regulatory affairs and quality assurance professionals from a variety of medical device organizations. The resulting report, *The Race to EU MDR Compliance*, offers insight into device markers' readiness for the new regulation.

REGULATORY AFFAIRS CERTIFICATION

SECTOR-SPECIFIC RACS INTRODUCED

RAPS launched two new Regulatory Affairs Certifications (RACs) that focus exclusively on the biopharma and medical device sectors, respectively—the RAC (Drugs) and RAC (Devices)—in addition to the four previously established, regional exams: US, EU, Canada and Global.

NEW RACs















CONGRATULATIONS

479 regulatory professionals were recognized in 2018 for earning the RAC.

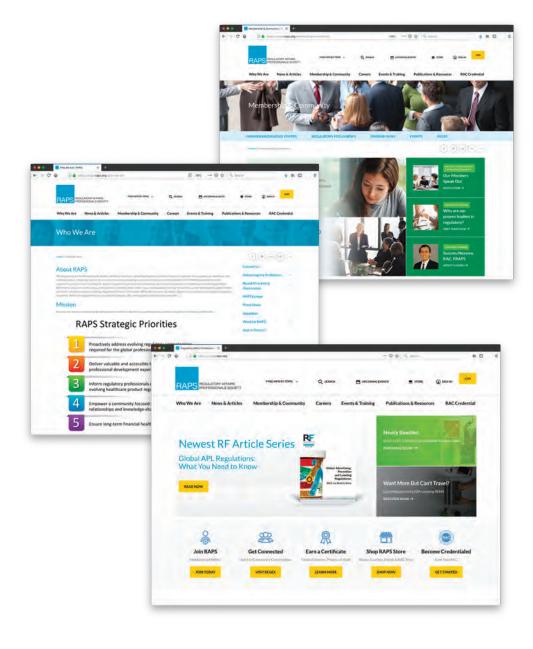


7,700+ have earned the RAC worldwide to date.

REDESIGNED **WEBSITE**, NEW FEATURES

Near the beginning of the year, we launched a redesigned website with a new look, faster page load times, updated menus and more intuitive navigation. Later, we also added more new features like the member-exclusive online Acronyms and Definitions Glossary and a salary calculator that has been updated based on data from the Compensation & Scope of Practice Survey.

Our goal is to bring you an outstanding user experience, and we will continue to make improvements and add new features and functionality.



expert speakers

100+

sessions

Attendees of RAPS' 2018 Regulatory Convergence in Vancouver were among the first to learn about important developments and the latest news on topics including the coming *EU Medical Device Regulation*, FDA's cybersecurity policies and the launch of the two sector-specific RAC credentials. The event also marked the first time RAPS' annual gathering has been held in Canada.



2,000+

participants







RECOGNIZING REGULATORY **EXCELLENCE**

We honored the recipients of the 2018 Founder's Award, RAPS' highest honor; and the Community Leadership Award; as well as the new class of RAPS Fellows.

FOUNDER'S AWARD



John Lim, MD, executive director, Center of Regulatory Excellence, Singapore



Justina Molzon, JD, former associate center director for international programs, Center for Drug Evaluation and Research, FDA



Barbara Schneeman, PhD, former director, Office of Nutrition, Labeling and Dietary Supplements, FDA



Mike Ward, coordinator, Regulatory System Strengthening Team, World Health Organization

COMMUNITY LEADERSHIP AWARD



Lena Cordie, president, Qualitas Professional Services



Alan McEmber, MS, RAC, head, therapeutic area regulatory strategy, Shire

FELLOWS



Daniel Mannix, PhD, FRAPS, vice president, regulatory affairs, MacroGenics Inc.



Sandra Matsumoto, PhD, RAC, FRAPS, vice president, regulatory affairs, Sebela Pharmaceuticals



Frank Pokrop, CPGP, CQA, CQE, CSQE, RAC, FRAPS, senior director, regulatory affairs and quality assurance, Sotera Wireless

TRACKING IMPORTANT NEWS

Regulatory Focus, RAPS' online publication, covers regulatory news and brings you articles specifically for regulatory professionals that you can't find anywhere else. It is a must-read for anyone tracking important developments in healthcare product regulation. More than 130,000 unique visitors read Focus every month, and more than 20,000 subscribe to its daily newsletter counterpart, RF Today.







RF ARTICLE SERIES

This past year, we launched a quarterly series of electronic publications for RAPS members. The RF Article Series features timely and relevant *Regulatory Focus* technical articles, case studies, interviews and research reports, with each collection of articles devoted to a specific topic. Topics in 2018 were: Q1 – *Global Reimbursement Strategy*; Q2 – *Transitioning to the New EU MDR and EU IVDR*; Q3 – *Orphan Drug Regulations: A Global Perspective*; and Q4 – *Global Advertising, Promotion and Labeling Regulations*.



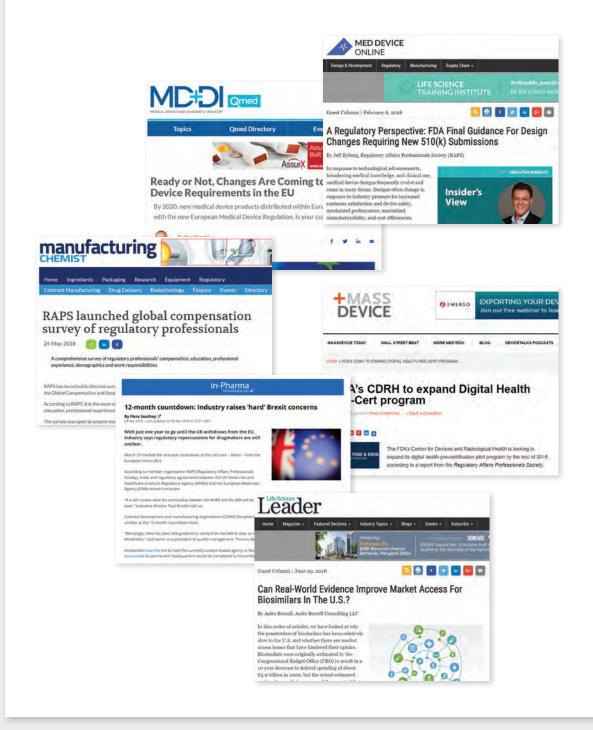


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RAPS IN THE **NEWS**

Industry publications and other media outlets rely on RAPS as an authoritative source of information on regulatory issues. In its unique position reporting regulatory news not covered elsewhere, *Regulatory Focus* is read by numerous healthcare reporters and editors, and its articles are frequently cited and linked to in other publications' articles. RAPS and *Regulatory Focus* were collectively mentioned more than 4,000 times in media coverage in 2018.





TRAINING, EDUCATION AND **RESOURCES**



IN PERSON

RAPS is dedicated to being the go-to source for the training, education and resources regulatory professionals need to acquire new skills, advance their careers and do their jobs better. In addition to the Regulatory Convergence, we hosted 15 live, face-to-face events and programs involving more than 500 participants, including four European events in Amsterdam, Brussels and Dublin.



live events



participants

ONLINE LEARNING

There were more than 15,000 enrollments in RAPS' online learning opportunities, with more than 5,000 courses completed and students earning 410 certificates.



15,000+ enrollments



5,000+ classes completed



410 certificates earned

VIRTUAL

We offered three sessions of the multiweek RAC Prep Virtual Program and 14 webcasts or virtual programs on topics such as change management, MDSAP and preparing for Advisory Committee meetings. More than 4,000 people participated.



webcasts/

virtual programs



participants

PUBLICATIONS

We published 10 books, including Fundamentals of International Regulatory Affairs, Fourth Edition; Risk Management Principles for Devices and Pharmaceuticals; and The European Medical Device Regulation, published in partnership with Meddev Solutions.



2018 BOARD OF DIRECTORS

Chairman of the Board

Susumu Nozawa, RAC, FRAPS

President

■ Don Boyer, RAC, FRAPS, president, BOYER@RegulatorySolns

President-Elect

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



to RAPS' distinguished and dedicated board of directors!

Treasurer

 Salma Michor, PhD, MSc, MBA, CMgr, RAC, founder and CEO, Michor Consulting and Trade Services

Directors

- Paul Brooks, executive director, RAPS
- Gert Bos, executive director and partner, Qserve Group
- David E. Chadwick, PhD, RAC, FRAPS, director of regulatory affairs and regulatory science, Cook Inc.
- Raina Dauria, MS, RAC, vice president of regulatory affairs, Cardiovascular and Specialty Solutions (CSS) Group, Part of the Johnson & Johnson Family of Companies
- Jethro Ekuta, DVM, PhD, RAC, FRAPS, vice president, regional head, North America, and global head, multiple franchises, Johnson & Johnson Consumer Inc.
- Laila Gurney, MSc, RAC, head of global regulatory affairs, GE Healthcare
- Michael C. Morton, principal, Michael C. Morton Regulatory Consulting LLC
- Nancy Singer, JD, LLM, RAC, FRAPS, president, Compliance Alliance LLC
- Susan Stewart, JD, RAC, FRAPS, president, Stewart Regulatory Consulting LLC
- Edward Tabor, MD, vice president, regulatory affairs North America, Fresenius Kabi

LOOKING AHEAD

MAY 5–8

Executive
Development Program
at the Kellogg School
of Management

MAY 13–14

RAPS Regulatory Conference Europe 2019 SEP 21–24

2019 Regulatory Convergence in Philadelphia MAR/ SEP

RAC exam application deadlines



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