RAPS 2020

Convergence

13–16 SEPT. LIVE ONLINE

PROGRAM BOOK

Why make **BSI** your Notified Body?

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of over 700; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards. **BSI Group is a global network of over:**

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Focus on service

Clients work with us because we understand the challenges medical device manufacturers face in bringing compliant products to market efficiently and safely. We offer a range of flexible product review services providing you with efficient pathways to bring your product to market.

Global market access

We are a global organization, trusted and recognized around the world. BSI has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

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Our comprehensive review process combined with our worldleading experience as a Notified Body will ensure that your conformity assessment process is both efficient and robust.

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Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations and certifications.

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MESSAGE FROM THE PRESIDENT

Greetings RAPS Community,

This year has certainly been one with unique circumstances. Yet, the passion and drive of our community are stronger than ever. Our community's determination and commitment to move the regulatory profession ahead is what the healthcare industry needs.

I am pleased that RAPS 2020 Convergence is accessible online. Now, more regulatory professionals around the globe can join virtually to expand their knowledge, grow their skills and explore the latest innovations from solutions providers. And the most important thing is that we can all do so while being safe and healthy. I know that many of you look forward to seeing colleagues, regulators and solutions partners in person each year. You can still do so and meet new people via video chats, the online community and group connections.

I am confident that the knowledge you will receive during this event will help you reinforce regulatory best practices across your organization, and that you will become a stronger leader to advance regulatory excellence at large.

I hope you enjoy the event and take away valuable resources to support your success—personally and professionally.

All the best!

Glenn N. Byrd, MBA, RAC
President, Regulatory Affairs Professionals Society (RAPS)

Convergence comes once a year, but RAPS membership lasts all year long

RAPS membership continues the conversations and expands the knowledge shared at Convergence throughout the year and beyond. Join our community of more than 24,000 dedicated and driven regulatory professionals. Get instant and exclusive access to the latest education, webcasts, publications and resources to keep you engaged and informed.

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RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

TABLE OF CONTENTS


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An equal opportunity employer (EOE Minorities/Females/Protected Veterans/ Disabled), Abbott welcomes and encourages diversity in our workforce.

NOTE: Program listings are subject to change. For the most updated agenda, please visit **https://rb.gy/u0pfdi**

Legend Online Premium Online

Biopharma (includes Biologics)

14 September 2020

10:00–11:30 am, EDT

Work-Sharing, Reliance, and Other Novel Approaches to Accelerating Review, Approvals and Access

Orphan Precedent and the Continued Evolution of the Orphan Drug Framework

Recent Developments of the US Legislative/ Policy Environment and Impact on Medical Products, Pricing and Patient Access

12:00–1:30 pm, EDT

Advanced Therapy—What Is It?

How to Be Patient-Centric In Regulatory Affairs?

2:05–3:00 pm, EDT

Rx to OTC Switch—Expanding Self-Care by Enabling Consumer Decision Making

Cannabis and Plant Derived Products as Pharmaceutical Products: Challenges and Harmonization

Thinking Big About the Future of Real-Time Review—A Catalyst Reaching Far Beyond Oncology

15 September 2020

9:35–10:30 am, EDT

Manufacturing Quality: Lessons Learned from dealing with the Nitrosamine Impurities Case and Covid-19

Are You RMAT Ready? Insights and Lessons Learned for Success

Brexit—Moving Forward and Leveraging the Experience

11:00 am–12:30 pm, EDT

Spurring Innovation and Accelerating Approval During a Crisis

Harnessing Regulatory Intelligence to Drive Change: Lessons Learned from Industry Forum and Individual Company Approach

Regulatory-Grade Evidence: Is There Global Consensus On Existing Real-World Evidence (RWE) Frameworks?

1:00–2:30 pm, EDT

Ensuring (Creating) Clinical Trial Diversity

AdPromo: Same, Similar or Superior Claims

Gene Editing—Where are we Now?

16 September 2020

10:35–11:30 am, EDT

The Regulatory Strategy of Drug Competition

Benefit-Risk from the Lens of the Patient

The Journey from Compassion to Affirmation—The Use of Expanded Access Trial Data in Drug Approvals



12:05–1:00 pm, EDT

Introduction to the Over the Counter Monograph Reform in the 2020 *CARES Act*

Introduction to Advanced Therapies: Focusing on Regulatory Considerations for the Development of CAR-T Cell Immunotherapy Products

The Secrets of Creating an Effective Regulatory Strategy and Avoiding Disastrous Mistakes

Business Acumen

14 September 2020

10:00–11:30 am, EDT

Building a Complete, Effective Communication Strategy as a Regulatory Affairs Professional

12:00–1:30 pm, EDT

The Future of the Regulatory Professional in the Digital World

2:05–3:00 pm, EDT

Technology and Innovation Case Studies in Regulatory Affairs

15 September 2020

9:35–10:30 am, EDT

Are You Ready For the Next Big Merger or Acquisition? Navigating a Successful M&A in a Dynamic Regulatory Environment

11:00 am–12:30 pm, EDT

Leadership Insights for Regulatory Professionals—Personal Brand Management

1:00–2:30 pm, EDT

Don't Let a Crisis Become a Disaster

16 September 2020

10:35–11:30 am, EDT

Regulatory Insights Throughout The Commercialization Realm and Product Lifecycle

12:05–1:00 pm, EDT

Regulatory Career Development Pathways, Risks and Rewards—Understanding Potential Obstacles and Breaking Down Barriers

Health Authority Forum

14 September 2020

10:00–11:30 am, EDT

Europe Forum

12:00–1:30 pm, EDT

ICH, ICMRA and Other Global Health Authority Collaboration—Exemplified by COVID-19 and Other Innovative Advancements From AI to AMR and Beyond

2:05–3:00 pm, EDT

Regulatory Innovation at Health Canada: Advancing Agile Regulations for Drugs and Devices

15 September 2020

9:35–10:30 am, EDT

LATAM Forum: Driving Regulatory Convergence, Optimizing Regulatory Capacities and Innovation

11:00 am–12:30 pm, EDT

CDRH Forum

1:00–2:30 pm, EDT

Oncology Center of Excellence (OCE) Forum

Medical Devices (includes IVDs)

14 September 2020

10:00–11:30 am, EDT

China NMPA (CFDA) Regulatory and Clinical Affairs Key Updates

Opening Panel on EU MDR and IVDR

The Shifting Regulatory Framework for Digital Health Software: Where We've Been and What's to Come

12:00–1:30 pm, EDT

Implementing Effective EU MDR Postmarket Surveillance (PMS) Processes to Deliver Your Periodic Safety Update Report (PSUR): Challenges and Practical Approaches

Medical Device Cybersecurity: Planning a Global Strategy

Transitioning From the Soft Transition: Technical Documentation and UDI

2:05–3:00 pm, EDT

FDA Medical Device Submissions in a Changing Regulatory Landscape, Including 510(k) and De Novo Process

How to Apply Risk to Your Total Product Lifecycle Using ISO 14971:2019

Japan Forum: Amendment of the *Pharmaceutical and Medical Device Act* and Regulatory Updates in Japan

15 September 2020

9:35–10:30 am, EDT

Do LDTs Have a Future? A Perspective from Both US and EU Post IVDR Implementation

Lessons Learned From First EU MDR/IVDR Certification

New Legislations in South Korea to Provide Patients with Earlier Access to Breakthrough Medical Technologies

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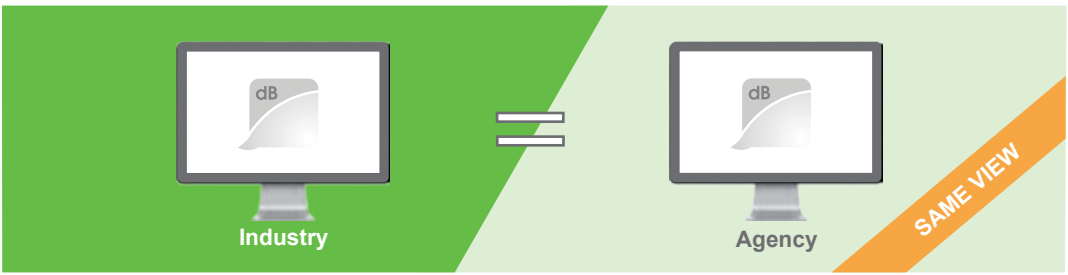

Visibility

- Identical content views as seen by multiple global regulatory agencies
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- Document lifecycle and sequence tracking

Collaboration

- Enhanced internal review through the ability to annotate and hyperlink
- Increased communication efficiency with those regulatory agencies using docuBridge
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11:00 am–12:30 pm, EDT

Economic Operators Under EU MDR

FDA Emergency Use Authorization (EUA) Program in Response to COVID-19

Global Regulatory Transformation for Medical Devices and Diagnostics: Industry, FDA and Notified Body Perspectives

1:00–2:30 pm, EDT

Impact of Patient Engagement Through the Total Product Lifecyle of Medical Devices

Leveraging Real World Data to Support Regulatory Decisions

Software as Medical Device—Has AI Learned Too Much?

16 September 2020

10:35–11:30 am, EDT

An Insight Into LATAM and Eurasian Economic Union Regional Regulatory Frameworks

Companion Diagnostics in an Evolving Global Regulatory Landscape: Alignment of Co-Development Strategies for Diagnostics and Targeted Therapies

Postmarket Surveillance Requirements of the EU MDR: Implementation Challenges and Solutions

12:05–1:00 pm, EDT

Applying Human Factors Engineering for Successful FDA Submissions

Clinical Evaluation Under the EU MDR With and Without Clinical Data

MDSAP Integration Across Medical Device Schemes Including EU MDR/IVDR

Multiple

14 September 2020

12:00–1:30 pm, EDT

Combination Product Development in the Age of the Digital Revolution

Plenaries

13 September 2020

12:00–1:30 pm, EDT

Convergence Kick-Off: Regulatory Success in Times of Disruption

15 September 2020

9:00–9:35 am, EDT

Professional Branding in a Virtual World

16 September 2020

10:00–10:35 am, EDT

Community Gathering: Getting Personal—The Impact of What We Do

AWARDS AND FELLOWS

The RAPS Awards Program celebrates individuals who have helped establish high standards for the regulatory profession and inspired the community to make extraordinary contributions to the field and to RAPS. The program recognizes leaders and change agents in the community, who support the RAPS organizational mission to develop and sustain a competent global regulatory workforce that drives good regulatory practice.

Each year, RAPS selects outstanding recipients who have gone above and beyond to provide for the greater good of regulatory affairs.

COMMUNITY LEADERSHIP AWARD

The Community Leadership Award recognizes RAPS members who have built networks and supported regulatory professionals in their communities. Awardees have acted as RAPS ambassadors; engaged in chapter or local activities, including networking and outreach, for at least three years; partnered with other organizations to further the profession; and served as thought leaders in the regulatory profession.

Kiran Gulati, MBA
Principal Medical Device Consultant, Kiran Gulati & Associates

Sylvie Verdon, MS, RAC, MPM
Senior Regulatory Consultant, Verdon Solutions, LLC

John Wilkinson, MBA
Chair of the Board of Trustees, Global Medical Devices Nomenclature Agency

David Jefferys, MD, FRAPS
Senior Vice President for Global Regulatory, Healthcare Policy and Corporate Affairs, Eisai Europe

Robert (Bob) Yocher, FRAPS
Retired

Linda Bowen, FRAPS, MSc, RAC
Head of Regulatory Policy and Intelligence, Seattle Genetics

FOUNDER'S AWARD

The Founder's Award recognizes exemplary regulatory professionals and is the profession's highest award. Honorees have shaped regulatory policy and practice; made a positive impact on the profession through education and mentoring; volunteered time to leadership pursuits such as serving on the RAPS board or Fellows program; promoted healthcare and patient well-being; advanced regulatory agility and raised awareness of the value of regulatory.

PATIENT-CENTERED HEALTH AWARD

This award recognizes groups, organizations or individuals who have made a significant impact to advance patient-centered policy, product development or regulatory decision making.

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

EPF European Patients Forum

RAPS FELLOWS

The RAPS Fellows program recognizes senior regulatory professionals for their continued significant contributions and leadership in advancing the profession. The following individuals have been accepted into the class of 2020 RAPS Fellows for their exceptional leadership and achievements in the regulatory field:

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

Mac McKeen, MBA, RAC
Fellow, Regulatory Science, Boston Scientific

Tara Creaven-Capasso, RAC, RQAP-GLP
Director and Founding Partner, Caduceus Medical Development Ltd.

VISIT US @ RAPS CENTRAL

The **Regulatory Affairs Professionals Society (RAPS)** is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products.

RAPS Central is your hub for accessing a variety of RAPS resources and services. We are your community, here to help you succeed. Visit our virtual booths throughout RAPS 2020 Convergence to meet our teams, get answers to your questions, enhance your regulatory toolbox, or simply say hello!

Regulatory Affairs Certification (RAC)

Get important insights into how the RAC credential can accelerate your career, how to apply and prepare for the exam, and how best to earn credits toward recertification.

Regulatory Focus™

Meet the editorial team consisting of editors and reporters dedicated to covering regulatory issues and delivering timely, high-quality regulatory news, information and analysis to you.

Membership

Learn about individual and enterprise membership options, volunteer opportunities and how best to maximize your benefits.

Store

Explore the latest books, courses and certification prep materials available to help advance your professional development.

Team members will be available in each booth via video chat during the following times:

- **Sunday, 13 September (1:30–2:00 pm)**
- **Monday, 14 September (11:30 am–12:00 pm and 1:30–2:05 pm)**
- **Tuesday, 15 September (10:30–11:00 am and 12:30–1:00 pm)**
- **Wednesday, 16 September (11:30 am - 12:05 pm)**

REGULATORY AFFAIRS • RAC • CERTIFICATION

Meet the authors of our latest RAPS publications.

RAPS STORE
Meet the Authors

Authors: Peter Takes, PhD, RAC, FRAPS, and Susumu Nozawa, RAC, FRAPS
Global Medical Device Regulatory Strategy, Second Edition
Monday, 14 September at 1:30–2:05 pm, EDT

Peter Takes

Susumu Nozawa

Authors: William K. Sietsema, PhD, and Monica Meacham, PhD
Global Pharmaceutical and Biologics Regulatory Strategy, Second Edition
Tuesday, 15 September 12:30–1:00 pm, EDT

William K. Sietsema

Monica Meacham

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To find out more, see RAPS.org/RAC

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REACH OUT AND REBOOT!

Just because we're virtual, that doesn't mean you can't connect and have a little fun at RAPS 2020 Convergence. Mark your calendars and join us for these engaging activities throughout the event.

Partner Connections

Explore the latest innovations and engage directly with **solutions providers** via video chat and virtual booth capabilities during exclusive networking windows:

- Sunday, 13 September (1:30–2:00 pm, EDT)
- Monday, 14 September (11:30 am–12:00 pm, EDT and 1:30–2:05 pm, EDT)
- Tuesday, 15 September (10:30–11:00 am, EDT and 12:30–1:00 pm, EDT)
- Wednesday, 16 September (11:30 am–12:05 pm, EDT)

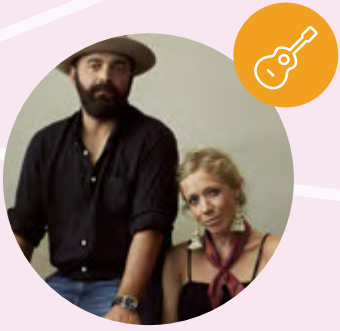
Monday Wrap-Up Experience
3:00–3:30 pm, EDT

Join us for a fun, interactive experience to reenergize yourself after an exciting day of learning. **DJ Stylus** will be spinning your favorite tunes for a great stress reliever with our virtual dance party (www.vibeconductor.com).

Photo: Les Talusan

Tuesday Wrap-Up Experience
2:30–3:00 pm, EDT

Is your brain twisted from another exciting day of learning? Let it be blown even further with some spell-bounding amazement as **Ben Corey** astounds us with some tricks of his own (www.meetingillusionist.com), sponsored by China Med Device.



Wednesday Closing Experience
1:00–1:30 pm, EDT

2020 Convergence may be wrapping up, but let's look ahead to 2021 in Nashville, TN—home of some of the greatest singer/songwriters you've ever heard. Listen to a taste of what you'll experience live next year with a special performance from **Drew and Ellie Holcomb** (www.drewholcomb.com).

Need a **boost** in your career?

Enroll in a RAPS Online University Certificate program.

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RAPS

SPONSORED PRESENTATIONS

Solutions providers keep their pulse on the regulatory community and have vital insights on the latest trends, technologies and innovations shaping our profession. Join us during RAPS 2020 Convergence for thought-provoking presentations from **BSI Group**, **KPMG LLC** and **Regulatory & Quality Solutions (R&Q)**.

Monday, 14 September
10:00–10:45 am, EDT

QMS Aspects of the IVDR

Monday, 14 September
12:00–12:45 pm, EDT

DEVICE L♥VE Live! #18: Generating Sufficient Clinical Evidence Under EU MDR

Tuesday, 15 September
9:35–10:20 am, EDT

Evolving From Compliance Enablement to Strategic Value: Driving Further Adoption of Digital Tools in Regulatory Affairs and Lessons Learned From Global RIM Implementations

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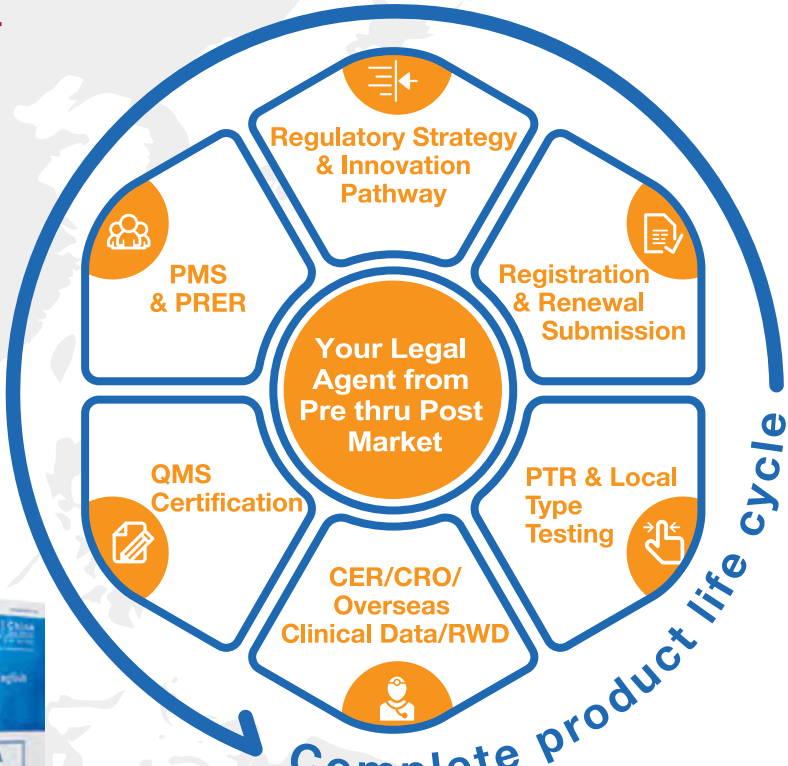

Free Gifts for RAPS Attendees from China Med Device—Visit Our Virtual Booth to Claim yours!

- Understand China medical device registration with English translation of major NMPA (CFDA) rules.
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Skype: gracefu2009

SOLUTION CIRCLES

Solutions Circles are where you and your fellow regulatory professionals gather to discuss what you've learned during Convergence and brainstorm together. These events are structured as collaborative peer-to-peer think tanks. Bounce ideas off your colleagues and examine your shared regulatory challenges.

Space is limited and is on a first-come, first-served basis. Some additional offerings may be added prior to the event.

14 September 2020

10:00–10:30 am, EDT

- How Can Modeling and Simulation be Used to Support MRI Safety Labeling of Medical Devices?
- How to Make Your Tech Work FOR not AGAINST You
- RA Strategy Considerations for the Development of a CDx for Rare Diseases

12:00–12:30 pm, EDT

- EO Sterilization FDA Initiative to Reduce EO Levels
- Writing Under Pressure: Making it Easy

2:05–2:35 pm, EDT

- How to Leverage Technology to Give Your Team a Lifeline—in the Moment and Behind the Scenes
- Top 10 GMP Issues Observed From FDA Inspections

15 September 2020

9:35–10:05 am, EDT

- CDRH Appeals and the Role of the Ombudsman in Preventing and Resolving Disputes
- Assessment of Applicable GSPR for a Pre-Filled Syringe

9:35–10:30 am, EDT

- Conversations That Matter—Interactions with Health Authorities

10:00–10:30 am, EDT

- LinkedIn Hot Seat

11:00–11:30 am, EDT

- How FDA Guidance on 3D Printer Manufacturing Can Influence Stand-Alone Software Medical Devices
- How to Break Through the Technology with Your Message
- LinkedIn Hot Seat

1:00–1:30 pm, EDT

- How Will FDA Regulate My Low Risk Device? Wellness, Mobile Apps and Decision-Support Devices
- Pediatric Medical Device Development – Update on Progression of FDA Initiatives

16 September 2020

10:35–11:05 am, EDT

- Study Design for Analytical Performance Characteristics of Point-of-Care Devices With Capillary Whole Blood Specimens; a MDIC Blueprint

10:35–11:30 am, EDT

- Conversations That Matter—Interactions with Health Authorities

12:05–12:35 pm, EDT

- How to Plan Your First Clinical Trial on Imaging-Based Artificial Intelligence Device Under NMPA Supervision
- Parallel Global Submissions: Navigating the Space between Submission and Approval

SOLUTION PROVIDERS

Explore the latest innovations and engage directly with solutions providers via video chat and virtual booth capabilities during exclusive networking windows.

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lracs.com

Med Institute
medinstitute.com

Metecon GmbH
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Mid-Link Technology
mid-link.net/english/index_en.html

NAMSA
namsa.com

Pacific Bridge Medical (PBM)
pacificbridgemedical.com

PAREXEL
parexel.com

Exhibition hours:

- **Sunday, 13 September (1:30–2:00 pm, EDT)**
- **Monday, 14 September (11:30 am–12:00 pm, EDT and 1:30–2:05 pm, EDT)**
- **Tuesday, 15 September (10:30–11:00 am and 12:30–1:00 pm, EDT)**
- **Wednesday, 16 September (11:30 am–12:05 pm, EDT)**

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Regulatory & Quality Solutions (R&Q)
RQTeam.com

Rimsys Regulatory Management Software
rimsys.io

San Diego State University, Regulatory Science Programs
regsci.sdsu.edu

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Don’t let your regulatory learning stop after Convergence! RAPS has redesigned its workshops to be offered virtually in one- and two-day sessions on a variety of regulatory topics all year long.

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"In regulatory, I believe one of our biggest leadership challenges is understanding business administration."

Diana Bordon, program alumna

The **RAPS Executive Development Program**, hosted in partnership with the Kellogg School of Management at Northwestern University, is the only leadership program that combines regulatory experts with faculty from one of the world's most prestigious business schools. Join your fellow and future regulatory leaders at Northwestern University next May.

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RAPS.org/Kellogg

THANK YOU

RAPS would like to send a big thank you to all of the members of the RAPS Convergence planning committee.

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Stephanie O. Omokaro, MD, deputy director, Division of Medical Policy Development, Office of Medical Policy Initiatives, Office of Medical Policy, CDER, FDA **FDA LIASION**

Carol Rehkopf, MS, deputy associate director for review management, CBER, FDA **FDA LIASION**

Maria Vrabie, RAC, director, regulatory and clinical affairs, Abbott Diagnostics Business **MEMBER**

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- Professional resources and training solutions?
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Then a **RAPS Enterprise Membership** is the perfect fit. Designed for businesses and companies with regulatory affairs staff or interest in regulations, an Enterprise Membership provides RAPS resources to all of their employees under one membership. Employees have access to the essential regulatory tools needed to keep business running in compliance with the latest regulatory policies. Also, RAPS offers consultation to enterprise members to help you maximize RAPS resources.

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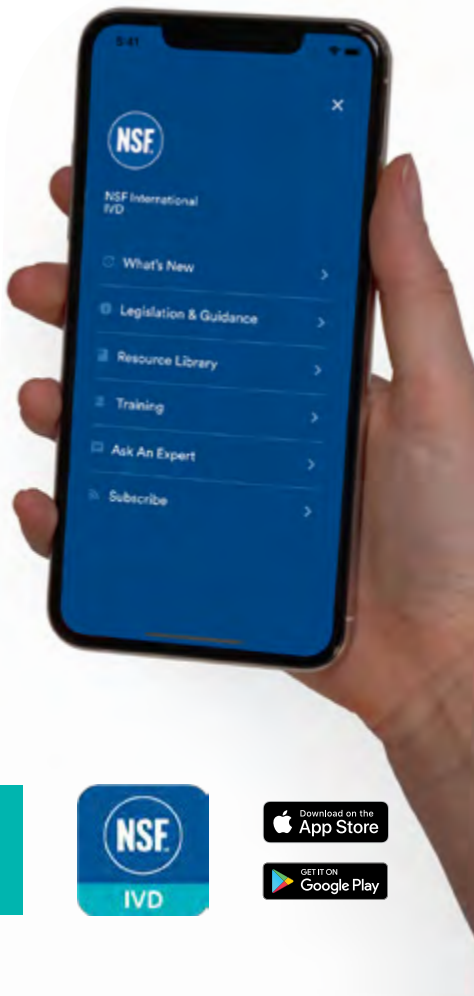

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