Continual Improvement of CDER BLA Submission, Assessment, and Facility Readiness/Inspection: CMC for Biologics & Biosimilars

Tuesday, August 20, 2024
9:30 am – 4:15 pm ET
Hybrid Public Meeting • National Press Club

Background and Meeting Objectives:

During this hybrid public meeting, FDA, sponsor companies, and other experts will explore the root causes of Complete Responses (CRs) related to quality and facility issues for CDER regulated original and biosimilar Biologic Licensing Applications (BLAs). The recent rate of CRs for BLAs may be attributed to various factors which include quality and facility issues. CRs can result in delayed access to treatment for patients and additional time and resource demands for FDA and sponsor companies.

This meeting will seek to identify opportunities and strategies to improve regulatory submissions and enhance regulatory assessment of BLAs. Topics will include:

- Common and recurring data, submission, and facility issues
- Opportunities to improve communication between sponsors, contract manufacturing organizations, FDA, and other relevant stakeholders
- Lessons from BLA successes

Meeting Agenda

9:30 am **Welcome**

9:40 am **Opening Remarks from FDA**

9:50 am **Overview of Trends in Complete Responses for Biologics License Applications**

FDA will present a high-level overview of observed changes in the number and rate of Complete Responses for BLAs in recent years. Presentations will also cover the most common causes of CRs.

10:30 am **Industry Perspective: Common Challenges in Biologics License Applications**

This session will consist of a high-level overview of key challenges associated with applying for Biologics Licenses from the industry perspective, with a particular focus on quality- and manufacturing-related requirements.

11:00 am **Moderated Panel Discussion and Audience Reaction**

This session will provide an opportunity for meeting participants to offer reflections on issues highlighted and identify any missing focus areas to incorporate into the broader discussion of key challenges and productive solutions.

11:30 am **Lunch**

1:00 pm **Improving Bi-Directional Communication for Effective Biologic Licensing Applications**

Panelists will discuss opportunities for improving communication around expectations for and common challenges associated with Biologics License Applications, both before and after an application is submitted.

2:00 pm **Strategies for Facility Readiness in Biologic and Biosimilar Manufacturing**

Panelists will discuss important developments in biologic and biosimilar manufacturing processes and opportunities to improve facility readiness as processes and products evolve.

3:00 pm **Break**

3:10 pm **Next Steps and Strategies for Improving Biologics License Applications and Review**

Synthesizing insights from the day, panelists will discuss concrete strategies for sponsors, regulators, and other stakeholders to reduce the likelihood of Complete Responses for Biologics License Applications and promote timely patient access to therapeutics.

4:00 pm **Closing Remarks and Adjournment**