

SESSION MATRIX

SUNDAY, 24 OCTOBER								
8:30 am–5:00 pm	PRECONFERENCE WORKSHOPS: Combination Products: Overview and Current Status Regulatory Considerations for Asia Pacific (Pharmaceuticals) - Session will begin at 8:00 am Regulatory Managers Boot Camp The Essentials: EU Regulatory Affairs The Essentials: US Regulatory Affairs							
MONDAY, 25 OCTOBER								
8:30–10:00 am	KEYNOTE							
10:00–10:30 am	BREAK							
TRACK	BIOLOGICS AND BIOTECHNOLOGY	CLINICAL	COMPLIANCE AND AUDITS	FOODS AND DIETARY SUPPLEMENTS	MEDICAL DEVICES AND IVDS	PHARMACEUTICALS	REGULATORY BUSINESS	MULTI-TRACK
10:30 am–12:00 pm	Regenerative Medicine: Regulatory Pathway in US, EU and Japan		Achieving Compliance During Equipment and Computer System Validation: A Risk-Based Approach Enforcement: A Review of the First Year of a New Era of Enhanced FDA Enforcement	Structure Function Claims and Scientific Substantiation	Bioresearch Monitoring Inspections Emerging Countries: Overview Information Proposed Changes to IVD Directive	Oncology Drug Development Pediatrics: Making a Global Program Work		
12:00–1:30 pm	LUNCH/SITUATION ROOMS (12:15–1:15 PM)							
1:30–3:00 pm	Update on Cell and Gene Therapy	Safety Review in Clinical Trials Including Vigilance Reporting	Good Laboratory Practice in Regulated and Non-Regulated Environments	Strategies for Implementing the "New" GMPs for Dietary Supplements and Reporting of Serious Adverse Events	Emerging Countries: Submission Details Japan Regulation for Devices	EMA Executive Staff Briefing Nanotechnologies The eCTD: Impacts on the Regulatory Professional		
3:00–3:30 pm	BREAK							
3:30–5:00 pm	Biosimilars Point of Care Devices Versus Combination Products	Considerations for Conducting Clinical Trials Outside the US and Europe Ethical Issues for the Contemporary Regulatory Affairs Professional	Clinical Trial Design for Drugs, Biologics and IVDS		eRegulatory Issues for Devices Challenges to Safeguard Your Product in a Global Market	CDER Executive Staff Briefing	The Role of Regulatory in Clearing the Fourth Hurdle (Reimbursement)	

TUESDAY, 26 OCTOBER

TRACK	BIOLOGICS AND BIOTECHNOLOGY	CLINICAL	COMPLIANCE AND AUDITS	FOODS AND DIETARY SUPPLEMENTS	MEDICAL DEVICES AND IVDS	PHARMACEUTICALS	REGULATORY BUSINESS	MULTI-TRACK
8:30–10:00 am		Best Practices in Critical Clinical Literature Review Precision Monitoring and Auditing Tools for Quality Clinical Trials	Application of DMAIC Methodology for Root Cause Analysis (RCA) and Corrective / Preventive Actions Implementation	Food Safety Regulation and Impact of Emerging Legislations	CDRH Executive Staff Briefing	Cardiac Safety Risk Management From a Global Perspective	Regulatory Business 201	
10:00–10:30 am	BREAK							
10:30 am–12:00 pm	Rapid Detection Methods for Biologics	Update From FDA's GCP Team and Revised MEDDEV Resulting From 2007/47/EC Revision	Rules for Good Clinical Practice/GCP Audits	Global Regulatory Environment or Selected Geographies Regulatory Environment (Europe or Canada)	PMDA Executive Staff Briefing Regulatory Strategies and Implications Unique Device Identifiers – Progresses and Perspectives	Global Pharmacovigilance	Starting Your Own Consulting Company	
12:00–1:30 pm	LUNCH/SITUATION ROOMS (12:15-1:15 PM)							
1:30–3:00 pm	Lessons Learned From H1N1 and HIV Programs		Preparing for a Preapproval Inspection/ How to Conduct an Effective Internal GMP Inspection: Global Perspectives		MDD: Recast of Directive & Informal Panel Discussion Translation/ Labeling Overview of China Medical Device Supervision, Regulation and Technical Evaluation	Drug Development With Reimbursement in Mind Latin America Regulatory Update (Pharma)	Establishing a Regulatory Intelligence Program: Challenges and Lessons Learned Views From the Other Side: Transitional From Agency to Industry	
3:00–3:30 pm	BREAK							
3:30–5:00 pm	CBER Executive Staff Briefing	Implications and Benefits of Trial Registration Around the World	Global Drug and Device Reporting Systems and Compliance	Enforcement and Compliance: Regulatory Compliance for Food, Dietary Supplement and Medical Food Companies	510(K) Program Update Understanding Preclinical Biocompatibility Testing for Medical Devices; Combination Products and Cosmetics	FDA Advisory Committee Meeting Preparation Risk/Benefit	The Role of the Regulatory Affairs Professional in the Due Diligence Process	

WEDNESDAY, 27 OCTOBER

TRACK	BIOLOGICS AND BIOTECHNOLOGY	CLINICAL	COMPLIANCE AND AUDITS	FOODS AND DIETARY SUPPLEMENTS	MEDICAL DEVICES AND IVDS	PHARMACEUTICALS	REGULATORY BUSINESS	MULTI-TRACK
8:30–10:00 am	Orphan Drugs	Clinical Requirements for ATMP			Cross-Cultural Communication Strategies for Successful International Medical Device Submissions	In-Vivo Diagnostics & Theranostics: Regulatory Framework & Challenges Milestone and Scientific Advice Meetings REMS	Talent Management and Regulatory Succession Planning	Current Issues in Advertising and Promotion in Today's Internet and Social Media World
10:00–10:30 am	BREAK							
10:30 am–12:00 pm	SPECIAL SESSION							