Navigating the Pre-Approval and Approval Process for Drugs and Biologics

Banner Witcoff's Mercedes Meyer, Ph.D., will present at the American Conference Institute's (ACI)FDA Bootcamp on Wednesday, March 19.

Mercedes and her co-presenter will discuss the pre-approval and approval process for drugs and biologics. The presentation will cover:

The Drug Review Process

- Reviewing the fundamentals of applications; from submission, through filing and beyond
- Making sense of PDUFA Goals, fast track, break through status, and other process enhancements
- Use of administrative appeals

Rx Drugs (Small Molecules)

- Understanding the difference between "new drugs" and other drugs
- Examining the research, development, and approval process for new drugs
- Dissecting the investigational new drug application (IND) vs. the new drug application (NDA)

Biological Products (Large Molecules)

- What are biological products in relation to traditional drugs?
- Deciphering the biologics license application (BLA)
- How do the research, development, and approval process for biological products differ from the process for new drugs?
- Exploring key similarities and differences between the drug and biological product schemes

NDAs and BLAs

- Differentiating between 505(b)(1)s, 505(b)(2)s, and BLAs
- Identifying applications for fixed-dose combination drugs
- Distinguishing complex molecules regulated through NDAs from from small molecules
- Examining standards for approvals
- REMS

More information about this event can be found by clicking here.