AGENDA

SATURDAY, 13 SEPTEMBER	
1:00–5:00 pm	Harvard University and John F. Kennedy Presidential Library and Museum Tour
1:00–3:00 pm	Behind the Scenes at Fenway Park Experience Tour
6:00–8:00 pm	Registration and Speaker Ready Room Open

SUNDAY, 14 SEPTEMBER	
7:00–8:00 am	Continental Breakfast – Preconference Rooms
7:00 am–5:00 pm	RAPS Information Station and Bookstore Open
7:00 am–6:00 pm	Registration and Speaker Ready Room Open
8:30 am–5:00 pm	Preconference Workshops Effective Medical Writing – Room 203 Regulatory Essentials: Canada – Room 306 Regulatory Essentials: EU – Room 304 Regulatory Essentials: Japan – Room 210 Regulatory Essentials: US – Room 302 Role of the Authorised Representative in the EU Medical Device Market – Room 206
10:30–11:00 am	Refreshment Break – Preconference Rooms
12:30–1:30 pm	Lunch – Preconference Rooms
12:30–5:00 pm	Career Center Open
1:00–2:15 pm	Boston Duck Tour
1:00–2:45 pm	Old Town Trolley Tour
1:00–5:00 pm	Explore Boston Tour
3:00–3:30 pm	Refreshment Break – Preconference Rooms

Note: Separate registration and payment required for the preconference workshops and the tours. Agenda subject to change. Last updated 15 August 2008.

MONDAY, 15 SEPTEMBER										
7:00–8:30 am	Continental Breakfast – Level 3 Ballroom									
8:30–10:00 am	Keynote Address – Level 3 Ballroom									
10:00–11:00 am	Refreshment Break, Exhibits, Keynote Book Signing – Exhibit Hall C and Auditorium, Level 2									
10:00 am–6:00 pm	Exhibit Hall Open – Exhibit Hall C, Level 2									
	BIOLOGICS/ BIOTECHNOLOGY	**BUSINESS STRATEGY**	**CLINICAL TRIALS**	**COMBO PRODUCTS**	**INTERNATIONAL REGULATORY ISSUES**	**MEDICAL DEVICES**		**PHARMACEUTICALS**		**PROFESSIONAL ISSUES**
11:00 am–12:00 pm	US and EU Regulatory Oversight of Vaccines – Room 306		Adaptive Clinical Trial Design: Mechanics – Room 312	Navigating Japanese and Chinese Regulations with a Combination Drug-Device Product – Room 309	Regulatory Hot Topics Overview: Asia – Room 311	GHTF Overview & Status – Level 3 Ballroom		Pediatric Drug Development in the US and EU – Room 302	Recent Advances in Oncology Drug Development – Room 304	How Did I Get Here? Career Development Panel – Room 310
12:00–1:30 pm	Lunch & Exhibits – Exhibit Hall C and Auditorium, Level 2									
1:30–3:00 pm	Follow-on Biologics (Biosimilars) – Room 304	Trends in FDA Enforcement – Room 311	Adaptive Clinical Trial Design: Case Studies – Room 312	Advertising and Promotion Requirements for Combination Products – Room 309		CDRH Executive Staff Briefing – Level 3 Ballroom		Emerging Markets and Regulatory Agencies: Latin America – Room 302	Issues with Bioavailability, Bioequivalence and Therapeutic Equivalence – Room 306	Internships/ Mentoring: Best Practices for Developing New Regulatory Professionals – Room 310
3:00–3:30 pm	Refreshment Break & Exhibits – Exhibit Hall C and Auditorium, Level 2									
3:30–5:00 pm	Understanding FDA Regulation on Human Tissue Products – Room 306		A Truly Global Product Development Plan – Room 312		Global Harmonization: Fact or Fiction? – Room 311	National Regulatory Requirements for EU: Beyond the CE Mark – Room 302	Advertising and Promotion of Medical Devices – Room 304	CDER Executive Staff Briefing – Level 3 Ballroom		Masters of Our Domain: Furthering the Regulatory Education of Busy Regulatory Professionals – Room 310
5:00–6:00 pm	Exhibitors' Reception – Exhibit Hall C and Auditorium, Level 2									
6:30 pm	Dine-Arounds, Depart from Prefunction Hall C 6:15 pm									

TUESDAY, 16 SEPTEMBER												
7:00–8:30 am	Continental Breakfast – Level 3 Ballroom											
8:30–10:00 am	Keynote Address and Fellows Induction – Level 3 Ballroom											
10:00–11:00 am	Refreshment Break, Exhibits, Keynote Book Signing – Exhibit Hall C and Auditorium, Level 2											
10:00 am–3:30 pm	Exhibit Hall Open – Exhibit Hall C, Level 2											
	BIOLOGICS/ BIOTECHNOLOGY	BUSINESS STRATEGY		CLINICAL TRIALS	COMBO PRODUCTS	INTERNATIONAL REGULATORY ISSUES		MEDICAL DEVICES		PHARMACEUTICALS		PROFESSIONAL ISSUES
11:00 am–12:00 pm	Understanding EU Regulations on Human Tissue Products – Room 310			Exploratory Clinical Trials – Room 309	Drug-Device Combination Products: A Regulatory Perspective – Room 302	Japan Regulatory and Reimbursement Update – Room 304	Pharmaceutical Anti-Counterfeiting Strategies – Room 313	Pre-IDE Process: Optimizing Your Results – Level 3 Ballroom		Seeking Balance: Regulation, Innovation and Cost-Containment of Orphan Biopharma-ceuticals – Room 306	Postmarket Surveillance for Pharmaceuticals – Room 311	Regulatory Affairs Career Options: Finding the One That's Right for You – Room 312
12:00–1:30 pm	Lunch & Exhibits – Exhibit Hall C and Auditorium, Level 2 | Poster Session and Chapter Showcase – Boylston Hallway, Level 3											
1:30–3:00 pm	CBER Executive Staff Briefing – Level 3 Ballroom			Strategic Global Allocation of Trials: Therapeutic Areas and Major Conditions – Room 306	Combination Products: Regulatory Challenges and Latest FDA Initiatives – Room 309	Regulatory Hot Topics Overview: Canada and Latin America – Room 311		Postmarket Clinical Registries – Room 304	Risk Management Interpretation of ISO 14971:2007 – Room 313	CHMP/EMEA Executive Staff Briefing – Room 302	Update on Defining Cardiac Safety Using QTc – Room 310	Communication Practices With Worldwide Regulatory Agencies: North America and Europe – Room 312
3:00–3:30 pm	Refreshment Break & Exhibits – Exhibit Hall C and Auditorium, Level 2											
3:30–5:00 pm		Risk Com-munication – Level 3 Ballroom	The Importance of Global Regulatory Strategy – Room 306	Emerging Safety Issues in Clinical Trials – Room 310	Combination Product Review in EU: Latest Initiatives – Room 309	Environmental Regulations: Impact on Drug Development & Product Stewardship – Room 313		Postmarket Surveillance for Medical Devices – Room 302	Product Testing and China's Regulatory Environment – Room 304	Quality By Design: ICH Q8, Q9 and Q10 – Room 311		Communication Practices With Worldwide Regulatory Agencies: Non-ICH regions and Japan – Room 312
6:00–8:00 pm	RAPS Annual Celebration – Sheraton Grand Ballroom, Second Level											

WEDNESDAY, 17 SEPTEMBER								
6:15–7:00 am	RAPS Foundation 5K Fun Run - Depart from Sheraton Boston Hotel Lobby							
7:30–8:30 am	Continental Breakfast – Level 3 Ballroom & Roundtable Exchange Breakfast – Room 312							
	BIOLOGICS/ BIOTECHNOLOGY	**BUSINESS STRATEGY**	**CLINICAL TRIALS**	**COMBO PRODUCTS**	**MEDICAL DEVICES**		**PHARMACEUTICALS**	
8:30–10:00 am		Emerging Opportunities/ Challenges in Product Lifecycle Management in US – Room 310	Clinical Trials Transformation Initiative, (CTTI): Clinical Aspects – Room 309	Drug-Biologic Combination Products: A Regulatory Perspective – Room 311	Clinical, Regulatory and Reimbursement Strategy – Room 302	IVD Multivariate Index Assays (IVDMIAs) – Room 304	Rx-to-OTC Switch – Room 306	Emerging Markets and Regulatory Agencies: Asia – Room 312
8:30–10:00 am	*Food and Drug Administration Amendments Act* of 2007 (*FDAAA*): One Year Later – Level 3 Ballroom							
10:00–10:30 am	Refreshment Break – Boylston Hallway, Level 3							
10:30 am–12:00 pm	EMEA Executive Staff Briefing – Room 304	Emerging Opportunities/ Challenges in Product Lifecycle Management in Asia and Europe – Room 310	Patient Reported Health Outcome Studies – Room 306	GMP and Adverse Event Reporting – Room 309	Reuse of Single-Use Devices (SUDs) – Room 302		Risk Assessment of Pharmaceuticals in the Environment (PIE) – Room 312	
12:00–2:00 pm	Closing Luncheon, Keynote Address and Awards Presentation – Level 3 Ballroom							
2:30–4:30 pm	RAC Exam Last-Minute Study & Effective Preparation – Room 312							