Regulatory Strategy for the Biologics Regulatory Professional
Tuesday, 2 October 2018

7:00 am	**Registration and Continental Breakfast**
8:00 am	**FDA and EMA Thinking on Totality of Evidence in Development of Biosimilars** The regulatory landscape for the development of biosimilars in the US and EU is dynamic as many of the guidances issued by European Medicines Agency (EMA) and US Food and Drug Administration (FDA) have undergone revisions based on experience gained through review and approval of biosimilars for the respective regions. • Discover how biosimilars are regulated in the US and EU • Learn key elements of step-wise development program for biosimilars to meet global requirements • Learn key insights into interactions with the FDA regarding development of biosimilars • Learn key insights into interactions with EMA regarding development of biosimilars • Understand regulatory authority expectations for CMC, nonclinical and clinical similarity exercises **Kamali Chance, MPH, PhD, RAC,** Chief Regulatory Officer, BioSciencesCorp.
8:45 am	**Interacting with Regulators** Effective communications with regulators can help facilitate development and mitigate late stage regulatory challenges. Important skills include: • Formulating effective questions • Preparing briefing package • Creating a collaborative relationship • Elicit learnings from regulators' experience **Jean Dehdashti, MSc, RAC,** regulatory project manager, CBER, FDA
9:30 am	**Comparability for Novel Biologics** • Biological therapies have compositional heterogeneity and this leads to an inability to demonstrate 'sameness' (as is typical for small molecules) which in turn has led to the development of the 'comparability paradigm.' Some very high-level concepts pertaining to comparability assessment for novel biologics will be reviewed. **Vanessa D'Souza, PhD,** global regulatory team leader, Pfizer
10:15 am	**Refreshment Break**

10:30 am	**Advanced Biological Formats: Antibody-drug Conjugates, Bifunctionals, and Combinations: Special Regulatory Considerations** • There are currently numerous types of recombinant biologics in development and approved, but in order to engage a target with a toxic payload, or to engage multiple targets simultaneously, an increasing number of antibody-drug conjugates, bispecific molecules, and novel combinations of biologics are entering development. Special regulatory development considerations that apply to these modalities will be reviewed. **Vanessa D'Souza, PhD,** global regulatory team leader, Pfizer
11:15 am	**Pediatric Strategy** • Europe and United States require either a pediatric plan or granting of a waiver. Europe urges a pediatric plan before conducting any pediatric studies and the United States expects a pediatric plan before conducting pivotal studies. Each region has its own procedures which might lead to separate studies by region, if no attempt is made to harmonize the studies. This presentation will review key regulations globally and offer suggestions for developing a globally harmonized and efficient pediatric plan. **William Sietsema, PhD,** executive director, global regulatory affairs, Caladrius Biosciences
12:00 pm	**Lunch**
12:45 pm	**Global Regulation of Cell Therapies** • This session will provide an overview of how cell therapies are regulated in the United States, Europe, Canada, and Japan. **William Sietsema, PhD,** executive director, global regulatory affairs, Caladrius Biosciences

1:15 pm	**Orphan Strategies**
	• This session will discuss the strategic considerations in developing an orphan drug. Topics of discussion will include:
	  ○ Categories of orphan drugs and how they coincide with your regulatory strategy
	  ○ Regional differences and similarities in orphan drug programs
	  ○ Incentives, risks, and challenges to developing an orphan drug
	  ○ The impact and recent trends of orphan drug programs
	
	Monica Meacham, PhD, senior manager, regulatory affairs, NantBio

2:00 pm	**Biosimilar Case Studies**

4:00 pm	**Adjourn**