Regulatory Strategy for the Biologics Regulatory Professional

Monday, 1 October 2018

8:00 am	**Registration and Continental Breakfast**
9:00 am	**Introductions and Icebreakers** • This session will focus on introducing the panel members as well as introduction of participants to their assigned team. **Linda Bowen, MS, RAC, FRAPS,** Regulatory Policy and Intelligence Expert **Kamali Chance, MPH, PhD, RAC,** Chief Regulatory Officer, BioSciencesCorp **Vanessa D'Souza, PhD,** global regulatory team leader, Pfizer **Jean Dehdashti, MSc, RAC,** regulatory project manager, CBER, FDA **Ning Go, MD,** principal scientist, global IVD lead, clinical biomarkers and diagnostics, Amgen **Monica Meacham, PhD,** senior manager, regulatory affairs, NantBio **William Sietsema, PhD,** executive director, global regulatory affairs, Caladrius Biosciences **Lei Xu, MD, PhD,** chief, general medicine branch 2, OTAT, CBER, FDA
9:15 am	**Key Elements of Regulatory Strategy** This session will examine the basics of regulatory strategy formulation: • Why is it important to have a strategy? • What is involved in developing a strategy? • How is a strategy document typically structured? • What chapters does it contain? • Importance of assessing regulatory landscape, intended claims, speed to market • Considerations for country-specific and global regulatory strategy • How strategy development differs for biosimilars **William Sietsema, PhD,** executive director, global regulatory affairs, Caladrius Biosciences
10:00 am	**The Regulatory Team** This session will evaluate: • The role of the regulatory team as strategic partners in business. • Discuss key players and obtaining buy-in for regulatory strategy. • How the team and its strategy may be impacted by a range of factors, such as business arrangements, regulatory environment changes, and the competitive landscape. **Monica Meacham, PhD,** senior manager, regulatory affairs, NantBio
10:30 am	**Refreshment Break**

10:45 am	**Companion Diagnostic Strategies** This session will cover: • Why is IVD/companion diagnostics strategy important? • Key codevelopment considerations and regulatory procedures in clinical investigation of a companion diagnostic **Ning Go, MD,** principal scientist, global IVD lead, clinical biomarkers and diagnostics, Amgen
11:30 pm	**Target Product Profiles** The Target Product Profile (TPP) is a living document that lays out the vision for the approval and optimal labeling of a safe and efficacious product. This session will: • Discuss the utility and value of a TPP • Provide an overview of the contents of a TPP • Advise on how to approach assembly of a TPP **Monica Meacham, PhD,** senior manager, regulatory affairs, NantBio
12:15 pm	**Lunch**
1:00 pm	**Clinical Development Strategies** This session will review key aspects of clinical development to enhance program efficiency and avoid challenges during regulatory review, including: • Maximize learnings from early clinical development • Optimize primary endpoint selection • Ensure adequacy of safety database **Lei Xu, MD, PhD,** chief, general medicine branch 2, OTAT, CBER, FDA
1:45 pm	**The Preclinical/Early Clinical Interface for Biologics** • The high targeting specificity, including often species specificity, as well as the often extended half-life of biologics versus the typical small molecule, has led to somewhat different concepts being applied at the interface of preclinical and clinical development. Some considerations of regulatory concepts applying to early phase development of biologics, including the preclinical/clinical interface, will be reviewed. **Vanessa D'Souza, PhD,** global regulatory team leader, Pfizer

2:30 pm	**Regulatory Intelligence** • This session will provide a brief overview of the role of regulatory intelligence in developing a global regulatory strategy document. Presentation of various sources of information available to stay current on the global regulatory environment. Provide tips on how to search for different type of information. **Linda Bowen, MS, RAC, FRAPS,** Regulatory Policy and Intelligence Expert
3:15 pm	**Refreshment Break**
3:30 pm	**Immunogenicity: Assessment and Implications for Regulatory Development** • Biological products can be recognized as foreign structures by the human immune system. High level concepts pertaining to immunogenicity assessment and the interpretation of regulatory relevance for different kinds of immunogenicity findings will be reviewed. **Vanessa D'Souza, PhD,** global regulatory team leader, Pfizer
4:15 pm	**Interchangeability of Biosimilars/Study Designs** FDA issued its long-awaited draft guidance for demonstrating biosimilar interchangeability in early 2017. This session will cover the following: • Demonstration of biosimilarity vs interchangeability • Interchangeability design considerations • Interchangeability as part of Phase 3 study design • Standalone interchangeability study design • Assessing interchangeability **Kamali Chance, MPH, PhD, RAC,** Chief Regulatory Officer, BioSciencesCorp
5:00 pm	**Adjourn**