RAPS Regulatory Convergence

9–12 September 2017

National Harbor at the DC Waterfront

RAPS.org/2017

WORKSHOPS DAY 1: SATURDAY, 9 SEPTEMBER 2017									
8:00–10:00 am	Workshop Registration								
8:00–9:00 am	Workshop Continental Breakfast								
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) • US Regulatory Essentials, Medical Devices and IVDs (National Harbor 2; National Harbor 7 (IVD Breakout)) • EU Regulatory Essentials, Pharmaceuticals and Biologics (National Harbor 3)					
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								
WORKSHOPS AND REGULATORY CONVERGENCE DAY 2: SUNDAY, 10 SEPTEMBER 2017									
7:00 am–6:00 pm	Registration Open								
7:00–8:00 am	Workshop Registration and Workshop Continental Breakfast								
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)			• EU Regulatory Essentials, Medical Device and IVDs: Transitioning From Current Directives Into Future (National Harbor 3; National Harbor 7 (IVD Breakout)) • US Regulatory Essentials, Pharmaceuticals and Biologics (National Harbor 2) • Regulatory Managers Boot Camp (Potomac 4-6) • Master Class in Regulatory Intelligence (Potomac 1-3)					
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									
7:00 am–6:00 pm	Registration Open								
7:00–8:30 am	Continental Breakfast								
7:30–8:15 am	Conversations That Matter 1: Interactions With Health Authorities (Chesapeake 1-3)								
	BIOPHARMACEUTICALS		**HEALTH-RELATED FOODS**	**MEDICAL DEVICES**			**IVDS**	**REGULATORY BUSINESS**	**MULTIPLE**
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)	US FDA Regulation Changes: Clinical Evaluation: Obtaining Full FDA Approval of an IDE (National Harbor 12-13)	Reprocessing of Medical Devices in the Light of the EU MDR (National Harbor 4-5)			
10:00 am–4:00 pm	Exhibit Hall and RAPS Central Open								
10:00–10:45 am	Beverage Break in the Exhibit Hall								
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)	ISO 13485:2016 (National Harbor 10-11)	Recalls/Corrections/Removals (National Harbor 12-13)	Human Factors Studies/Usability Engineering (National Harbor 4-5)		Regulatory Obligations and How to Deal With Unethical Requests (Potomac 1-3)	Roundtable: What's New in Europe (National Harbor 2)
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: India (National Harbor 4-5)	Regulatory Strategy and Rapid Technology Innovation: From Additive to Algorithm (National Harbor 12-13)		Mergers and Acquisitions (Potomac 1-3)	
2:45–3:45 pm	Beverage Break in the Exhibit Hall								
3:00–3:45 pm	Sponsored Education Session by Maetrics; 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 With an Aim to Improve Clinical Research (Hosted by RAPS Fellows) (Chesapeake 1-3) | RAC Mini-Session 1 (Chesapeake 4-5)								
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 Foods/FSMPs—Access and Convenience Matters (Potomac 4-6)	EU MDR: Clinical Evaluation/Classification (National Harbor 10-11)	Medical Device Innovation Consortium (MDIC) Including the National Evaluation System for Health Technology (NEST) (National Harbor 12-13)	Global Regulation Changes: Latin America (National Harbor 2)		The Secrets of Successful Meetings With Health Authorities—What You Don't Know May Hurt You (Potomac 1-3)	
6:00 pm	Dine-Arounds								
REGULATORY CONVERGENCE DAY 4: TUESDAY, 12 SEPTEMBER 2017									
7:00 am–6:00 pm	Registration Open								
7:00–8:30 am	Continental Breakfast								
7:30–8:15 am	Conversations That Matter 3: 101 Ways to Develop an Exciting Regulatory Career (Chesapeake 1-3)								
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)			EU IVDR: Classifications/Performance Evaluation (National Harbor 12-13)	Key Takeaways From the Master Class in Regulatory Intelligence: RI as a Strategic Imperative (Potomac 1-3)	Social Media Use in Regulated Industries (National Harbor 4-5)
10:00 am–4:00 pm	Exhibit Hall and RAPS Central Open								
10:00–10:45 am	Beverage Break in the Exhibit Hall								
10:45 am–12:15 pm	Accelerating Approval for Medical Products in the US: Implications of Recent US Legislation (Potomac 4-6)	AdPromo: Communications, Conversations and Elucidations (National Harbor 2)		EU MDR and IVDR: Postmarket Expectations Including PMCF (National Harbor 10-11)	Medical Device Harmonization Initiatives (National Harbor 12-13)	How to Prioritize Your CAPA Activities (National Harbor 4-5)	IVDs in China: Navigation of Type Testing and Clinical Evidence Expectations (National Harbor 3)		Cybersecurity: Considerations for the Medical Device Industry (Potomac 1-3)
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 Open Exhibit Time								
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 10-11)	The Art of Getting CFDA Premarket Approval in the Shortest Time Possible (National Harbor 12-13)	Regulatory Strategies and Techniques for Faster Market Access (National Harbor 4-5)	Current State: *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens (National Harbor 3)	Does Your Firm Have Issues with Data Integrity? Red Flags Investigators Look For (Potomac 1-3)	
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 Fellows) (Potomac 4–6) | Conversations That Matter 5: Interactions With Health Authorities (Hosted by RAPS Fellows) (Chesapeake 1-3) | RAC Mini-Session 2 (Chesapeake 4-5)								
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 Medical Device (National Harbor 12-13)	Global Regulation Changes: China (National Harbor 4-5)	US Regulatory Landscape for Laboratory Developed Tests (LDTs) (National Harbor 3)		Recent Developments in Off-label Promotion (Potomac 1-3)
5:30–6:30 pm	**Closing Reception—Next Stop: Vancouver 2018 (Potomac Foyer)**								