Next Stop: Vancouver 2018

RAPS Regulatory Convergence

1–4 October 2018
Vancouver, BC

REGISTER BEFORE RATES GO UP FOR 2018:
Sign up before 31 December to get 2017 rates on the 2018 RAPS Regulatory Convergence. Registration is open now at RAPS Central in the Exhibit Hall.

RAPS.org/2018
It is my great pleasure to welcome you to this year’s Regulatory Convergence at the beautiful Gaylord Resort at National Harbor on the DC Waterfront. This year’s Convergence features more than 70 educational offerings and over 200 expert speakers, including top regulatory officials, senior executives, innovators and thought leaders here to share knowledge, update us on the latest developments, discuss trends and examine regulatory issues in depth from multiple angles. In addition, we are honored this year to have FDA Commissioner Scott Gottlieb, MD, delivering the Monday lunch plenary.

Regulatory is your profession, and Convergence is your annual gathering. This is where you immerse yourself in all things regulatory. Here, you can learn, grow, connect and reinvigorate among peers who understand and appreciate your daily work and challenges. Not only will you attend some great sessions, you will also meet great people, expand your professional network and have some fun along the way.

As a profession, I am happy to say we are continuing to move in a positive direction. In an environment of ever-evolving regulations, rapidly developing technologies, political uncertainty and continuous change within the healthcare sector, regulatory professionals provide critical expertise that helps organizations and global authorities chart their course to regulatory excellence.

For me personally, it has been one year since I took on the executive director role at RAPS. In that time, I have learned quite a lot. As a longtime regulatory professional and RAPS member myself, I have always valued the knowledge, networking and resources RAPS provides. Now, I think I have come to value you—the members and the global regulatory community—more than ever. You are what make RAPS a great organization and you are a key element of what makes Convergence a must-attend event. I look forward to meeting and speaking with as many of you as I can this year to hear your ideas and perspectives.

Paul Brooks

Executive Director, RAPS
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## SCHEDULE AT A GLANCE

### SATURDAY, 9 SEPTEMBER
- 8:00–10:00 am: Workshop Registration
- 8:00–9:00 am: Workshop Continental Breakfast
- 9:00 am–5:00 pm: Workshops
- 10:30–11:00 am: Beverage Break in Chesapeake and National Harbor Foyer
- 12:30–1:30 pm: Lunch
- 3:00–3:30 pm: Beverage Break in Chesapeake and National Harbor Foyer

### SUNDAY, 10 SEPTEMBER
- 7:00–8:00 am: Workshop Registration and Continental Breakfast
- 7:00 am–6:00 pm: Registration Open
- 8:00 am–4:00 pm: Workshops
- 10:00–10:30 am: Beverage Break in Chesapeake and National Harbor Foyer
- 12:00–1:00 pm: Lunch
- 2:30–3:00 pm: Beverage Break in Chesapeake and National Harbor Foyer
- 4:30–6:00 pm: Opening Plenary Session, Awards and Recognition
- 6:00–7:30 pm: Grand Opening of Exhibit Hall and RAPS Central: Taste of National Harbor Reception

### MONDAY, 11 SEPTEMBER
- 7:00 am–6:00 pm: Registration Open
- 7:00–8:30 am: Continental Breakfast
- 7:30–8:15 am: Conversations That Matter (Hosted by RAPS Fellows)
- 8:30–10:00 am: Education Sessions
- 10:00 am–4:00 pm: Exhibit Hall and RAPS Central Open
- 10:00–10:45 am: Sponsored Session
- 10:45 am–12:15 pm: Education Sessions
- 12:15–1:15 pm: Grab and Go Lunch and Keynote by FDA Commissioner Gottlieb
- 1:15–2:45 pm: Education Sessions
- 2:45–3:45 pm: Beverage Break in the Exhibit Hall
- 3:00–3:45 pm: Sponsored Session
- 3:45 pm–5:30 pm: Conversations That Matter (Hosted by RAPS Fellows)
- 4:00–5:30 pm: Education Sessions
- 6:00 pm: Dine-Arounds

### TUESDAY, 12 SEPTEMBER
- 7:00 am–6:00 pm: Registration Open
- 7:00–8:00 am: Continental Breakfast
- 7:30–8:15 am: Conversations That Matter (Hosted by RAPS Fellows)
- 8:30–10:00 am: Education Sessions
- 10:00 am–4:00 pm: Exhibit Hall and RAPS Central Open
- 10:00–10:45 am: Sponsored Session
- 10:45 am–12:15 pm: Education Sessions
- 12:15–1:15 pm: Grab and Go Lunch and Open Exhibit Time
- 12:15–1:00 pm: Sponsored Session
- 1:15–2:45 pm: Education Sessions
- 2:45–3:45 pm: Beverage Break in the Exhibit Hall
- 3:00–3:45 pm: Sponsored Session
- 3:45 pm–5:30 pm: Conversations That Matter (Hosted by RAPS Fellows)
- 4:00–5:30 pm: Education Sessions
- 5:30–6:30 pm: Closing Reception—Next Stop: Vancouver 2018

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### PARTICIPATING AGENCIES

Great things happen when the regulatory world comes together and this year is no exception:

- Austrian Agency for Health and Food Safety
- China National Center for Food Safety Risk Assessment
- European Medicines Agency
- Federal Agency for Medicines and Health Products, Belgium
- Federal Commission for Protection against Sanitary Risks, Mexico
- Food Safety and Standards Authority of India
- Health Canada
- Joint FAO/WHO Expert Committee on Food Additives
- Joint Institute for Safety and Applied Nutrition
- Medicines and Healthcare products Regulatory Agency, UK
- Ministry of Health, El Salvador–Central America
- National Administration of Drugs, Food and Medical Technology, Argentina
- National Food and Drug Surveillance Institute, Colombia
- National Health Surveillance Agency, Brazil
- National Regulatory Authority, Cuba
- Pan American Health Organization
- Paul-Ehrlich-Institut, Germany
- Pharmaceuticals and Medical Devices Agency, Japan
- US Food and Drug Administration

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### TODAY

Your daily source for regulatory news and analysis on pharmaceuticals, biotechnology products, medical devices and the inside scoop on regulators around the world.

Sign up today at RAPS.org/focus
THE GAYLORD NATIONAL RESORT &

GENERAL SESSION
POTOMAC BALLROOM

POTOMAC BALLROOM & CONFERENCE ROOMS
BALLROOM LEVEL
CONVENTION CENTER FLOOR PLAN

CHESAPEAKE CONFERENCE ROOMS
BALLROOM LEVEL

NATIONAL HARBOR CONFERENCE ROOMS
NATIONAL HARBOR LEVEL

EXHIBIT HALL
LOCATED ON LOWER ATRIUM LEVEL
GENERAL INFORMATION

Bag/Coat Check

**Tuesday, 12 September | 7:00 am–7:00 pm | Potomac Foyer**

First-Time Attendees

New to the Regulatory Convergence? Be sure to visit RAPS Central located in the Exhibit Hall to meet RAPS staff members and volunteers who are ready to answer any questions and provide tips on how to make the most of your conference experience. Pick up your “First-Time Attendee” ribbon at RAPS Central so you can locate other first timers.

Name Badge

Please wear your name badge at all times. This is your ticket to all education sessions and the Exhibit Hall. The barcode on your badge will serve as your electronic business card when you network with exhibitors.

WiFi in the Convention Center

WiFi is complimentary throughout the convention center.
Network Name: RAPS2017 | Password: convergence

RAPS Central

**Sunday, 10 September | 6:00–7:30 pm**
**Monday, 11 September | 10:00 am–4:00 pm**
**Tuesday, 12 September | 10:00 am–4:00 pm**

Located in the Exhibit Hall, RAPS Central is your go-to place to get answers to all of your conference questions, up-to-the-minute news and information and to purchase the publications you've been looking for. This is your destination for RAPS membership information, and where RAPS members can get a free professional headshot at the Headshot Café. Increase your member engagement and sign up for volunteer opportunities. Stop by to get questions answered and advice from the RAPS staff on hand to help you make the most of your membership. Plus, new this year, attend a series of informative sessions at the RAPS Central Learning Lounge.

SNAP & POST

Want to update your online profile pic? RAPS members are eligible to get a free professional headshot. Stop by the Headshot Café located at RAPS Central during exhibit hall hours.

Get Plugged In

For your convenience, outlets will be provided at RAPS Central if you need to charge any of your devices.

Twitter

Show us your best 140 characters. The official Twitter hashtag for the 2017 RAPS Convergence is #2017RAPS. Be sure to tag us when tweeting about your conference experience.

Regulatory Affairs Certification (RAC) Credits

Full conference attendees who hold the RAC credential earn up to 12 RAC recertification credits for attending the conference and also may earn between six and 12 credits for attending preconference workshops. If you’re an RAC holder, stop by the RAC booth at Member Central to get a gift and information about recertifying. If you’re interested in earning the RAC, be sure to attend one of the RAC informational mini-sessions.

RAC Mini-Sessions

**Monday, 11 September | 3:00–3:45 pm | Chesapeake 4–5**
**Tuesday, 12 September | 3:00–3:45 pm | Chesapeake 4–5**

Talk with members of the Regulatory Affairs Certification Board and RAC holders about where the RAC credential can take your career. Whether you’re wondering if you’re eligible to take the exam or building a study plan, these open discussions are a great way to get your questions answered.

RAPS Events Mobile App

The RAPS Events mobile app is a great place to engage with fellow colleagues attending the Convergence. You can follow people and post updates in the activity feed, search for attendees and even private message others to schedule meetups.

GET THE APP

To download the app from the Apple App Store or Google Play Store, search RAPS Regulatory Events.

For those accessing the app from a laptop, click on http://bit.ly/2vs8vsz and select the HTML 5 version.

Log on with the email and password you used to register.

Press Room

**Sunday, 10 September | 2:00–6:00 pm | Chesapeake 12**
**Monday, 11 September | 7:30 am–6:00 pm | Chesapeake 12**
**Tuesday, 12 September | 7:30 am–6:00 pm | Chesapeake 12**

Tell Us What You Think

Our goal is to have each and every attendee leave the conference on a high note. Please be sure to provide us with feedback about your experience by completing the evaluations in the mobile app.
NETWORKING AND SPECIAL EVENTS

Grab and Go Lunch Networking

_Tuesday, 12 September_ | 12:15–1:15 pm

Enjoy lunch while connecting with regulatory professionals from around the world.
- Attend the Monday Lunch Plenary with US FDA Commissioner Scott Gottlieb
- Enjoy a lunch session during a Sponsored Session in the Exhibit Hall
- Dine in the Exhibit Hall or outside on the Exhibit Hall Patio
- Come to the 12:30–1:15 pm Learning Lounge sessions at RAPS Central in the Exhibit Hall

Grand Opening of the Exhibit Hall and Taste of National Harbor Reception

_Sunday, 10 September_ | 6:00-7:30 pm | Exhibit Hall

*Hosted by Medtronic*

Come enjoy some of National Harbor’s finest fare and local beer and wine while connecting with colleagues and company representatives in a fun, relaxed environment inside the Exhibit Hall.

Dine-Arounds

_Monday, 11 September_ | 6:00 pm

This popular dining out event is a great opportunity to spend quality time with friends and colleagues outside the convention center and enjoy some of the great restaurants at National Harbor. Sign up at registration in Potomac Foyer. Departure for the Dine-Arounds will be in the Gaylord National lobby, next to Belvedere Lobby Bar.

Restaurants:
- Brother Jimmy’s, 177 Fleet Street
- Grace’s Mandarin, 188 Waterfront Street
- Granite City, 200 American Way
- Redstone American Grill, 155 National Plaza
- Rosa Mexicano, 153 Waterfront Street
- Sauciety at The Westin, 171 Waterfront Street
- The Walrus Oyster & Ale House, 152 Waterfront Street

Closing Reception—Next Stop: Vancouver 2018

_Tuesday, 12 September_ | 5:30–6:30 pm | Potomac Foyer

Join us to celebrate a successful Convergence with a DJ, food and cocktails. Plus get started on your plans for 2018 Convergence in Vancouver, BC.

**Interested in drug regulation and pharmaceutical product lifecycles?**

This non-thesis, part-time program for professionals with Bachelor’s degrees requires 30 credits of coursework and is taught online. The program covers all major areas of drug product regulatory science, including:
- Chemistry, Manufacturing, and Controls (CMC)
- Clinical Research
- Pharmacovigilance
- Phase IV Research (e.g., Pharmacoepidemiology)
- Drug Discovery

Visit us at booth #315

For more information on the program, visit [www.pharmacy.umaryland.edu/regulatoryscience](http://www.pharmacy.umaryland.edu/regulatoryscience)
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Visit us at booth #739
OPENING PLENARY

Sunday, 10 September | 4:30–6:00 pm | Potomac Ballroom

OPENING REMARKS, AWARDS AND RECOGNITION

Paul Brooks, RAPS Executive Director and Todd Chermak, Chair, RAPS Board of Directors

DANIEL DIERMEIER: REGULATORY EXCELLENCE IN TIMES OF CHANGE AND UNCERTAINTY

Daniel Diermeier is the provost at the University of Chicago. Prior to his appointment as provost he served as the dean of the University’s Harris School of Public Policy Studies from 2014–2016. He is the David Lee Shillinglaw Distinguished Service Professor in the Harris School. He is a fellow of the American Academy of Arts and Sciences, the Guggenheim Foundation, and the Canadian Institute of Advanced Research (CIFAR).

Prior to joining the University of Chicago, Diermeier taught at the Graduate School of Business at Stanford University and the Kellogg School of Management, Northwestern University, most recently as IBM Professor of Regulation and Practice in the Department of Managerial Economics and Decision Sciences (MEDS), and director of the Ford Motor Company Center of Global Citizenship. During his time at Northwestern’s Kellogg school, he served as a distinguished faculty member for the RAPS Executive Development Program at Kellogg. He also held appointments in Economics, Political Science, Linguistics, and the School of Law at Northwestern University.

At Northwestern, he won 13 teaching awards including the 2001 Kellogg Lavengood Professor of the Year Award and the 2013 Kellogg Alumni Professor of the Year Award. He was named among the World’s 50 Best Business School Professors and was the 2007 recipient of the Faculty Pioneer Award from the Aspen Institute named the “Oscar of Business Schools” by the Financial Times. Diermeier has been an advisor to the world’s leading companies. Clients include Accenture, BP, McDonald’s, Shell, Ernst &Young, and the Federal Bureau of Investigation.

MONDAY LUNCH PLENARY

Monday, 11 September | 12:15–1:15 pm | Potomac Ballroom

FDA COMMISSIONER SCOTT GOTTLIEB, MD

US Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD, will deliver the opening keynote remarks at the 2017 Regulatory Convergence. Gottlieb has always been passionate and outspoken on public health policy, and we eagerly look forward to hearing directly from him on his vision for FDA and the overall direction of healthcare.

Gottlieb became the 23rd FDA commissioner in May. In his initial speech to agency staff, he called this “a time of great promise” for healthcare. Since taking over as head of FDA, he has identified addressing the national opioid addiction crisis, and increasing generic drug competition and speeding new generics to market as among his top priorities.

Gottlieb has an extensive resume, having worked in many prominent public health roles. He is a physician, medical policy expert and public health advocate who previously served as FDA’s deputy commissioner for medical and scientific affairs and before that, as a senior advisor to the commissioner. Prior to being sworn in as FDA commissioner, he was a resident fellow at the American Enterprise Institute and a clinical assistant professor at the New York University School of Medicine.

OUTSTANDING LEADERS. COMMITTED TO REGULATORY.

The RAPS Fellows program recognizes senior regulatory professionals, with a minimum of 15 years of regulatory experience, for their continued significant contributions and leadership in advancing the profession. The following individuals have been accepted into the class of 2017 RAPS Fellows for their exceptional leadership and achievements in the regulatory field:

2017 ACCEPTED FELLOWS

- Kaia Agarwal, MSc, FRAPS, president, Regulatory Compass, LLC
- Mark De Rosch, PhD, FRAPS, senior vice president, regulatory affairs, quality assurance, and CMC, Akebia Therapeutics
- Susan Hamann, MS, RAC, MT (ASCP), FRAPS, president, Hamann QR Consulting
- Joel Kent, RAC, FRAPS, manager, regulatory affairs, GE Healthcare
- Darin Oppenheimer, PhD, RAC, FRAPS, executive director, head, Drug Device Center of Excellence, Merck
- Joanne Palmisano, MD, FACP, FRAPS, vice president, regulatory affairs, Boehringer Ingelheim Pharmaceuticals Inc.
PRECONFERENCE WORKSHOPS

Stretch your learning potential during our one- and two-day workshops. Each is designed as an opportunity for you to take an extensive, in-depth look into specific regulatory topics, organized and led by industry experts. Pre-registration is required to attend any workshop.

SATURDAY, 9 SEPTEMBER AND SUNDAY, 10 SEPTEMBER

Regulatory Strategy Forum for Biologics

**Saturday | 9:00 am–5:00 pm | National Harbor 4**

**Sunday | 8:00 am–4:00 pm | National Harbor 4**

Knowing how to develop an effective global regulatory strategy is an essential skill for regulatory professionals. In this two-day strategic workshop, experts will take you on a guided tour through the process of developing regulatory strategy. You will work in teams and learn how to maximize commercial opportunities for healthcare product manufacturers while minimizing company risk.

**Speakers:**
- Linda Bowen, MS, RAC, FRAPS, senior director, regulatory science and policy, Sanofi
- Eric Brass, MD, PhD, professor emeritus of medicine, David Geffen School of Medicine at UCLA
- Kamali Chance, MPH, PhD, RAC, vice president and head, global biosimilars regulatory strategy, QuintilesIMS
- Vanessa D’Souza, PhD, global regulatory team leader, Pfizer
- Ning Go, MA, MD, principal scientist, clinical biomarkers and in vitro diagnostics, medical sciences, Amgen
- Monica Siegenthaler, PhD, regulatory affairs and quality assurance director, AiVita Biomedical
- William Sietsema, PhD, executive director, global regulatory affairs, Caladrius Biosciences

Regulatory Strategy Forum for Medical Devices

**Saturday | 9:00 am–5:00 pm | Chesapeake 4–5**

**Sunday | 8:00 am–4:00 pm | Chesapeake 4–5**

Knowing how to develop an effective global regulatory strategy is an essential skill for regulatory professionals. In this two-day strategic workshop, experts will take you on a guided tour through the process of developing regulatory strategy. You will work in teams and learn how to maximize commercial opportunities for healthcare product manufacturers while minimizing company risk.

**Speakers:**
- Brad Hossack, international vice president, regulatory affairs, Stryker Medical Corporation
- Megha Deviprasad Iyer, MS, RAC, senior manager, regulatory affairs, Thermo Fisher Scientific
- Nicole Landreville, PEng, RAC, FRAPS, program manager, regulatory affairs, GE Healthcare
- Patrick Lee, MBA, MS, RAC, senior director of RA/QA, Vascular Dynamics

The RAPS Awards Committee launched two new awards this year, focused on celebrating 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 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.

**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; and partnered with other organizations to further the profession.

**Founder’s Award**
- Susan Alpert, MD, PhD, FRAPS, principal, SFA Consulting LLC
- Junshi Chen, MD, head, International Life Sciences Institute Focal Point, China
- Agnes Klein, MD, senior medical advisor, Director General’s Office, Health Canada
- Murray Lumpkin, MD, deputy director integrated development and lead for global regulatory systems initiatives, Bill & Melinda Gates Foundation

**Community Leadership Award**
- Kimberly Belsky, MS, senior director, regulatory policy and intelligence, Mallinckrodt Pharmaceuticals
- Jacqueline Monteiro, RAC, director, regulatory affairs, APAC-Dental Platform, KAVO Kerr
- Michelle Ragozzino, PhD, regulatory affairs manager, Cordis Corporation

The RAPS Awards Committee launched two new awards this year, focused on celebrating 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.
Peeling the 510(k) Onion: From Fundamentals to Latest Topics

Saturday | 9:00 am–5:00 pm | Chesapeake 1–3
Sunday | 8:00 am–4:00 pm | Chesapeake 1–3

This interactive, two-day workshop provides a robust baseline in the fundamentals of 510(k) submissions. The latest developments in the 510(k) environment will be reviewed with helpful tips on the corresponding optimal regulatory strategy, when and how to contact FDA and how to optimize opportunities for a predictable 510(k) review experience.

Speakers:
Patrick Axtell, PhD, program operations staff, ODE, CDRH, FDA
Calley Herzog, senior consultant, Biologics Consulting Group
Melissa Kann, senior manager regulatory affairs, Stryker Instruments
Mark Leahey, president and CEO, Medical Device Manufacturers Association
Maura Norden, JD, senior vice president, medical devices and combination products, Greenleaf Health Inc.
Fatemeh Razjouyan, 510(k) program lead/policy analyst, OIR, CDRH, FDA
Mike Santalucia, vice president regulatory affairs, Terumo BCT
Marjorie Shulman, MBA, chief of premarket notification 510(k) section, ODE, CDRH, FDA
Steve Terman, JD, principal consultant, Frank, Weeda, Terman, and Matz PC
Donna-Bea Tillman, PhD, MPA, FRAPS, medical device team leader, Biologics Consulting
Hollace Saas Rhodes, senior director, orthopedic regulatory affairs, Musculoskeletal Clinical Regulatory Advisers, LLC
Heather Rosecrans, FRAPS, executive vice president, medical devices and combination products, Greenleaf Health LLC and vice president, regulatory affairs, MDMA
April Veoukas, director of regulatory affairs, Abbott Quality & Regulatory

Regulatory Leadership Institute

Saturday | 9:00 am–5:00 pm | National Harbor 5
Sunday | 8:00 am–4:00 pm | National Harbor 5

Take the next step in your career with expert-led leadership training with the Regulatory Leadership Institute. Facilitated by professional executive trainers, the Regulatory Leadership Institute immerses you in two fast-paced days of the skills you need to advance your career or step into a leadership role well-equipped and attuned to the challenges ahead.

Speakers:
Trista Schoonmaker, partner, copia
Ginger Swassing, RAC, executive director, Device and Diagnostics Regulatory LLC

EU Regulatory Essentials, Pharmaceuticals and Biologics

9:00 am–5:00 pm | National Harbor 3

A comprehensive overview of EU regulatory affairs for pharmaceuticals and biologics, this workshop will benefit individuals who are new to the regulatory profession, changing product line or industry or preparing for the RAC (EU) examination. Regulations, directives and policies affecting Europe’s regulatory system with specific issues and information addressing development considerations, clinical trials, marketing applications, pre- and postmarketing requirements will be covered.

Speakers:
Patricia Anderson, RAC, FRAPS, vice president, regulatory affairs, RedHill Biopharma Ltd.
Matthias Dormeyer, PhD, managing director, MDC RegAffairs GmbH
Karl-Heinz Huemer, MD, PhD, Scientific Office, AGES, Austria
Walter Janssens, PhD, coordinator, Early Phase Development, FAMHP, Belgium
Andrea Laslop, MD, head, Scientific Office, AGES, Austria
Beate Schmidt, MSc, MDRA, RAC, consultant pharma and biotech, benefits tailor-made regulatory consulting
Piet Vervaet, MD, vice president drug safety and pharmacovigilance, Haloyme Therapeutics
Bettina Ziegele, MA, head, Innovation Office, Paul-Ehrlich-Institute Germany

US Regulatory Essentials, Medical Devices and IVDs

9:00 am–5:00 pm | National Harbor 2 and National Harbor 7 for IVD Breakout

A comprehensive overview of US regulatory affairs for devices and IVDs, this workshop will benefit individuals who are new to the regulatory profession, changing product line or industry or preparing for the RAC (US) examination. Laws and policies affecting US regulation of devices and IVDs; an overview of the agency structures regulating these products; advertising, labeling and promotional aspects; and postmarket, compliance and enforcement requirements will be covered.

Speakers:
Tony Blank, senior advisor, Barton & Blank LLC
David E. Chadwick, PhD, RAC, FRAPS, director, regulatory affairs/regulatory science, Cook Inc.
Rita Hoffman, RAC, principal consultant, Regs & Recall Strategies LLC
Deborah Livornese, of counsel, Arnall Golden Gregory LLP Jon Speer, founder and VP of QA/RA, greenlight.guru
Lorry Weaver Huffman, MT (ASCP), CLS, principal consultant, Qserve Group US Inc.
SUNDAY, 10 SEPTEMBER

EU Regulatory Essentials, Medical Devices and IVDs: Transitioning From Current Directives Into Future Regulations
8:00 am – 4:00 pm | National Harbor 3 and National Harbor 7 for IVD Breakout

Transition continues for medical devices and IVDs from the current European directives to new European regulations. The Active Implantable Medical Device Directive (AIMDD) and Medical Devices Directive (MDD) will be transformed into the new Medical Device Regulation (MDR). For IVDs, the In Vitro Diagnostic Directive (IVDD) will be replaced by the In Vitro Diagnostic Regulation (IVDR). This workshop will divide into two tracks. Each track will reconfirm the essentials of the current directives, address the changes introduced by the regulations and provide input for planning a successful transition process. Experts will provide attendees with a solid understanding of what remains the same, what changes and the new requirements that must be addressed.

Speakers:
Bassil Akra, PhD, director, Clinical Centre of Excellence, TÜV SÜD Product Service GmbH
Philippe Auclair, PharmD, PhD, FRAPS, senior director, regulatory strategy and advocacy, EMEA, Abbott
Connie Del Buono, founder, director regulatory and compliance, Synoptyx
Stefan Burde, PhD, IVD product expert, BSI Americas
Sabina Hoekstra-van den Bosch, MSc, PharmD, FRAPS, senior manager global regulations and standards, Philips
Glenda Marsh, senior director, global policy implementation, Johnson & Johnson
Mindy McCann, MS, ChE, vice president, regulatory compliance, Qserve Consultancy BV
Julien Senac, PhD, certification project manager, LNE/G-MED North America Inc.
Sue Spencer, global service line director, UL
Erik Vollebregt, LLM, partner, Axon Lawyers
Anja Wiersma, PhD, CEO and senior consultant, mi-CE consultancy

US Regulatory Essentials, Pharmaceuticals and Biologics
8:00 am – 4:00 pm | National Harbor 2

A comprehensive overview of US regulatory affairs for biologics and pharmaceuticals, this workshop will benefit individuals who are new to the regulatory profession, changing product line or industry or preparing for the RAC (US) examination. Laws and policies affecting US regulation of biologics and pharmaceutical products; an overview of the agency structures regulating these products; advertising, labeling and promotional aspects; and postmarket, compliance and enforcement requirements will be covered.

Speakers:
Nancy Bower, senior director, regulatory affairs-nonclinical, Eisai Inc.
Kevin Dransfield, director, drug regulatory affairs, Boehringer Ingelheim
Amanda Goodwin, director, global regulatory strategy, Eisai Inc.
Alan McEmber, MS, RAC, head, regulatory strategy immunology, vice president global regulatory affairs, Shire
Mary Mease, senior director, market product safety services, Quintiles
Robert Merrill, JD, co-founder and managing partner, OneSource Regulatory
Kristin Murray, MS, vice president, head of global regulatory affairs CMC, Shire

Regulatory Managers Boot Camp
8:00 am – 4:00 pm | Potomac 4–6

First impressions are everything. Do you know what image you are projecting when talking to your manager or another decision maker? During this high-energy, interactive workshop, you will receive feedback about how others perceive you. This awareness will help you, as you can influence your image. You also will learn techniques that will enable you to write clear and concise documents, even when you are under pressure. Finally, industry leaders will share their experiences and provide the dos and don’ts for managing challenging situations in the workplace.

Speakers:
Susan Alpert, MD, PhD, FRAPS, principal, SFA Consulting, LLC
Don Boyer, RAC, FRAPS, president, BOYER@RegulatorySolns
Todd Chermak, RPh, PhD, divisional vice president innovation and development, established pharmaceuticals, Abbott
Daniela Drago, PhD, RAC, director regulatory affairs, The George Washington University
Virginia Perry, RAC, FRAPS, founder and partner, Perry-D’Amico and Associates
Amra Racic, MBA, principal regulatory affairs policy and advocacy specialist, Medtronic
Nancy Singer, JD, LLM, RAC, FRAPS, president, Compliance-Alliance
John Tomczak, director of quality, Bard Electronic Systems - Dymax Facility
Rainer Voelksen, FRAPS, vice president regulatory and quality affairs, Occlutech
Robert Yocher, MS, RAC, CQA, FRAPS, senior vice president regulatory and quality, HeartWare Inc. (retired) and member, RAPS Affiliate Board
Master Class in Regulatory Intelligence

8:00 am–4:00 pm | Potomac 1–3

This interactive workshop will examine the fundamentals of global regulatory intelligence (RI), including what it is and isn’t, how it is conducted, the strategic value it brings to key partners and how it is imperative to regulatory decision making throughout a development program and lifecycle management of a therapeutic product. Discussion and hands-on exercises will provide insights on the collection, analysis, communication and management of regulatory intelligence, with an emphasis on translating RI into a competitive advantage. The workshop will cover prescription drugs, biologics and medical devices with a focus on the US, EU and Canada.

Speakers:
Kimberly Belsky, MS, senior director, regulatory policy and intelligence, Mallinckrodt Pharmaceuticals
Linda Bowen, MS, RAC, FRAPS, senior director, regulatory science and policy, Sanofi
João Duarte, MPharm, MSc, associate director, Europe regulatory policy and intelligence, Takeda
Robert Kester, associate director, global regulatory affairs and chief of staff Oncology & IVD group, Merck & Co Inc.
Matt Medlin, manager US regulatory affairs R&D Pipeline, Chiesi
James Monroe, MS, RAC, CQA, director, regulatory affairs, Pentax Medical

EDUCATION BY DESIGN

At Convergence, attendees can engage in a variety of sessions covering multiple areas of focus within the regulatory world. The following program tracks are available this year:

**BIO Biopharmaceuticals**
From small molecules to biologics, hear about the latest in drug development tools, accelerated pathways, advanced therapies, labeling and advertising, user fees, and regional updates.

**FOOD Health-Related Foods**
Having a hunger and thirst for regulatory is a must for this discipline. Experts are ready to serve you the latest updates in the ever-changing global regulatory environment for health-related foods. Choose from our sessions about dietary supplements, medical foods and new dietary ingredients.

**IVD In Vitro Diagnostics**
Expand your scope and knowledge of the in vitro diagnostics field. Our sessions will explore global trends in both emerging and developed markets, including the new European IVD Regulation and agency changes as well as other topics impacting the regulatory professional throughout the product lifecycle including clinical, quality and compliance.

**MED Medical Devices**
Expand your scope and knowledge on medical devices. Sessions will address the new EU Medical Device Regulation, changes from FDA and IMDRF’s Medical Device Single Audit Program and much more, covering devices’ throughout the product lifecycle.

**MULTI Multiple Themes**
Overarching themes span the entire regulatory field. With so many disciplines, these valuable sessions provide key insights into multiple program tracks.

**BUS Regulatory Business**
Reviewing your regulatory business plan will put you on the path to advance your core objectives. Learn how to become a key strategic partner, execute efficiently and effectively, plus new tips to keep you on time and under budget. Jump on the leadership track as it focuses on career development, communication, regulatory intelligence, strategy and decision making.

**CON Conversations That Matter**
Connect with RAPS Fellows and senior regulatory professionals as they lead discussions on topics relevant to the profession. These informal sessions are not recorded and are not subject to attribution. Come prepared to ask your questions and share your personal insights during these small, intimate roundtable discussions. Conversations That Matter are open to everyone at all career levels, but seating is limited and is managed on a first come, first served basis.
SPONSORED SESSIONS

Unified Rim: End-To-End Submissions Development—From Planning Through Archival
Sponsored by Veeva

Monday, 11 September | 10:00–10:45 am | Exhibit Hall

Companies should be able to plan and complete submissions within a single system—not five, ten or more. If commitments are unified with submission planning, regulatory professionals can track the status of responses easily. If content plans are unified with document management, regulatory operations can track the progress of expected components. And with unified publishing, a continuous publishing process would reduce cycle times and stress levels during crunch times. See how unified RIM can transform work-streams for HQ, affiliates, and partners.

Speakers:
Marc Gabriel, Sr. Director, Vault RIM
Rachel Belani, Director, Vault RIM

The New Medical Device Regulation in Europe
Sponsored by Maetrics

Monday, 11 September | 3:00–3:45 pm | Exhibit Hall

The biggest single change to the medical device regulations in Europe since CE marking was first introduced back in 1993. This talk from Maetrics will take you through the main changes to the regulations from the old Medical Devices Directive and will outline the key requirements affecting manufacturers moving forward into the new era. With no grandfathering of existing products being permitted, this new regulation affects all devices being sold in Europe. If you have not begun planning your transition already, now is the time to act, or you risk missing the boat altogether.

Speaker:
Pete Rose, managing director, Europe, Maetrics

Document Management for Compliance in MasterControl
Sponsored by MasterControl

Tuesday, 12 September | 12:15–1:00 pm | Exhibit Hall

From a DHF to your volumes of product submission documents, the process of collecting all of the content across your organization can be extremely daunting. This session will highlight the pains of managing registrations for multiple products across multiple markets and demonstrate how MasterControl can help you with project visibility and organization using the latest in regulatory best practices.

Speaker:
Alex Butler, product marketing manager, MasterControl

A Notified Body’s Perspective – Managing the Impacts of EU IVDR and MDR
Sponsored by Lloyd’s Register

Tuesday, 12 September | 3:00–3:45 pm | Exhibit Hall

With the publication of the new IVD and MD Regulations, regulatory professionals and device manufacturers are seeking clarification on how to implement the new requirements within their organizations. These new regulations tighten and strengthen the approval system and introduce several key changes manufacturers will need to implement. This includes the scope of regulated medical devices and IVDs, identification and traceability, premarket scrutiny procedure, and classification and conformity assessment requirements. Join this session and find out answers to the industry’s frequently asked questions for a better understanding of the key changes, impact, transition phase and steps to be taken.

Speaker:
Nick Baker, LRQA - Medical Devices Technical Manager (IVDR)

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When you tap into RAPS resources, you get the tools to empower your team to drive toward regulatory excellence. Our three-tiered approach enhances your team development with customized online learning, onsite training and the advantages of Enterprise membership.

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CONVERSATIONS THAT MATTER

Join RAPS Fellows and senior regulatory professionals for informal discussions on key challenges facing today’s regulatory professionals. These sessions are not recorded and no slides will be presented, but they are a relaxed setting for informal conversations with industry leaders. Come prepared to ask your questions and share your personal insights. Each session is open to everyone at all career levels, but seating is limited and is managed on a first-come, first-served basis.

Conversations That Matter 1: Interactions With Health Authorities

Monday, 11 September | 7:30–8:15 am | Chesapeake 1–3

The way you communicate and establish your relationship with regulatory agencies could make or break your professional reputation. Every interaction with health authorities provides an opportunity to build your credibility. The panel of regulators and industry from around the world, including FDA, EMA, PDMA and HC, join RAPS attendees in an interactive discussion that includes an open question and answer session, policy updates, agency collaborations and current trends. We want to hear from you during this informal session. There is no presentation, so come prepared with your questions or discussion topics.

Conversations That Matter 2: TransCelerate Biopharma Inc.—How 18 Companies are Collaborating on Global Regulatory Engagement With an Aim to Improve Clinical Research

Monday, 11 September | 3:00–3:45 pm | Chesapeake 1–3

TransCelerate BioPharma Inc., launched in 2012, is a nonprofit organization created with a vision to improve the health of people around the world by accelerating, simplifying and enhancing the research and development of innovative new therapies. TransCelerate is known for its ability to work harmoniously with various stakeholder groups within the clinical research ecosystem, which is central to the organization’s strategy. One key stakeholder group is Global Health Authorities, who are critical to building innovative, industry-transforming solutions. TransCelerate established a Regulatory Council in early 2013, with the mission to advise the many TransCelerate Initiatives and the Oversight Committee on regulatory strategies and processes, and delivers engagement approaches for collaborating with Health Authorities around the world. In addition, it identifies how the initiatives align with the Health Authority objectives. In this session, panelists will discuss details of our novel approaches for regulatory engagement and also share success stories from several initiatives.

Conversations That Matter 3: 101 Ways to Develop an Exciting Regulatory Career

Tuesday, 12 September | 7:30–8:15 am | Chesapeake 1–3

In this session, RAPS Fellows will facilitate informal discussions on strategies in career development and how they transitioned and repurposed skills from their lifecycles of learning. Discussion topics will include appropriate training and credentials (RAC, certificate, master’s degree), the importance of developing a professional network, and the best ways to use social media.

Conversations That Matter 4: FDA’s Newly Launched Oncology Center of Excellence

Tuesday, 12 September | 3:00–3:45 pm | Potomac 4–6

This session explores the structure and function of the newly formed FDA Oncology Center of Excellence (OCE). OCE leverages the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices (including diagnostics) to expedite the development of oncology and hematology products for the treatment of cancer.

Conversations That Matter 5: Interactions With Health Authorities

Tuesday, 12 September | 3:00–3:45 pm | Chesapeake 1–3

The way you communicate and establish your relationship with regulatory authorities could make or break your professional reputation. Every interaction with health authorities provides an opportunity to build your credibility. The panel of regulators and industry from around the world, including FDA, EMA, PDMA and HC, join RAPS attendees in an interactive discussion that includes an open question and answer session, policy updates, agency collaborations and current trends. We want to hear from you during this informal session. There is no presentation, so come prepared with your questions or discussion topics.

Upcoming Training Programs From RAPS

Whether you’re near or far, RAPS training events deliver expert instruction on the latest regulatory requirements.

Intermediate Course for Regulatory Submissions in eCTD Format
17–18 October 2017
San Diego, CA

Intermediate Course for DMF, Module 3 Submissions in eCTD Format
6–7 November 2017
Frankfurt, GER

RAPS.org/events
RAPS CENTRAL LEARNING LOUNGE

SUNDAY, 10 SEPTEMBER

Ask RAPS Anything
6:00–7:30 pm
Want a recommendation for a training course? How to prepare for the RAC? The best book to buy to aid your career? The RAPS staff is here to answer your questions.

MONDAY, 11 SEPTEMBER

The ABCs of the RAC
10:00–11:30 am
When you earn the RAC, you gain regulatory professional credibility. Come learn about how to make earning the RAC a priority to your professional development. If you’re already an RAC holder, find out the necessary steps to maintain certification.

Courses, Workshops & Training...Oh My!
11:30 am–12:30 pm
From online to in-person educational opportunities, check out the abundant list of RAPS professional development resources that will help strengthen your career.

Community Counts. Membership Matters.
12:30–1:15 pm
Whether you are a RAPS member or are interested in becoming one, this is a great opportunity to get answers to any questions you have about RAPS benefits. Find out how to enhance your network, expand your regulatory knowledge and advance your career with a RAPS membership.

Volunteer With RAPS
2:45–3:45 pm
Help impact the future of the regulatory profession. Come learn about the latest RAPS volunteer opportunities.

TUESDAY, 12 SEPTEMBER

The ABCs of the RAC
10:00–11:30 am
When you earn the RAC, you gain regulatory professional credibility. Come learn about how to make earning the RAC a priority to your professional development. If you’re already an RAC holder, find out the necessary steps to maintain certification.

VOLUNTEER TODAY

Impact the Regulatory Profession’s Future

Become a RAPS volunteer by sharing your knowledge and talent. RAPS provides dozens of opportunities for you to volunteer that can give you an edge throughout your regulatory career development, help you earn RAC credits, and give you an opportunity to network—all while giving back to the profession.

1. Log on to connect.raps.org/volunteer.
2. Complete your volunteer profile.
3. Make volunteer selections that best meet your expertise.

We look forward to working with you. Thanks for joining our league of volunteers!

Regulatory Exchange
11:30 am–12:30 pm
RegEx is a place for great networking and finding invaluable connections. Get tips on how to make the most of its resources: the RAPS Career Community portal, our popular online discussions, information on your local RAPS chapter, and so much more.

Courses, Workshops & Training...Oh My!
12:30–1:15 pm
From online to in-person educational opportunities, check out the abundant list of RAPS professional development resources that will help strengthen your career.

Regulatory Exchange
2:45–3:45 pm
RegEx is a place for great networking and finding invaluable connections. Get tips on how to make the most of its resources: the RAPS Career Community portal, our popular online discussions, information on your local RAPS chapter, and so much more.
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EDUCATION SESSIONS

MONDAY, 11 SEPTEMBER

**BIO**  Global Development of Biosimilars

8:30–10:00 am  |  National Harbor 3

The regulatory landscape for developing biosimilars in the US and EU is very dynamic as regulators have gained an extensive amount of experience in biosimilars’ review and approval since 2004. Sponsors have demonstrated that quality biosimilars can be developed using state-of-the-art analytical and biological methods. Further, head-to-head clinical trials have confirmed these products are safe and effective. This session is designed to provide the current status of biosimilar guidelines in the US and EU. Get major updates that will help you navigate through the complex requirements for regulatory approval of biosimilars in the US and EU. You also will receive unique insights based on not only regulations and guidelines in place in major markets but actual hands-on experience working with biosimilars.

**Speakers:**
- Enrica Alteri, MD, head, Human Medicines Research and Development Support Division, EMA
- Kamali Chance, MPH, PhD, RAC, vice president, head, global biosimilars regulatory strategy, Quintiles IMS
- Leah Christl, PhD, associate director for therapeutic biologics and lead of the therapeutic biologics and biosimilars staff, OND, CDER, FDA
- Andrea Laslop, MD, head, Scientific Office, AGES, Austria

**BIO**  Regional Regulatory Update: Canada

8:30–10:00 am  |  National Harbor 2

This session will provide a clear overview of recent regulatory updates in Canada. Key topics covered will include the recent amendment to the Food and Drugs Act known as “Protecting Canadians From Unsafe Drugs Act (Vanessa’s Law),” plain language labeling (PLL) requirements, the new product monograph template, submissions relying on third party data (SRTDs) and orphan drug legislation. Learn what has changed, why and how industry should approach Canadian filings in light of these updates. This is an ideal opportunity to hear directly from Health Canada officials on these activities’ implementation and developing a greater understanding from an industry perspective on the practical applications.

**Speakers:**
- Heather Cherry, senior regulatory project manager, Therapeutic Products Directorate, Health Canada
- Fiona Frappier, PhD, senior policy analyst, Office of Policy and International Collaboration, Biologics and Genetic Therapies Directorate, Health Canada
- Tracy Porter, RAC, senior manager, regulatory affairs, Intrinsik Health Sciences Inc.
- Maxime Sasseville, human therapeutic product submission assessment reviewer, Therapeutic Products Directorate, Health Canada

**FOOD**  Functional Foods and Dietary Supplements: Manufacturing, Claims and Marketing

8:30–10:00 am  |  Potomac 4–6

Gain regulatory insights from experts in the field on dietary supplement manufacturing, labeling and claims across key markets. Markets covered will include US, EU and China. Key topics in this session will be: the EFSA claims review process, an overview of marketing a functional food in China and updates on the US GMPs and labeling. Join us if you’re planning on marketing dietary supplements in one of these key markets.

**Speakers:**
- Laura Alvarez, head of health products and self care, Normon Laboratories Spain
- Gretchen Miller Bowker, MS, RAC, FRAPS, chief operating officer and co-founder, Pearl IRB
- Bird Shi, regional regulatory director, Abbott Nutrition
- Andrea Wong, PhD, vice president, scientific and regulatory affairs, Council for Responsible Nutrition

**MED**  Medical Device Single Audit Program (MDSAP)

8:30–10:00 am  |  National Harbor 10–11

IMDRF has begun developing a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers’ quality management systems. The standard will be applicable to Competent Authority auditing groups/inspectorates, as well as third-party organizations that conduct such audits. The MDSAP Work Group has completed its work and has moved to the implementation phase. The MDSAP audit is, in fact, quite different than an ISO 13485 or Notified Body audit. Join us to learn about the experiences of auditing organizations and manufacturers on their pre-audit planning activities, auditing approaches and post-audit activities. Plus, hear about factors necessary for the long-term success of the program from all stakeholders involved.

**Speakers:**
- Hiromi Kumada, assessor, Division of Registered Certification Body Assessment, Office of Manufacturing, Quality and Compliance, PMDA
- Patricia Murphy, global head, MDSAP Program, BSI
- Nancy Shadeed, special advisor, International Programs Division, Health Canada
- Kim Trautman, MS, executive vice president, medical device international services, NSF International
MED | US FDA Regulation Changes: Clinical Evaluation: Obtaining Full FDA Approval of an IDE
8:30–10:00 am | National Harbor 12–13

Obtaining full FDA approval of an investigational device exemption (IDE) is a critical step in the process of obtaining practical clinical experience and gathering valuable clinical evidence with your medical device. During the presentation, FDA will share its perspectives on the pitfalls and opportunities associated with preparing an IDE submission and interacting with the agency before, during and after the submission. The goal is to convey important observations and recommendations that will help you understand how FDA reviews IDE submissions and how to prepare a submission that “tells your story” while fulfilling all of the applicable regulatory requirements and providing all of the technical details. Ultimately, FDA would like to make the IDE submission and review process as efficient as possible for everyone involved, sponsors and FDA review staff. This presentation also will include perspectives from an experienced sponsor/CRO, to help you understand how to apply what you learn.

Speakers:
Richard Kotz, senior medical research scientist, NAMSA
Jennifer Mischke, MPH, director of biostatistics and data management, NAMSA
Ken Skodacek, policy analyst, Clinical Trials Program and Payer Communication Task Force, CDRH/FDA
Andreas Wiegand, RAC, director, US affairs, Siemens Healthcare Diagnostics

MED | Reprocessing of Medical Devices in the Light of the EU MDR
8:30–10:00 am | National Harbor 4–5

Everybody is focusing on the compliance of higher risk devices, but what about surgical instruments and high-risk devices that are to be reprocessed by Central Sterile Supply Departments (CSSD) in hospitals? What about your Single Use Devices (SUDs) that may be reprocessed under the conditions defined in the MDR? The awareness about these aspects of the new European MDR is not yet sufficiently present among manufacturers and it is time for regulatory professionals to make a wakeup call. In this session, you will get the answers to your questions related to reprocessing of surgical instruments and SUD in Europe’s new regulatory environment.

Speakers:
Bill Enos, global head of microbiology, medical devices, BSI Healthcare
Michael Maier, senior partner, Medidee Services SA

BIO | Impact of PDUFA VI and 21st Century Cures on Regulatory Strategy
10:45 am–12:15 pm | National Harbor 3

Both PDUFA VI and the 21st Century Cures Act create opportunities to integrate new science and technology into regulatory decision making and continue to support FDA’s review processes. Our panel will discuss the regulatory provisions of 21st Century Cures Act, PDUFA VI and other recent legislative actions and how they may impact product development. Learn what pathways are available to integrate novel endpoints, patient perspectives, real-world evidence and other novel approaches into product development successfully.

Speakers:
E. Cartier Esham, PhD, executive vice president, emerging companies; vice president, science and regulatory affairs, Biotechnology Innovation Organization
Patrick Frey, MPP, director, Office of Program and Strategic Analysis, CDER, FDA
Kim Quaintance-Lunn, vice president and head, US regulatory policy, pharmaceuticals, Bayer US
Khyati Roberts, head US/Canada regulatory policy and intelligence, Abbvie

BUS | Regulatory Obligations and How to Deal With Unethical Requests
10:45 am–12:15 pm | Potomac 1–3

Have you ever found yourself in a situation where you knew it was wrong but didn’t know how to handle it? As a regulatory professional, there is a code of conduct we should follow, but sometimes it’s not that easy. Have you been asked to sign a document before reading it? What do you do when someone back dates a signature in front of you? Or what if you know data in a report have been falsified? After this session, you will have new tools for dealing with these situations and others. Come test your skills in this interactive session. There will be time to ask questions, acquire new tools and share your stories.

Speakers:
Stephen Amato, PhD, MBA, RAC, program director-associate professor graduate regulatory affairs/market access program portfolio, Northeastern University
Tamas Borsai, division manager, MHS customer service and quality, TUV SUD America
Jan Flegeau, regulatory affairs manager, Sterilmed, a Johnson & Johnson Company
Kara Haas, MD, MPH, FACS, director of worldwide strategic regulatory affairs for medical devices and diagnostics, Johnson & Johnson
Exporting Food Safety to the Global Supply Chain

10:45 am–12:15 pm | Potomac 4–6

Long gone are the days of getting all our food from local farmers’ markets. Today our food and the ingredients that make up our food come from all over the world including many emerging markets. FDA’s Foreign Supplier Verification Program recognizes food safety is a global effort. What are emerging markets doing to address food safety? During this session, you will learn about some of the efforts and challenges emerging markets face when developing modern food safety systems to produce domestic and exported food supplies. We also will discuss partnerships that exist to assist to build the capacity of a global food safety system.

Speakers:
Junshi Chen, MD, head, International Life Sciences Institute Focal Point, China
Clare Narrod, PhD, research scientist and manager, risk analysis program, JIFSAN
Vish Prakash, MD, PhD, FRSC, FIFT, FINAE, FIAFoST, FNAAS, FAFST(I), FINAS, FNAS, distinguished scientist of CSIR-INDIA, Mysore, INDIA director of research, development, management and innovation, JSS-MVP
Chad Weida, associate director, regulatory affairs, Abbott

ISO 13485:2016

10:45 am–12:15 pm | National Harbor 10–11

The revised ISO 13485:2016 is the international standard that defines quality management system requirements for organizations that are or may become involved in one or more stages of the medical device product lifecycle. ISO 13485:2016 certifications now can officially be issued to suppliers or external parties that provide product and quality management system-related services to such organizations. Join us to learn key changes in this standard’s scope, other important changes that might not have been noticed, suggestions on how to perform the necessary gap analysis, and how to prepare for the transition deadline of 1 March 2019.

Speakers:
Brian Ludovico, executive director, MDSAP regulatory certification, NSF Health Sciences
Patricia Murphy, global head, MDSAP Program, BSI
Kim Trautman, MS, executive vice president, medical device international services, NSF International

Recalls/Corrections/Removals

10:45 am–12:15 pm | National Harbor 12–13

Protecting a patient’s health is everyone’s job and despite technology’s impact on manufacturing processes, recalls and corrections remain a daily fact of life. How we conduct recalls and corrections can determine the fate and success of companies and careers alike, so it is essential that industry puts its best foot forward in these demanding situations. In this session, FDA and industry representatives will discuss a broad array of topics and answer questions that can help guide our approach to field actions, what strategies works best, how to communicate with FDA, hospitals and patients and how to react to public inquiries. Learn what to do if your firm has a Class I recall, common mistakes companies make when recalling products, the best ways to communicate with FDA headquarters, points to include in an effective notification letter and so much more.

Speakers:
Rita Hoffman, RAC, principal consultant, Regs & Recall Strategies LLC
Robin Newman, MSN, EdD, director, Office of Compliance, CDRH/FDA
Frank Pokrop, director, quality and regulatory affairs, BD

Human Factors Studies/Usability Engineering

10:45 am–12:15 pm | National Harbor 4–5

Join us to get an understanding of the usability engineering process as set forth in IEC 62366-1 and 62366-2 and how it differs from IEC 62366:2007. We will discuss ways to implement the process effectively, referencing a variety of real-life examples of approaches that worked and didn’t work. This presentation will also discuss the differences between IEC 62366:2007 and IEC 62366-1:2015 and the role of IEC 62366-2. Get a review of real-life case studies of various medical devices, plus hear successes and lessons learned, so you can apply tips for practical implementation to your own device projects.

Speakers:
Xin Feng, PhD, human factors reviewer, human factors premarket evaluation team, CDRH, FDA
Kim Kontson, PhD, Biomedical Research Fellow, Division of Biomedical Physics, OSEL, CDRH, FDA
Bob Marshall, chief editor, Med Device Online
Theresa Miles, director of client solutions, Regulatory and Quality Solutions LLC (R&Q)
Pooja Roychoudhury, MS, MBA, principal engineer, Regulatory and Quality Solutions LLC (R&Q)
MUL Roundtable: What’s New in Europe

10:45 am–12:15 pm | National Harbor 2

The European regulatory landscape for medicines and medical devices is undergoing changes that need to be taken into account in the context of global regulatory strategies. Please join us for this interactive roundtable session to hear from representatives from European health authorities who will provide an update on key topics and discuss their impact on how medicines and medical devices will be regulated in the near future. Whether you have a global or a regional role, your input will be immensely valuable to understand in practice how these changes will affect your work.

Speakers:
Enrica Alperi, MD, head, Human Medicines Research and Development Support Division, EMA
João Duarte, MPharm, MSc, associate director, Europe regulatory policy and intelligence, Takeda
Karl-Heinz Huemer, MD, PhD, Scientific Office, AGES, Austria
Walter Janssens, PhD, coordinator early phase development, FAMHP, Belgium
John Wilkinson, MBA, director of devices, Medicines and Healthcare products Regulatory Agency
Bettina Ziegele, MA, head, Innovation Office, Paul-Ehrlich-Institut

BIO Latin America Regulatory Convergence—Challenges Faced in the Regulations of Bio-therapeutic Products

1:15–2:45 pm | National Harbor 2

Presently, biotherapeutic products represent a paradigm to pharmacological innovation, while fulfilling an imperative need to treat diseases that do not count with an adequate, effective treatment option, also providing important patient benefits. The complexities involved in the elaboration, assessment and implementation of effective regulations covering the various stages from drug development to finished product manufacturing most certainly pose challenges to the national regulatory authorities across the Latin America region. Join us to learn about the challenges, experiences and best practices faced by the Latin American regulatory reference agencies while implementing the most adequate regulations and procedures helping to ensure patient access to safe, effective and high quality bio-therapeutic products and related technologies.

Speakers:
Patricia Aprea, director evaluation and control of biological products and biopharmaceuticals, ANMAT
Silvia Bendiner, member, 2017 Regulatory Convergence Planning Committee
Javier Guzmán Cruz, director general, National Food and Drug Surveillance Institute, Colombia
Rafael Perez Cristiá, head, National Regulatory Agency, Cuba
Julio Sánchez y Tépoz, commissioner for sanitary development, COFEPRIS (Mexico)

BIO Regulatory Considerations in Clinical Study Design

1:15–2:45 pm | National Harbor 3

Design and selection of clinical endpoints almost always spark a lively debate and regulatory professionals are key participants in the discussion. Selection of key endpoints acceptable to health authorities, and also to support the company’s marketing claims, is of paramount importance. This session will discuss strategic approaches to selecting key primary endpoints for novel or preventative therapies, especially those not covered specifically by regulatory guidance or reference products. The session also will include the EU perspective on novel therapies. In addition, the value of the FDA and EMA Drug Development Tool/Novel Methodologies Qualification process will be presented as it relates to clinical endpoint selection.

Speakers:
Karl-Heinz Huemer, MD, PhD, Scientific Office, AGES, Austria
John Powers, MD, professor of clinical medicine, George Washington School of Medicine
Brian Schlager, MA, MS, vice president, head of US drug regulatory affairs, Idorsia Pharmaceuticals Ltd.

BUS Mergers and Acquisitions

1:15–2:45 pm | Potomac 1–3

Mergers and acquisitions (M&A) are perhaps the most common means for growing market access and product portfolios in the medical device industry and beyond. In addition to due diligence of the target acquisition’s quality systems and regulatory standing, an integration plan that merges two cultures and practices also is in order. During this session, we will walk you through real-life examples of recent M&A activities in our industry. You will learn how to look for potential issues in the quality system and where to find the hidden items. Find out what to do when you face a potential challenge, including risk-based tactics for remediation. Plus, we’ll review what success looks like once challenges are addressed adequately.

Speaker:
Roberta Goode, MS, president, CEO, Goode Compliance International
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FOOD  Introduction of Supply Chain Complexity by Multiple Food-Grade Specifications: Is There a Path Forward?
1:15–2:45 pm  |  Potomac 4–6

Establishing specifications (purity and impurities) for food ingredients and additives is important for creating effective food safety systems. There are many internationally recognized agencies that are responsible for establishing these specifications, such as the Food Chemicals Codex, Joint FAO/WHO Expert Committee on Food Additives and US Pharmacopeia. All of these agencies rely on similar risk assessment and risk management processes to evaluate and establish specifications. However, for many food ingredients, there often are differences among the specifications established by different agencies. With increasing emphasis in certain regulatory frameworks on meeting the specifications established by a particular agency, food manufacturers face challenges in terms of ensuring global compliance to multiple specifications. This session aims to improve the understanding of the similarities in the processes used by the different agencies to establish these specifications, and whether different specifications can be considered equivalent in terms of ensuring consumer safety.

Speakers:
Junshi Chen, MD, head, International Life Sciences Institute Focal Point, China
Daniel Folmer, PhD, review chemist, Division of Petition Review, Office of Food Additive Safety, CFSAN/FDA
Paul Hanlon, director, regulatory affairs, Abbott Nutrition
Kristie Laurvick, MS, acting director, science-food standards, USP
Markus Lipp, PhD, senior food safety officer, FAO

MED  EU MDR and IVDR: Overview
1:15–2:45 pm  |  National Harbor 10–11

With the publication of the new EU Medical Device and IVD Regulations, are you prepared to comply with the requirements by 2020? Start planning now by attending this session. Learn the major changes between the Medical Devices Directive and regulations, including differences between the proposed and final text. We will highlight timelines for implementation. Learn the Notified Body expectations of manufacturers, expected challenges, timelines, readiness to audit, and impact of Brexit on the CE marking process. Hear industry perspectives on the planning process and unexpected challenges during the transition. Plus, we will discuss the impact on legacy directive products and re-accreditation of legacy product based on postmarket data.

Speakers:
Roshana Ahmed, associate director, regulatory affairs, medical devices, Mapi Group
Philippe Auclair, PharmD, PhD, FRAPS, senior director, quality and regulatory, EMEA, Abbott Laboratories Inc.
Gert Bos, PhD, FRAPS, executive director and partner, Qserve Group
Tina Lochner, MS, MBA, president, MEDCERT-USA, LLC
Valérie Nys, project manager, FAMHP, Belgium

MED  Global Regulation Changes: India
1:15–2:45 pm  |  National Harbor 4–5

The Indian government recently introduced a significant overhaul of its system for regulating medical devices and IVDs. Compliance is required quickly, in January 2018. You can expect more formalized registration requirements for currently registered devices. Additionally, risk-based classification is a new approach in this geography, as well as manufacturing audits we have not seen in the past. How ready is your business? Join our panel of experts in providing a detailed description of what you can expect and how to take advantage of the transition period best to comply with the new regulations following the 2018 implementation.

Speakers:
Mukesh Kumar, PhD, RAC, adjunct assistant professor, clinical research and leadership, George Washington University
Amra Racic, MBA, principal regulatory affairs policy and advocacy specialist, Medtronic
Sumati Randeo, director global strategy regulatory affairs and advocacy, Abbott
BIO Labeling as a Driver of Regulatory and Commercial Strategy

4:00–5:30 pm | National Harbor 4–5

The goal of drug product development is creating a safe and effective product with global commercial success. Continuous alignment of key stakeholders over the development timeline is essential to ensuring optimal labeling from approval through lifecycle management. This session will describe the target product profile (TPP) process and its use in early label development to the company core data sheet (CCDS), including a case study of how the label is used as a driver in regulatory and commercial strategy. Get an in-depth look at labeling compliance expectations from the emerging markets and steps to keep up to date on global products within country-specific environments.

Speakers:
Suresh Nair, director, portfolio expansion, established pharmaceuticals division, Abbott
Gerrit-Jan Nijveldt, senior director global labeling, Sanofi
Rupal Patel, Chugai Pharma
Kathleen Wessberg, senior director regulatory affairs, Abbott

BIO Effective Orphan Drug Development in a Challenging Regulatory Environment

4:00–5:30 pm | National Harbor 3

The strategy to obtain and retain orphan drug designation and exclusivity is multifaceted. Through insights and case studies, this session will explore the regulations governing orphan drug designation, the new technical amendments to address orphan drug clinical superiority and repurposing, and how competitors may enter the market using the orphan drug clinical superiority or the generic carve out pathway. Attendees will be better prepared to identify risks and mitigations for their orphan drug programs.

Speakers:
Kimberly Belsky, MS, senior director, regulatory policy and intelligence, Mallinckrodt Pharmaceuticals
Kurt Karst, JD, director, Hyman Phelps and McNamara
Alexander Varond, associate, Goodwin Proctor

BUS The Secrets of Successful Meetings With Health Authorities—What You Don’t Know May Hurt You

4:00–5:30 pm | Potomac 1–3

Imagine you had a reputation for preparing meetings with health authorities that led to great outcomes. Well-run meetings are effective ways to make decisions, solve problems and build long-term positive relationships with regulators. Mastering the art and science of effective regulatory interactions can make a difference in your job. During this facilitated interactive session, a panel of thought leaders will offer hands-on advice for challenging scenarios. You will be fully engaged and will walk away with best practices on how to prepare and run successful regulatory meetings.

Speakers:
Don Boyer, RAC, FRAPS, president, BOYER@RegulatorySolns
Daniela Drago, PhD, RAC, director regulatory affairs, The George Washington University
Michael Morton, FRAPS, vice president, corporate regulatory affairs, Medtronic (retired)
Fortunato Senatore, MD, PhD, FACC, medical officer, OND, CDER, FDA

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**Medical Foods/FSMPs—Access and Convenience Matters**

*4:00–5:30 pm | Potomac 4–6*

Medical food, also known as food for special medical purposes (FSMP), is a category of foods for specific dietary uses that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. Healthcare practitioners are closest to their patients and decide on their safety and best usage of a medical food. In case dietary change is impossible, unrealistic or very difficult. In that case, food targeting a medical condition is no longer simply for convenience but may become a medical necessity to allow the patient to access his or her best possible disease management. This session will explore the benefits of science-based medical foods for patients and healthcare systems as well as global issues to apply the law to emerging scientific and regulatory matters for the dietary disease management of patients.

**Speakers:**

- Junshi Chen, MD, head, International Life Sciences Institute Focal Point, China
- Eric H. W. Kossoff, MD, professor, neurology and pediatrics, Johns Hopkins School of Medicine
- Mark Pohl, Esq., biotech general counsel, PPA, LLC—Pharmaceutical Life Cycle Management Solutions™
- Manfred Ruthsatz, PhD, RPh, DABT, RAC, FRAPS, global head regulatory advocacy, Nestlé Health Science, Switzerland
- William Yan, PhD, director, Bureau of Nutritional Sciences, Food Directorate, Health Canada

**EU MDR: Clinical Evaluation/Classification**

*4:00–5:30 pm | National Harbor 10–11*

The requirements, including the extent of clinical evidence needed, for the EU’s clinical evaluation is evolving continually. With the release of Revision 4 of the MEDDEV 2.7/1 guidance entitled *Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC*, as well as the new *Medical Device Regulation (MDR)*, it is critical that manufacturers understand and address requirements to facilitate rapid market access to countries relying on the CE Mark. Key takeaways from this session include strategies for literature evaluation, scoring “the right” research questions and perspectives on leveraging data from equivalent competitive products. Upcoming MDR requirements also will be considered.

**Speakers:**

- Bassil Akra, PhD, director, Clinical Centre of Excellence, TÜV SÜD Product Service GmbH
- Carine Cochereau, PhD, QRA and clinical director EMEA, Cardinal Health
- Robin Fitzgerald Martin, MBA, RAC, co-founder and chief regulatory strategist, Kinetic Compliance Solutions LLC
- Keith Morel, PhD, vice president, regulatory compliance, Qserve Group US Inc.

**Medical Device Innovation Consortium (MDIC) Including the National Evaluation System for Health Technology (NEST)**

*4:00–5:30 pm | National Harbor 12–13*

FDA has awarded the Medical Device Innovation Consortium (MDIC) $3 million (US) in seed funding to establish the Coordinating Center for the Medical Device National Evaluation System for health Technology (NEST). Simultaneously, NEST’s establishment is moving the industry toward greater utilization of real-world data (RWD) sources. As NEST seeks to leverage and aggregate practice data from various real-world data sources including clinical registries, electronic health records and medical billing systems to enable patients and providers to make better data-driven treatment decisions, the industry is faced with many questions. Join FDA and other leading experts as they discuss how this collaboration could affect the medical device industry and what changes we can expect as a result of this new effort.

**Speakers:**

- Paul Brooks, executive director, RAPS
- Rachael Fleuruncce, PhD, executive director, National Evaluation System for health Technology Coordinating Center (NESTcc)
- Michelle McMurry-Heath, vice president regulatory affairs, Johnson & Johnson
- Bill Murray, president and CEO, MDIC
- Greg Pappas, MD, PhD, associate director, National Device Surveillance, Center for Devices and Radiological Health, FDA
- Pat Shrader, vice president, global regulatory affairs, Medtronic

**Global Regulation Changes: Latin America**

*4:00–5:30 pm | National Harbor 2*

Medical devices are essential for the prevention, diagnosis, treatment and rehabilitation of diseases. In the last few decades, these products have acquired great relevance across the healthcare sector with associated economic repercussions on a worldwide basis, also becoming relevant to the future of medicine. The national regulatory authorities (NRA) across the Latin American region are responsible for medical devices’ safety, effectiveness and quality, implementing effective and timely controlled regulatory systems to guarantee patient access to safe health technologies. Join us to gain insights on the national experiences and regional initiatives across Latin America presented by the key NRAs in an effort to help strengthen the regulation of medical devices across the Americas. These initiatives have been spearheaded, supported and coordinated in recent years by the PAHO/WHO Collaborating Center for Health Technology Regulation of the CECMED (Cuban National Regulatory Agency) at a regional level.

**Speakers:**

- Jarbas Barbosa da Silva Jr., president, National Agency of Health Surveillance, Brazil
- Silvia Bendiner, member, 2017 Regulatory Convergence Planning Committee
- José Coto, MD, head, Ministry of Health, El Salvador
- Javier Guzmán Cruz, director general, National Food and Drug Surveillance Institute, Colombia
- Alexandre Lengruber, regional advisor, health technologies, PAHO/WHO
- Rafael Perez Cristiá, head, National Regulatory Agency, Cuba
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**TUESDAY, 12 SEPTEMBER**

**BIO**  Incorporating Patient Reported Outcomes in Regulatory Strategy  
*8:30–10:00 am | Potomac 4–6*

Incorporating patient reported outcome (PRO) into trials is an important step to integrate patient voices into drug development and regulatory decision making. PRO, a direct measure of clinical benefit, seldom has been used as a key endpoint in oncology trials or in labeling claims due to the hurdles in oncology (e.g., short development timeline, missing data due to disease burden, lack of fit-for-purpose PRO tools). Although FDA has made progress in allowing flexibility in implementing PRO principles, gaps still exist in bringing PRO into oncology development. Join us as we examine the importance of incorporating PROs into cancer research and policy formation.

**Speakers:**  
Jeff Allen, PhD, president and CEO, Friends of Cancer Research  
Alicyn Campbell, MPH, global head, patient-centered outcomes research for oncology, Genetech  
Paul Kluetz, MD, associate director for clinical science, OHOP, CDER, FDA  
Sarah Stellzljeni, PharmD, manager, regulatory sciences, bluebird bio  
Margaret Woo, PharmD, MS, global regulatory director, EMD Serono

**BUS**  Key Takeaways From the Master Class in Regulatory Intelligence: RI as a Strategic Imperative  
*8:30–10:00 am | Potomac 1–3*

Join us for a hands on session on the role of regulatory intelligence and locating and using precedent in an ever-evolving global environment of therapeutic product regulatory strategy. Here’s a chance for you to be part of a regulatory team tasked with addressing several real-world examples of strategic issues encountered during development. Case studies of properly executed RI demonstrate how to provide actionable intelligence leading to innovative solutions solving common problems encountered in product development. The panelists will provide key takeaways from Sunday’s Master Class in Regulatory Intelligence Workshop and examine scenarios and case studies and walk through the process of gathering precedent, analyzing the information and providing actionable regulatory intelligence.

**Speakers:**  
Kimberly Belsky, MS, senior director, regulatory policy and intelligence, Mallinckrodt Pharmaceuticals  
Linda Bowen, MS, RAC, FRAPS, senior director, regulatory science and policy, Sanofi  
João Duarte, MPharma, MSc, associate director, Europe regulatory policy and intelligence, Takeda  
Robert Kester, associate director, regulatory affairs international, Merck  
Matt Medlin, manager, US regulatory affairs, R&D Pipeline, Chiesi  
James Monroe, MS, RAC, CQA, director, regulatory affairs, Pentax Medical

**IVD**  EU IVDR: Classifications/Performance Evaluation  
*8:30–10:00 am | National Harbor 12–13*

The new EU IVD Regulation, the counterpart to the Medical Device Regulation, will see a vast increase in the number of manufacturers needing a Notified Body. This session will include strategies and expectations from both industry and Notified Bodies on how to deal with the legacy products situations.

**Speakers:**  
Stefan Burde, PhD, IVD product expert, BSI  
Connie Del Buono, founder, director regulatory and compliance, Synoptyx Inc.  
Ian Purdy, PhD, senior vice president quality and regulatory affairs, Haemonetics  
Sue Spencer, head of global medicine device services, UL

**MED**  US FDA Regulation Changes: When to Submit a 510(k) for a Change to an Existing Device  
*8:30–10:00 am | National Harbor 10–11*

In August 2016, FDA released two draft guidance documents for manufacturers on when changes to a device or software would require a change to be made to a 510(k) submission. The update from the 1997 guidance further clarifies when device makers are required to submit a 510(k) if a change could significantly affect the device’s safety or effectiveness. This session will dissect the difference between the current and newly proposed guidance, clarify this guidance and show how risk management is utilized to determine when change requires a 510(k).

**Speakers:**  
Steven Binion, PhD, MBA, senior director, corporate regulatory policy, BD  
Michael Ryan, regulatory advisor, ODE, CDRH/FDA  
Marjorie Shulman, MBA, chief of premarket notification 510(k) section, ODE, CDRH, FDA  
April Veoukas, director of regulatory affairs, Abbott Quality & Regulatory
MUL  Social Media Use in Regulated Industries
8:30–10:00 am  |  National Harbor 4–5

While social media began as a means of communication among individuals, there now is widespread use not only by institutions, but by media and even government agencies. Increasingly, patients seek information not only on the Internet but through multiple digital platforms. However, as highly regulated industries, pharma and biotech have unique challenges, leaving many to wonder how they can use digital platforms and remain compliant with FDA advertising and promotion rules. Join us to review how the industry is using social media today to promote products, services and brands. We’ll survey the tools evolving in social media, and teach you how to develop a sound social media compliance policy. Attendees also will be able to participate in a panel discussion of best practices and lessons learned.

Speakers:
Glenn Byrd, MBA, senior director, promotional regulatory affairs, Astrazeneca
Heidi Gertner, JD, partner, Hogan Lovells
Nicole Landreville, PEng, RAC, FRAPS, program manager, regulatory affairs, GE Healthcare
Margaret Mucha, MJ, CQA, RAC, FRAPS, senior leader RA and QA, IBM Watson
Nancy Parsons, counsel, Nancy M. Parsons Law
Mark Senak, JD, senior vice president and partner, Fleishman Hillard
Alina Vargas, social media and communications specialist, Medtronic

BIO  Accelerating Approval for Medical Products in the US: Implications of Recent US Legislation
10:45 am–12:15 pm  |  Potomac 4–6

Join us for an update on recent advances in accelerating development and approval of products for serious and unmet medical needs. Hear insights from regulators and regulated industry on accelerated approval, breakthrough therapy and the new regenerative medicine advanced therapy designations, including a case study on the first RMAT designation, and how the Oncology Center of Excellence is partnering with the biopharmaceutical industry.

Speakers:
Linda Bowen, MS, RAC, FRAPS, senior director, regulatory science and policy, Sanofi
Brant Hamel, PhD, regulatory affairs manager, Humacyte
Peter Marks, MD, PhD, director, CBER/FDA
Peggy McCann, DVM, PhD, executive director, regulatory affairs, Merck
Marc Theoret, MD, associate director for immunotherapeutics, OHOP, OND, CDER, FDA

BIO  AdPromo: Communications, Conversations and Elucidations
10:45 am–12:15 pm  |  National Harbor 2

Prescription drug advertising—the regulatory environment is evolving and industry no longer is focused on the healthcare professional. Come learn about the types of conversations that are happening today, the new audiences and decision makers in today’s healthcare environment. You will learn about what ‘new data’ are considered acceptable and what continue to be areas of high enforcement. Our panel also will discuss changes in enforcement language, how the First Amendment has shifted the philosophical view on claims and what may be anticipated in the future.

Speakers:
Fadwa Almanakly, PharmaD, director, advertising and promotions, regulatory affairs, Bayer HealthCare
Kimberly Belsky, MS, senior director, regulatory policy and intelligence, Mallinckrodt Pharmaceuticals
Glenn Byrd, MBA, senior director, promotional regulatory affairs, Astrazeneca
**MUL**  Cybersecurity: Considerations for the Medical Device Industry

10:45 am–12:15 pm | Potomac 1–3

“Opportunity makes the thief” and with the Internet, opportunities are indefinite. Cybersecurity is the state of being protected against the criminal and unauthorized use of electronic data or the measures taken to achieve this. What does cybersecurity mean to the medical device industry? What regulations are in place and how much effect does this have on the regulatory community? These are just some of the questions we will discuss in this session with FDA experts and major influencers in the industry. From the intrinsic safety of the embedded software and operation system in place to the end user in the hospital, the hospital network, the Cloud and the Internet itself, opportunities to protect our data are equally indefinite. Join us in understanding where we are in this space and how to move on safely to the next chapter.

**Speakers:**
- Bill Hagestad, senior principal cyber security engineer, R&D, Smiths Medical
- Jos Kraus, PharmD, FRAPS, senior consultant medical technology, Academic Medical Centre of the University of Amsterdam
- Matt Russo, senior director, product security, Medtronic
- Suzanne Schwartz, MD, MBA, associate director for science and strategic partnerships, CDRH, FDA

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**MED**  EU MDR and IVDR: Postmarket Expectations Including PMCF

10:45 am–12:15 pm | National Harbor 10–11

This session will explore the upcoming changes resulting from the new EU MDR with respect to preclinical and postmarket surveillance, including postmarket clinical follow-up and continuous reporting of the postmarket clinical follow-up activities via Postmarket Clinical Follow-up Reports (PMCFR). You will benefit from an overview of the requirements as well as the insight from a Notified Body, a manufacturer and a CRO’s perspective.

**Speakers:**
- Mindy McCann, MS, ChE, vice president, regulatory compliance US, Qserve Group
- Florianne Torset-Bonfillou, director, regulatory, education and quality, LNE/G-MED North America Inc.
- Michael Maier, senior partner, Medidee Services SA
- David Rutledge, director, Abbott Vascular

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**MED**  Medical Device Harmonization Initiatives

10:45 am–12:15 pm | National Harbor 12–13

Regulatory harmonization, cooperation and systems strengthening are the focus of global and regional initiatives involving regulators, the World Health Organization and other stakeholders in medical device regulation. These initiatives align regulatory requirements and advance public health through collaboration and mechanisms including adopting technical guidance and standards and common practices and procedures. Join us to receive an overview from industry on current harmonization initiatives, the relationships between initiatives and common work areas. Plus, gain information and insight from representatives of IMDRF, AHWP and PAHO on the following topics: key work items, the best approach for monitoring the work of these organizations and how to become more involved as a stakeholder.

**Speakers:**
- Philippe Auclair, PharmD, PhD, FRAPS, senior director, quality and regulatory, EMEA, Abbott Laboratories Inc.
- Alexandre Lemgruber, regional advisor, health technologies, PAHO/WHO
- Marcela Saad, MSc, PharmD, RAC (Global), FRAPS, president and senior consultant, MarcM Consulting Canada
- Diana Salditt, FRAPS, regulatory advocacy program director, Medtronic
- Nancy Shadeed, special advisor, International Programs Division, Health Canada

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**IVD**  IVDs in China: Navigation of Type Testing and Clinical Evidence Expectations

10:45 am–12:15 pm | National Harbor 3

As the Chinese regulations evolve around both devices and diagnostics, the pathway becomes less clear for those in the international market. This session aims to bring local experts directly from China and the Asia-Pacific region to provide first-hand experience in gaining approvals for IVDs in China. The presentation will include testing requirements, what’s expected of a clinical trial, clinical evidence and, most importantly, how to get the product approved.

**Speakers:**
- Grant Bennett, CEO and senior consultant, Brandwood Biomedical
- Arthur Brandwood, PhD, FRAPS, founder and principal consultant, Brandwood Biomedical
- Carole Ledford, international regulatory affairs manager, BD
- Mingming (Matt) Wang, associate project manager, George Clinical
MED  How to Prioritize Your CAPA Activities
10:45 am–12:15 pm  |  National Harbor 4–5

When auditors and investigators uncover deficiencies in medical device manufacturers’ quality systems, the challenge is to take corrective action in a timely manner. Distinguishing between corrective actions that are urgent, important or nonessential is problematic. In a high-energy, interactive session, attendees will discuss best practices for prioritizing their remedial activities for quality system deficiencies, including those for legacy products and processes. They will have the opportunity to compare their answers with former and current FDA officials and industry experts.

Speakers:
Captain Sean Boyd, deputy director of regulatory affairs, OC, CDRH, FDA
Denise Dion, vice president, regulatory and quality services, Eduquest
Nancy Singer, JD, LLM, RAC, FRAPS, president, Compliance-Alliance

BIO  Gene Therapy Clinical Trials in the Global Regulatory Landscape
1:15–2:45 pm  |  National Harbor 2

Gene therapies and the use of genetically modified organisms (GMOs) are sparking great interest due to the possibility of permanently curing many diseases. However, these therapeutic products face special regulatory challenges for clinical trial conduct as many jurisdictions require approvals in addition to those from the regulatory agency and ethics committee (e.g., Ministry of Environment). While some countries have a well-defined regulatory framework for gene therapies, other countries do not and the requirements may be less clear. The various additional approvals and/or requirements need to be investigated comprehensively to determine a time- and cost-effective regulatory strategy, particularly with the increased emphasis on conducting global clinical trials. We will discuss challenges associated with gene therapy trials from the industry and provide a regulatory agency perspective full of additional considerations.

Speakers:
Enrica Alteri, MD, head, Human Medicines Research and Development Support Division, EMA
Kirsten Messmer, PhD, principal regulatory affairs specialist, PPD
Tara O’Meara, vice president, clinical development operations, bluebird bio
Ramjay Vatsan, PhD, biologics team leader, division of cellular and gene therapy, CBER/FDA

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**BIO**  An Update on the First Reauthorization of GDUFA

1:15–2:45 pm  |  Potomac 4–6

As FDA Commissioner Scott Gottlieb has made it a goal to speed the review of generic drugs, the next iteration of the Generic Drug User Fee Amendments (GDUFA) will add new funding for faster reviews and more FDA staff reviewing the backlog of generic applications. Join us to gain a better understanding of GDUFA, its implications regarding drug master files (DMFs), who in industry is impacted and the required fees.

Speakers:
- Kurt Karst, JD, director, Hyman, Phelps and McNamara
- Lisa Parks, RPh, vice president, sciences and regulatory affairs, Association for Accessible Medicines
- Scott Tomsky, MS, vice president, generics regulatory affairs, North America, Teva Pharmaceuticals
- Penny (Levin) Toren, MS, director, regulatory affairs, Teva Pharmaceuticals

**BUS**  Does Your Firm Have Issues With Data Integrity? Red Flags Investigators Look For

1:15–2:45 pm  |  Potomac 1–3

During drug and device inspections, investigators may ask about the systems your organization uses to ensure data accuracy and consistency. When firms fail to have a system, or the system is inadequate, FDA officials issue 483 Observations or send Warning Letters. During this high-energy interactive session, you will learn why FDA has started to focus on data integrity. You also will hear about key guidance documents and actions you can take to ensure your data’s integrity. Additionally, you will learn about the red flags FDA investigators are trained to look for.

Speakers:
- John Avellanet, FDA compliance expert, managing director and principal consultant, Cerulean Associates LLC
- Nancy Singer, JD, LLM, RAC, FRAPS, president, Compliance-Alliance
- Robert Tollefsen, national expert investigator for computer systems, Division of Field Investigations, ORA/FDA

**IVD**  Current State: In Vitro Diagnostic Device Studies Using Leftover Human Specimens

1:15–2:45 pm  |  National Harbor 3

The use of collected human specimens is essential to biomedical research and the development of new in vitro diagnostics. Join our discussion for an update on the requirements for informed consent for use of specimens in FDA-regulated IVD studies. Plus, after rounds of negotiation and revision, we’ll discuss the industry impact of the EU MDR’s impending regulatory requirements.

Speakers:
- Connie Del Buono, founder, director regulatory and compliance, Synoptyx Inc.
- Chitra Edwin, PhD, RAC, senior vice president of regulatory affairs and compliance, Spotlight Innovation Inc.
- Erik Vollebregt, LLM, partner, Axon Lawyers

**MED**  EU Medical Device Regulation (MDR): Which Issues Are Still Open?

1:15–2:45 pm  |  National Harbor 10–11

Industry can expect many milestones between now and May 2020, when the new EU Medical Device Regulation comes into force. A new and complex regulation has been published, but several sub-regulations are in the pipeline, along with guidance documents, common specifications, new standards, harmonized electronic forms and a new European medical device databank (EUDAMED). Attend this session to better understand how, when and why these milestones will enable, or endanger, your compliance plans.

Speaker:
- Daniel Moelands, PharmD, MBA, senior director, global regulatory and operations, Medtronic
MED  The Art of Getting CFDA Premarket Approval in the Shortest Time Possible
1:15–2:45 pm | National Harbor 12–13

China is the second largest medical device market in the world, with double-digit growth. This session will cover how CFDA medical device and IVD regulatory changes affect the registration process and the best practice to cope with the regulations. Clinical evaluation and clinical trial changes will be covered as well. Seasoned experts will identify common mistakes made and provide constructive strategies to reduce registration time and cost, plus shorten time to market for medical devices and IVDs.

Speakers:
Grace Fu Palma, CEO, China Med Device, LLC
Danielle Giroud, MBA, CEO, MD-CLINICALS SA
Xiaoyun (Linda) He, manager, global strategy, China regulatory affairs, DePuy Synthes
Qianqian Zhu, MBA, LLM, RAC, international regulatory affairs manager, Immucor Inc.

MED  Regulatory Strategies and Techniques for Faster Market Access
1:15–2:45 pm | National Harbor 4–5

By using advanced methods and tools, leading regulatory professionals are managing multiple product registration processes in many countries in real-time, more effectively than ever. This session will outline the importance of building global requirements into a device’s design from concept phase and to engage regulatory, senior management and other departments from the very beginning of the development. You will learn how to deal with the changing global regulations, communicate them to key stakeholders within your company and develop a successful regulatory strategy that can make your company successful globally. Get a demonstration on how to execute regulatory strategies in any market, independent of third parties, using the most advanced product registration technology available to the medical technology industry. Find out how technology can align business and regulatory strategies toward generating growth while expediting time-to-market and significantly cutting regulatory costs.

Speakers:
Maham Ansari, MS, RAC, director of regulatory affairs, Synaptive Medical
Benjamin Arazy, founder and CEO, Arazy Group Consultants Inc.
### WORKSHOPS DAY 1: SATURDAY, 9 SEPTEMBER 2017

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| 9:00 am–5:00 pm| • Peeling the 510(k) Onion: From Fundamentals to Latest Topics (Chesapeake 1-3)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
| 10:30–11:00 am| Beverage Break in Chesapeake and National Harbor Foyer               |
| 12:30–1:30 pm | Lunch                                                                  |
| 1:30–3:30 pm  | Beverage Break in Chesapeake and National Harbor Foyer               |

### WORKSHOPS AND REGULATORY CONVERGENCE DAY 2: SUNDAY, 10 SEPTEMBER 2017

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:00 am–6:00 pm</td>
<td>Registration Open</td>
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<tr>
<td>7:00–8:00 am</td>
<td>Workshop Registration and Workshop Continental Breakfast</td>
</tr>
</tbody>
</table>
| 8:00 am–4:00 pm| • Peeling the 510(k) Onion: From Fundamentals to Latest Topics (Chesapeake 1-3)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
  • Regulatory Strategy Forum for Medical Devices (Chesapeake 4-5)  
  • Regulatory Leadership Institute (National Harbor 5)  
  • Regulatory Strategy Forum for Biologics (National Harbor 4)  
| 10:00–10:30 am| Beverage Break in Chesapeake and National Harbor Foyer               |
| 12:00–1:00 pm | Lunch                                                                  |
| 2:30–3:00 pm  | Beverage Break in Chesapeake and National Harbor Foyer               |
| 4:30–6:00 pm  | Opening Plenary Session: Daniel Diermeier: Regulatory Excellence in Times of Change and Uncertainty, Awards and Recognition |
| 6:00–7:30 pm  | Grand Opening of Exhibit Hall and RAPS Central: Taste of National Harbor Reception |

### REGULATORY CONVERGENCE DAY 3: MONDAY, 11 SEPTEMBER 2017

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:00 am–6:00 pm</td>
<td>Registration Open</td>
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<tr>
<td>7:00–8:30 am</td>
<td>Continental Breakfast</td>
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<tr>
<td>7:30–8:15 am</td>
<td>Conversations That Matter 1: Interactions With Health Authorities (Chesapeake 1-3)</td>
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</table>
| 8:30–10:00 am | Global Development of Biosimilars (National Harbor 3)  
  Regional Regulatory Update: Canada (National Harbor 2)  
  Functional Foods and Dietary Supplements: Manufacturing, Claims and Marketing (Potomac 4-6)  
  Medical Device Single Audit Program (MDSAP) (National Harbor 10-11)  
  ISO 13485:2016 (National Harbor 10-11)  
  USFDA Regulation Changes: When to Submit a 510(k) for a Change to an Existing Device (National Harbor 10-11)  
  Recall/Coronel (12-13)  
  Global Regulation Changes: China (National Harbor 12-13)  
  Global Regulation Changes: India (National Harbor 10-11)  
  Global Regulation Changes: Latin America (National Harbor 12-13)  
| 10:00 am–4:00 pm| Exhibit Hall and RAPS Central Open                                    |
| 10:00–10:45 am| Sponsored Education Session by Veeva; Unified Rim: End-To-End Submissions Development — From Planning Through Archival (Exhibit Hall) |
| 10:45 am–12:15 pm| Impact of PDUFA VI and 21st Century Cures on Regulatory Strategy (National Harbor 3)  
  Exporting Food Safety to the Global Supply Chain (Potomac 4-6)  
  EU MDR and IVDR: Overview (National Harbor 10-11)  
  Global Regulation Changes: China (National Harbor 12-13)  
| 12:15–1:15 pm | Grab and Go Lunch and Keynote by FDA Commissioner Gottlieb           |
| 1:15–2:45 pm  | Latin America Regulatory Convergence—Challenges Faced in the Regulations of Bio-therapeutic Products (National Harbor 2)  
  Regulatory Considerations in Clinical Study Design (National Harbor 3)  
  Introduction of Supply Chain Complexity by Multiple Food-Grade Specifications: Is There a Path Forward? (Potomac 4-6)  
  EU MDR and IVDR: Overview (National Harbor 10-11)  
  Global Regulation Changes: China (National Harbor 12-13)  
| 2:45–3:45 pm  | Beverage Break in the Exhibit Hall                                   |
| 3:00–3:45 pm  | Sponsored Education Session by MasterControl: The New Medical Device Regulation in Europe (Exhibit Hall)  
  Conversations That Matter 2: TransCelerate Biopharma Inc.—How 18 Companies are Collaborating on Global Regulatory Engagement |
| 4:00–5:30 pm  | Labeling as a Driver of Regulatory and Commercial Strategy (National Harbor 4-5)  
  Effective Orphan Drug Development in a Challenging Regulatory Environment (National Harbor 3)  
  Medical Devices (National Harbor 4-5)  
  EU MDR: Clinical Evaluation/Classification (National Harbor 10-11)  
  Medical Devices (National Harbor 4-5)  
  Global Regulation Changes: China (National Harbor 12-13)  
| 6:00 pm       | Dine-Arounds                                                          |

### REGULATORY CONVERGENCE DAY 4: TUESDAY, 12 SEPTEMBER 2017

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<tr>
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<tr>
<td>7:00 am–6:00 pm</td>
<td>Registration Open</td>
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<tr>
<td>7:00–8:30 am</td>
<td>Continental Breakfast</td>
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<tr>
<td>7:30–8:15 am</td>
<td>Conversations That Matter 3: 101 Ways to Develop an Exciting Regulatory Career (Chesapeake 1-3)</td>
</tr>
</tbody>
</table>
| 8:30–10:00 am | Incorporating Patient Reported Outcomes in Regulatory Strategy (Potomac 4-6)  
  US FDA Regulation Changes: When to Submit a 510(k) for a Change to an Existing Device (National Harbor 10-11)  
  The Art of Getting the Shortest T  
| 10:00 am–4:00 pm| Exhibit Hall and RAPS Central Open                                    |
| 10:00–10:45 am| Sponsored Education Session by MasterControl: Document Management for Compliance in MasterControl (Exhibit Hall) |
| 10:45 am–12:15 pm| Accelerating Approval for Medical Products in the US:  
  Implications of Recent US Legislation (Potomac 4-6)  
  AdPROM: Communications, Conversations and Exclusions (National Harbor 2)  
  EU MDR and IVDR: Postmarket Expectations Including PMCF (National Harbor 10-11)  
  Medical Device (National Harbor 12-13)  
| 12:15–1:00 pm | Sponsored Education Session by MasterControl: Document Management for Compliance in MasterControl (Exhibit Hall) |
| 12:15–1:15 pm | Grab and Go Lunch and Keynote by FDA Commissioner Gottlieb           |
| 1:15–2:45 pm  | Gene Therapy Clinical Trials in the Global Regulatory (National Harbor 2)  
  An Update on the First Reauthorization of GDUFA (Potomac 4-6)  
  EU MDR: Which Issues Are Still Open? (National Harbor 12-13)  
| 2:45–3:45 pm  | Beverage Break in the Exhibit Hall                                   |
| 3:00–3:45 pm  | Sponsored Education Session by LRQA: A Notified Body’s Perspective – Managing the Impacts of EU IVDR and MDR (Exhibit Hall)  
  Conversations That Matter 4: FDA’s Newly Launched Oncology Center of Excellence (Hosted by RAPS) |
| 4:00–5:30 pm  | Challenges in Incorporating Real World Data Into Your Regulatory Strategy (National Harbor 2)  
  EU MDR and IVDR: International Impact of the New EU Regulations (National Harbor 10-11)  
  Software as a Device (National Harbor 10-11)  
<p>| 5:30–6:30 pm  | Closing Reception—Next Stop: Vancouver 2018 (Potomac Foyer)           |</p>
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<tr>
<th>MEDICAL DEVICES</th>
<th>IVDS</th>
<th>REGULATORY BUSINESS</th>
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<td>Reprocessing of Medical Devices in the Light of the EU MDR (National Harbor 4-5)</td>
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<td>Human Factors Studies/Usability Engineering (National Harbor 4-5)</td>
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<td>Regulatory Obligations and How to Deal With Unethical Requests (Potomac 1-3)</td>
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<td>Roundtable: What’s New in Europe (National Harbor 2)</td>
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<td>Global Regulation Changes: Latin America (National Harbor 2)</td>
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<td>The Secrets of Successful Meetings With Health Authorities—What You Don’t Know May Hurt You (Potomac 1-3)</td>
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<td>EU IVDR: Classifications/Performance Evaluation (National Harbor 12-13)</td>
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<td>Key Takeaways From the Master Class in Regulatory Intelligence: RI as a Strategic Imperative (Potomac 1-3)</td>
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<td>Social Media Use in Regulated Industries (National Harbor 4-5)</td>
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<td>How to Prioritize Your CAPA Activities (National Harbor 4-5)</td>
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<td>IVDs in China: Navigation of Type Testing and Clinical Evidence Expectations (National Harbor 3)</td>
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<td>Cybersecurity: Considerations for the Medical Device Industry (Potomac 1-3)</td>
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<td>Regulatory Strategies and Techniques for Faster Market Access (National Harbor 4-5)</td>
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<td>Current State: In Vitro Diagnostic Device Studies Using Leftover Human Specimens (National Harbor 3)</td>
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<td>Does Your Firm Have Issues with Data Integrity? Red Flags Investigators Look For (Potomac 1-3)</td>
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<td>ECSF (Potomac 4-6)</td>
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<td>Conversations That Matter 5: Interactions With Health Authorities (Hosted by RAPS Fellows) (Chesapeake 1-3)</td>
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<td>RAC Mini-Session 2 (Chesapeake 4-5)</td>
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<td>Medical Device (National Harbor)</td>
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<td>Global Regulation Changes: China (National Harbor 4-5)</td>
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<td>US Regulatory Landscape for Laboratory Developed Tests (LDTs) (National Harbor 3)</td>
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<td>Recent Developments in Off-label Promotion (Potomac 1-3)</td>
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**BIO** Challenges in Incorporating Real World Data Into Your Regulatory Strategy

4:00–5:30 pm | National Harbor 2

The amount of data life sciences companies are compiling offers them a unique opportunity to use that data to enhance monitoring and compliance programs. Data also can be used in a predictive manner to identify trends and outliers in day-to-day operations. Sales data, open payment data, prescription data, even publicly available data sources can be utilized in more ways than ever before. Join us for this session and leave with an understanding of various data sources and how they can be used and learn the tools available to perform certain analytics.

**Speakers:**
Enrica Alteri, MD, head, Human Medicines Research and Development Support Division, EMA
Jonathan Jarow, MD, senior medical advisor, Office of Center Director, CDER, FDA
Stephanie Lewko, associate director, Navigant Consulting
Peter Pitts, president, CMPI; chief regulatory officer, Adherent Health LLC

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**IVD** US Regulatory Landscape for Laboratory Developed Tests (LDTs)

4:00–5:30 pm | National Harbor 3

Do you wonder what is happening with the regulation of Laboratory Developed Tests in the US since the FDA draft guidances were published in 2014, a public workshop was held in 2015 and a discussion paper was issued in early 2017? Diagnostic industry and clinical laboratory experts will share their insight on the current status of this area and future prospects for how the regulatory landscape is taking shape.

**Speakers:**
Shirley Furesz, PhD, RAC (CAN), associate director, medical devices, Mapi Group
Mark DuVal, JD, FRAPS, president, DuVal & Associates PA
Steven Gutman, MD, MBA, strategic advisor, Myraqa, Illumina, Inc.
Thomas Sparkman, vice president, government relations, ACLA
**EU MDR and IVDR: International Impact of the New EU Regulations**

4:00–5:30 pm  | National Harbor 10–11

The impact of the new EU regulations will be felt globally, beyond the immediate effect on device access in the EU. You will hear experts from Med Tech Europe, the EU Commission, MHRA and other key opinion leaders discuss the international challenges and opportunities they foresee. We are offering you a great in-depth discussion around emerging market registrations and tenders, the EU’s coordination efforts with other international regulators and partners, and the potential Brexit impact on the regulatory community. This course will help tie it all together.

**Speakers:**
Daniel Moelands, PharmD, MBA, senior director, global regulatory and operations, Medtronic
Jesús Rueda Rodríguez, director international affairs, MedTech Europe
John Wilkinson, MBA, director of devices, Medicines and Healthcare products Regulatory Agency

**Software as a Medical Device**

4:00–5:30 pm  | National Harbor 12–13

With technology moving at a rapid pace, software has seen significant growth in medical devices from standalone devices to mobile apps. This fast-paced creation of software products may be placing users and patients at risk due to a lack of regulatory clarity from authorities. This session will clarify what regulations actually apply and whether your software product qualifies as a medical device.

**Speakers:**
Steven Binion, PhD, MBA, senior director, corporate regulatory policy, BD
Michelle Jump, MS, MSRS, RAC, principal regulatory affairs specialist, Stryker
Bakul Patel, associate center director for digital health, CDRH/FDA

**Global Regulation Changes: China**

4:00–5:30 pm  | National Harbor 4–5

Regulations for the Supervision and Administration of Medical Devices, formally known as Order 650, now has been named Order 680. How much has changed in the latest overhaul of China’s system for regulating medical devices and IVDs, and how does this affect your business? Are you up to date with the Green Channel opportunities in China? Have the Clinical Evidence Reports become more defined? In our session, learn the best strategies for handling China’s fast moving regulatory environment and ensure you are prepared with your new generation of devices entering that market.

**Speakers:**
Kerry George, clinical study manager, Medtronic
Seth Goldenberg, PhD, director, product development strategy, NAMSA
Amra Racic, MBA, principal regulatory affairs policy and advocacy specialist, Medtronic
Echo Yu, MS, RAC (Global), regulatory compliance manager, IBM Watson Health

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**Recent Developments in Off-label Promotion**

4:00–5:30 pm | Potomac 1–3

The area of off-label promotion has been heating up over the past few years with numerous court cases and new FDA guidance. This session will focus on developments over the past year in FDA guidance, new state laws and case law updates that have resulted from off-label promotion. This session will include a review of the recently issued FDA draft guidances and a memorandum offering its recommendations on appropriate medical product communications in different contexts, while also reminding industry the agency will not remain silent if it objects to product messaging. We also will examine Arizona’s The Free Speech in Medicine Act, allowing off-label discussions. Plus, hear an assessment of recent FDA actions for off-label promotion and what we can learn from them.

**Speakers:**
Alan Minsk, partner, leader, food and drug practice team, Arnall Golden Gregory LLP
Margaret Mucha, MJ, CQA, RAC, FRAPS, senior leader RA and QA, IBM Watson
Elizabeth Mulkey, associate, food and drug law practice team, Arnall Golden Gregory LLP

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**2017 REGULATORY CONVERGENCE PLANNING COMMITTEE**

Ayse Baker, PhD, MBA, FRAPS, head regulatory affairs, Chugai Pharma—USA
Kimberly Belsky, MS, senior director, regulatory policy and intelligence, Mallinckrodt Pharmaceuticals
Silvia Bendiner, director regulatory affairs Latin America, Mapi Group
Gert Bos, PhD, FRAPS, executive director and partner, Qserve Group
Linda Bowen, MS, RAC, FRAPS, senior director, regulatory science and policy, Sanofi (vice chair)
Mayank Choudhary, MS, senior manager international regulatory affairs, BD Life Sciences
Daniela Drago, MS, PhD, RAC, director regulatory affairs, The George Washington University
João Duarte, MPharm, MSc, associate director, Europe regulatory policy and intelligence, global regulatory affairs, Takeda Development Centre Europe Ltd.
David Kern, MBA, RAC, senior director, regulatory affairs, Illumina
Jacqueline Monteiro, RAC, director, APAC- Dental Platform, KAVO Kerr
Margaret Mucha, MJ, CQA, RAC, FRAPS, senior leader RA and QA, IBM Watson
David Norr, MBA, senior director, Abbott Nutrition
Susumu Nozawa, RAC, FRAPS, director, regulatory and technical policy, corporate regulatory affairs, BD (chair)
Amra Racic, MBA, principal regulatory affairs policy and advocacy specialist, Medtronic

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Join us in the Exhibit Hall for opportunities to network with companies offering the services and solutions that make it easier for you to excel in your current job. Visit the exhibits during refreshment breaks and at the Taste of National Harbor Reception.

Exhibit Hall Hours

- **Sunday, 10 September** | 6:00–7:30 pm | Exhibit Hall
- **Monday, 11 September** | 10:00 am–4:00 pm | Exhibit Hall
- **Sunday, 10 September** | 6:00–7:30 pm | Exhibit Hall
- **Tuesday, 12 September** | 10:00 am–4:00 pm | Exhibit Hall
- **Monday, 11 September** | 10:00 am–4:00 pm | Exhibit Hall

Attendee Lounge

- **Sunday, 10 September** | 6:00–7:30 pm | Exhibit Hall
- **Monday, 11 September** | 10:00 am–4:00 pm | Exhibit Hall
- **Tuesday, 12 September** | 10:00 am–4:00 pm | Exhibit Hall

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2. Fill in your contact information
3. Visit all the exhibitors listed on the passport and get your passport stamped
4. Drop your exhibitor passport in the box located at RAPS Central by 3:30 pm on Tuesday

Winners will be announced at the closing reception on Tuesday night. You must be present to win.

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Arbour Group is a leading provider of regulatory products and services for the pharmaceutical, medical device and biotechnology industries. These life sciences companies are the singular focus of our organization. Arbour Group is headquartered in Oakbrook Terrace, IL with offices also in California, Massachusetts and New Jersey and Global Test Centers in Dubai, U.A.E. and Manila, Philippines.

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