PDA CDMO Partnership Workshop 2025

Agenda

Monday, 5 May

SGT Standard Time (UTC +8:00)

08:30 – 09:00	**Registration**
09:00 – 09:10	**Welcome and Workshop Introduction** **Jennifer Cheung** , VP of Global Quality Assurance Operations, *Gilead Sciences*
09:10 – 09:50	**Global Regulatory Requirements and Trends for Outsourced Operations** The evolving regulatory landscape in parenteral packaging impacts CDMO businesses significantly. With stricter compliance requirements and increasing quality standards, CDMOs must adapt swiftly to remain competitive. This presentation will explore these changes and emphasize the importance of collaboration between pharmaceutical companies and CDMOs. Through open communication and shared goals, these partnerships can drive innovation, ensure product safety, and accelerate time-to-market, ultimately benefiting both parties and enhancing patient care. **Bettine Boltres PhD**, Director Scientific Affairs, Integrated Systems, *West Pharmaceutical Services*
09:50 – 10:30	**Sourcing Decision: From RFP to Contract Award – What is on the Mind of Sponsor versus CDMO** Manufacturing process development for complex biologics and cell and gene therapies has significantly increased the demand of specialized talents in the industry. Sponsors often face challenges including internal skill gaps, resource and budget constraints, as well as timeline stress from research, development to manufacturing and IND application. The decision for biopharma to outsource to Contract Research Development and Manufacturing Organization (CRDMO) may reduce operational cost and supply chain limitation, shorten development timeline, and accelerate IND readiness through effective technology transfer and process optimization while maintaining regulatory compliance. Here we present the key considerations and what is on the mind of the sponsor to make the decision from request for proposal (RFP) to CRDMO contract award. **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)*
10:30 – 11:00	**Coffee Break**
11:00 – 12:00	**CDMO Selection Case Study** In this small group exercise, participants will be provided a list of CDMO with varying profiles, strengths, and weaknesses. The goal is to simulate how to define selection process parameters based on your business need, so you can select the right CDMO to enable business success. This concept of this case study can be used to build you own selection tools and will help you to impact the business result in a positive manner. **Jennifer Cheung** , VP of Global Quality Assurance Operations, *Gilead Sciences*
12:00 – 13:00	**Lunch break**
13:00 – 13:40	**How To Craft A Winning RFP: From Process, How to Select Contract Testing Laboratory and Consulting Services** ***Related Technical Reports (TR): Technical Report No.90: Contamination Control Strategy Development*** **Miriam Guest** , Senior Principal Scientific Advisor, *Charles River Labs, Microbial Solutions*
	How to Effectively Manage Technology Transfer – Sponsor versus CDMO Technology transfer (TT) from a product company (Sponsor) to a CDMO with research capability (CRDMO) requires proactive and thoughtful investment by a dedicated technical team to leverage expertise in research, process development, optimization and scale up manufacturing. This session will depict the details of CRDMO selection and collaboration, which have several

13:40 – 14:30	key steps and considerations from the request for proposals (RFP), TT, raw material gap, facility fit to comprehensive risk assessment, and how to capture information in development and analytical reports that can lead to optimizing final lockdown process parameters in manufacturing and enable successful regulatory submission. **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)*
14:30 – 15:00	**Coffee Break**
15:00 – 16:20	**It Is All About Relationship Management** Effectively navigating a sponsor-CDMO partnership is a complex task with a mutually beneficial outcome. The chosen CDMO significantly impacts business success and maintaining a strong relationship hinges on recognizing each partner's strengths and capabilities. This session will delve into potential partnership conflicts and the importance of working through short-term tensions to achieve long-term goals. Participants will apply the insights acquired from our presenters to navigate a sponsor-CDMO conflict, discovering effective ways to address the disagreement with respect, even in the face of unforeseen challenges. **Jennifer Cheung** , VP of Global Quality Assurance Operations, *Gilead Sciences*
16:20 – 16:50	**Panel Discussion / Q&A** **Jennifer Cheung** , VP of Global Quality Assurance Operations, *Gilead Sciences* **Miriam Guest** Senior Principal Scientific Advisor *Charles River Labs, Microbial Solutions* **David Y.H. Chang, Ph.D.** CEO *Taiwan Bio-Manufacturing Corporation (TBMC)* **Bettine Boltres PhD** Director Scientific Affairs, Integrated Systems *West Pharmaceutical Services*
16:50 – 17:00	**Closing Remarks** **Jennifer Cheung** , VP of Global Quality Assurance Operations, *Gilead Sciences*