



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

NDA 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 small molecules
- Examining standards for approvals
- REMS

More information about this event can be found by [clicking here](#).