Optimizing Your Strategy: Expedited Pathways and More!
Monday, 1 October 2018

Facilitators:

Ayse Baker – Head of Regulatory Affairs, Chugai Pharma USA
Meredith Brown-Tuttle - Regulatory Consultant, Regulatorium
Ruth Turner, Senior Director, Strategy Lead – Immunology, Global Regulatory Affairs, Shire

8:00 am – 9: 00 am	**Registration and Continental Breakfast (Ballroom D)**
9:00 am – 10:30 am	Overview of Expedited Pathway provisions and other opportunities to expedite develop and approval - *Ayse, Meredith, and Ruth* • Expedited Pathways Provisions • Health Authorities offering expedited pathways • Benefits of each pathway (additional meetings, communication, shortened marketing application review time, etc.) • What is expected of a Sponsor with an expedited product • How interacting with an Agency is different with an expedited product
10:30 am – 11:00 am	**Refreshment Break (Level 1 & 2 Burrard Foyer)**
11:00 am – 12:30 pm	Class Exercise: Locating and analyzing precedent of already approved (and rejected) products – *Ayse, Meredith, and Ruth*
12:30 pm – 1:30 pm	**Lunch (Ballroom D)**
1:00 pm – 2:30 pm	Case Exercise: Locating and analyzing precedent of already approved (and rejected) products - *Ayse, Meredith, and Ruth*
3:00 pm – 3:30 pm	**Refreshment Break (Level 1 & 2 Burrard Foyer)**
3:30 pm – 5:00 pm	Case Study – breakout groups will develop an expedited pathway strategy for an assigned product and present rationale and justification to the group. - *Ayse, Meredith, and Ruth*
5:00 pm	**Adjournment**