US Regulatory Essentials, Pharmaceuticals and Biologics
Sunday, 10 September 2017

7:00 am	**Registration and Continental Breakfast**
8:00 am	**Welcome and Workshop Introduction** **Alan McEmber, MS, RAC,** head, regulatory strategy immunology, vice president global regulatory affairs, Shire
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 **Kevin Dransfield,** director, drug regulatory affairs, Boehringer Ingelheim
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 **Kristin Murray, MS,** vice president, head of 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, regulatory affairs—nonclinical, Eisai Inc.
10:00 am	**Refreshment Break**
10:15 am	**Early Clinical Development Essentials** • IND: phase 1 through phase 2 considerations • Study protocol • Investigator brochure • Annual reports • The end of phase 2 meeting **Alan McEmber, MS, RAC,** head, regulatory strategy immunology, vice president global regulatory affairs, Shire

11:00 am	**Late Clinical Development Essentials**
	• IND: phase 3 considerations
	• Special regulatory considerations
	  o Orphan drug designation
	  o Fast track or breakthrough designation, accelerated approval
	  o 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, market product safety services, Quintiles
2:00 pm	**Advertising, Promotion and Labeling Essentials** • AdPromo fundamentals • Promotional review committees • Labeling overview and relationship to promotion • New technology, the internet and social media **Robert Merrill, JD,** co-founder and managing partner, 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** **Alan McEmber, MS, RAC,** head, regulatory strategy immunology, vice president global regulatory affairs, Shire
4:00 pm	**Adjourn**