Partnering with CMOs and CTOs - Opportunities and Challenges for Effective Collaboration and Lifecycle success

Outsourcing : some points to consider.

Mayflower Hotel, Washington D.C.
27Jan 26, Chinese Room 13:45 – 15:00

Workshop Session 1 - Partnering With CMOs and CTOs - Opportunities and Challenges for Effective Collaboration and Lifecycle Success

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

Overview

- Across the biopharma sector, the use of outsourced development and manufacturing partners has become a critical lever for flexibility, speed, and innovation. Large pharma organizations rely on external providers to expand capacity, while small and emerging biotech companies often depend on CDMOs to turn early concepts into viable products. Yet moving from partner selection through development, manufacturing, and ultimately regulatory submission presents both significant opportunities and operational challenges. This session will examine the realities of navigating outsourced models—highlighting issues such as misaligned KPIs, limited internal resources, differing expectations around timelines and risk, and the complexity of coordinating across multiple technical and operational interfaces. We will discuss practical strategies to strengthen collaboration, improve decision-making, and build more resilient, transparent, and effective working relationships with CDMOs to support lifecycle success.

Areas to consider

1. Outsourcing and Regulatory Reality
- Where do outsourcing models most often succeed or break down when quality and compliance are on the line?
- How do regulatory expectations change the risk profile of CDMO partnerships?
- What's the cost of discovering quality gaps too late?

Essentially: "Would this partnership survive a regulatory inspection?"

2. Outsourcing and CDMO Regulatory & Development Experience
- What does experience count for across biopharma models
- Is a CDMO track record on Development and Inspection history a comfort for regulatory agencies?

3. The ever increasing need to shorten Development / Manufacturing timelines
- Particular focus on China
- Cost v Quality v Speed
- How do sponsors keep track of quality?
- A shared responsibility for Quality, Compliance and IND

4. Smaller companies v Large Pharma
- VC dependent, Increased competition

5. Building Inspection-Ready, Trust-Based Partnerships
- What does "inspection readiness" look like in a shared-responsibility model?
- How can sponsors and CDMOs create transparency without triggering defensive behavior?
- What governance practices actually strengthen quality culture across organizations?