US Regulatory Essentials, Pharmaceuticals and Biologics
Tuesday, 2 October 2018

7:00 am	**Registration and Continental Breakfast**
8:00 am	**Welcome and Workshop Introduction**
8:05 am	**Basic Concepts of Drugs and Biologics** • Regulatory definition of drugs and biologics • Law and guidance, practice and precedent • Regulatory organizations at FDA and in industry **Alan McEmber**, Vice President, Global Regulatory Affairs, Shire
8:30 am	**Quality Essentials** • Role of CMC regulatory professional • Common technical document: Quality organization • Special considerations for biologics • Generic drugs and biosimilars • Drug master files • Postapproval activities **Alicia Jeannotte**, Director, Global Regulatory Affairs CMC, Shire
9:15 am	**Nonclinical Essentials** • Pharmacology, pharmacokinetics and toxicology • Considerations for biologicals • IND phase issues • NDA expectations **Nancy Bower,** Senior Director, Global Nonclinical Regulatory, Eisai Inc
10:00 am	**Refreshment Break**
10:15 am	**Early Clinical Development Essentials** • IND overview and timing • Pre-IND consultation • IND requirements/content • FDA review process/outcomes • IND amendments and maintenance (clinical)• • Phase 1 and 2 objectives & considerations • End of Phase 2 meeting **Kevin Dransfield**, Executive Director, Regulatory Affairs, Boehringer-Ingelheim

11:00 am	**Late Clinical Development Essentials**
	• IND: phase 3 considerations
	• Special regulatory considerations
	  ○ Orphan drug designation
	  ○ Fast track or breakthrough designation, accelerated approval
	  ○ Pediatric development
	
	Amanda Goodwin, Director, Global Regulatory Strategy, Eisai Inc

11:45 am	**Lunch**
12:30 pm	**Approval and Postmarketing Essentials** • FDA review timeline and stages • Advisory committee preparations • Labeling negotiations • Postapproval commitments and follow up **Amanda Goodwin**, Director, Global Regulatory Strategy, Eisai Inc
1:15 pm	**Drug Safety Essentials** • Pharmacovigilance overview • Definitions: adverse events vs. adverse reactions, serious events, expectedness • Regulatory reporting essentials **Mary Mease**, Senior Director, Benefit-Risk Management, Lifecycle Safety, Iqvia
2:00 pm	**Advertising, Promotion and Labeling Essentials** • U.S. Prescription Drug Advertising and Promotion • Laws and Regulations • Types of Advertising and Promotion • The Internet and Social Media • Consistent with FDA-Required Labeling and Communications with Payors • Key Considerations for Promotional Review **Wilmar Estrada**, Director, Onesource Regulatory
2:45 pm	**Refreshment Break**
3:00 pm	**Panel discussion** **All Presenters**
3:45 pm	**Review of the Day: Tying It All Together**
4:00 pm	**Adjourn**