## Contents

1. **A Message From Executive Director Paul Brooks**
2. The Regulatory Community
3. Regulatory Convergence
4. RAPS European Conference
5. Regulatory Affairs Certification
6. Recognizing Regulatory Excellence
7. Tracking Important Regulatory News
8. Education and Knowledge
9. 2019 Board of Directors
10. Looking Ahead
A Message From Executive Director Paul Brooks

Our work as regulatory professionals gets more challenging every year. Laws and regulations change, medical technology advances, regulators introduce new guidelines and the impact of new regulatory approaches can take years to fully understand. We must contend with multiple stakeholders with differing priorities and expectations. And we must make the inherently unpredictable as predictable as possible.

That’s a lot to take on. To do it well, I think, requires a strong sense of purpose. I was curious to hear directly from members about what motivates you, so we asked attendees of this year’s Regulatory Convergence, “What’s your why?”

The answers provided some insight into why you are so dedicated, and while everyone’s “why” is a little different, some common themes emerged. The profession is challenging, exciting and rewarding. You do it for the benefit of patients, to improve public health and for the sake of helping others. You love that you are constantly learning, solving problems and supporting innovation.

These are all such great reasons. I am so honored and proud to be a part of this vital professional community. I like to think of RAPS as your support group. Although you may work for different employers or in different sectors, we are all in this together. Members are always helping other members—sharing knowledge, providing guidance, building and supporting the community every day.

2019 was an outstanding year for RAPS! Thank you for being part of it.

Paul Brooks
Executive Director, RAPS
The Regulatory Community

Membership. RAPS membership around the world continues to grow.

- 24,000+ members worldwide
- 93 countries
- 3,200+ European members
- 102 Enterprise members

Volunteerism. RAPS’ dedicated members generously giving their time makes much of what we do possible. Thank you!

- 3,000+ volunteers
- 4,000+ volunteer hours

Chapters. RAPS’ growing network of local chapters and groups connects local communities of regulatory professionals.

- 2 new chapters launched this year, in Colorado and Germany
- 19 chapters
- 8 local networking groups
- 60+ events
- 2,200+ participants

Regulatory Exchange. The Regulatory Exchange online community connects members no matter where in the world they are to ask and answer questions, share best practices and develop their professional networks.

- 2,000+ discussions
- 7,000+ messages

Social Media.

- 90,000+ followers across LinkedIn, Twitter and Facebook
Regulatory Convergence

The largest annual gathering of regulatory professionals was held in Philadelphia this year and garnered record attendance.

2,100+ participants  
200+ speakers  
70 sessions  
130 exhibitors  
11 workshops
RAPS launched a successful new European conference, which will be renamed RAPS Euro Convergence beginning next year.

- **350+ participants**
- **50+ speakers**
- **30 sessions**
- **2 workshops**
Regulatory Affairs Certification

There are now two product-sector-specific Regulatory Affairs Certification (RAC) exams, RAC (Devices) and RAC (Drugs).

1,300+ applicants; most since 2014 when eligibility rules were tightened

449 recognized for earning RAC
Recognizing Regulatory Excellence

Founder’s Award

Alison Cave, PhD
Principal Scientific Administrator, European Medicines Agency

Basil Mathioudakis
Basil Mathioudakis Consulting

Robert Temple, MD
Deputy Center Director for Clinical Science, CDER, FDA

Community Leadership Award

Daniela Drago, PhD, RAC
Senior Director, US Regulatory Sciences, Biogen

João Duarte
Associate Director, Regulatory Intelligence, Global Regulatory Affairs, Alexion Pharmaceuticals

RAPS Fellows

Lisa Baumhardt, FRAPS
Senior Manager of Global Regulatory Affairs, Artificial Intelligence Strategy, Watson Health Imaging, an IBM Company

Bradley Hossack, FRAPS
Global Corporate Vice President Regulatory Affairs, Stryker Corporation

Natalie Kennel, RAC, FRAPS, ASQ, CQE, CQMgrD
Founder, NJK & Associates

Georgiann Keyport, RAC, FRAPS
Senior Partner and Co-founder, Canopy Medical LLC

New in 2019: Patient-Centered Health Award

NORD®
National Organization for Rare Disorders
Tracking Important Regulatory News

100,000+ monthly readers
Education and Knowledge

Published. Fundamentals of US Regulatory Affairs, 11th Edition

- 19 face-to-face events
- 4 virtual programs
- 19 webcasts

Online Learning

- 6,800+ enrollments
- 4,700+ classes completed
- 449 certificates earned
2019 Board of Directors

Thank you to RAPS’ board of directors for their dedication to RAPS and to the regulatory profession.

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Senior Vice President, Regulatory Affairs & Quality, Kaleido
Looking Ahead

RAPS 2020 Euro Convergence will offer expansive content designed by European regulatory affairs professionals for European regulatory professionals. It's where the regulatory community will gather:

- to discuss the most pressing regulatory topics;
- share experiences;
- and network with other stakeholders.

A wide range of current issues facing medical device, IVD and regulatory professionals will be covered, as well as general subjects that impact all professionals in the healthcare products space.

Walk away with actionable insights and strategies!

Register Now: https://raps.org/europe-2020

Regulatory Affairs Professionals Society (RAPS) is the largest global organization serving regulatory professionals and the regulatory profession worldwide.

11–13 May 2020 ★ Brussels, Belgium

RAPS Regulatory CONVERGENCE

12–15 September 2020
San Antonio, TX