



# Agenda

## 2024 PDA CDMO Partnership Workshop

Thursday, 28 March

08:00 – 09:00

Continental Breakfast

Room 104B

08:00 – 17:30

Registration Open

Promenade Lobby

09:00 – 10:45

P1: “The Climb”: The Start of CDMO Journey

Room 104A

The 2024 PDA CDMO Partnership Workshop will cover various aspects of the sponsor-CDMO journey, spanning decisions from outsourcing and relationship management to regulatory insights and technology transfer. The opening plenary will begin with a presentation from the U.S. FDA regarding the regulatory landscape of CDMO relationships. Next, strategies for making insourcing vs. outsourcing decisions will be reviewed. Upon choosing outsourcing, the intricacies of CDMO selection, including search criteria, evaluation metrics, and best practices will be explored.

**Moderator: Jackie Veivia-Panter, Consultant**

**Alternate Moderator: William Rohrs, PDA**

09:00 – 09:10

Welcome and Opening Remarks from Workshop Chair

**Chair: Jackie Veivia-Panter, Consultant**

09:10 – 09:35

Regulatory Perspective on Sponsor-CDMO Partnerships

**Presenter: Steven S. Oh, PhD, Deputy Office Director, OCTHT, CBER, U.S. FDA**

09:35 – 09:55

“Should I Stay or Should I Go?” Insourcing vs. Outsourcing

**Presenter: Zeke Johnston, Senior Director, External Manufacturing and Supply Chain, Avenge Bio**

09:55 – 10:15

"Hello, Is It Me You're Looking For": How to Determine Search Criteria and Evaluate CDMOs

**Presenter: Apneet Hayer, Principal Quality Site Mgr GxP Supplier Quality, Roche Genentech**

10:15 – 10:45



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## 2024 PDA CDMO Partnership Workshop

Q&A

10:45 – 11:15

### Networking Break in the Exhibit Area

Room 104B

11:15 – 12:30

### P2: It All Starts with Selecting the Right Collaboration Partner

Room 104A

Outsourcing of a pharmaceutical project is a strategic decision that has a huge influence on the success of the project for years to come. This session will introduce the critical step following the decision to outsource: selecting the right partner for the project.

**Moderator: Morten Munk**, Director, Global Alliance Management, *FUJIFILM Diosynth Biotechnologies*

11:15 – 11:40

#### CDMO Selection and Performance Management

**Presenter: Firelli Alonso, PhD**, Consultant, *ConsultFi Biologics LLC*

11:40 – 12:05

#### Lessons Large and Small: CDMO Interactions from the Big Pharma and Start-up Perspectives

**Presenter: Jay Howlett, MSc, PEng**, Director, External Manufacturing, *Vir Biotechnology, Inc.*

12:05 – 12:30

Q&A

12:30 – 13:30

### Networking Lunch in the Exhibit Area

Room 104B

13:30 – 15:00

### Small Group Work: CDMO Selection Exercise

Room 104A

This session will give participants hands-on experience with the CDMO selection process. With the support of experienced instructors, small groups will work together on a project case study, which will include: an RFP, a list of selection criteria, detailed responses from a number of different types of CDMOs, and a tool to compare and score the different criteria. Utilizing this scoring tool, teams will assess and compare CDMOs to determine the most cost-effective and reliable option.

**Moderator: Morten Munk**, Director, Global Alliance Management, *FUJIFILM Diosynth Biotechnologies*

13:30 – 14:10



# Agenda

## 2024 PDA CDMO Partnership Workshop

Case Study Introduction

13:45 – 14:30

CDMO Selection Exercise

14:30 – 15:00

Report Out and Discussion

15:00 – 15:30

Networking Break in the Exhibit Area

Room 104B

15:30 – 17:00

P3: Walking the Technology Transfer Tightrope

Room 104A

Technology transfer (TT) is not only an integral piece of CDMO partnership but is an art in crafting collaboration. In this session, the presenters will use case studies to review the fundamentals of TT throughout the product lifecycle including common pitfalls, regulatory considerations, and the importance of contracts and the quality agreement.

**Moderator: Grace Lee, PhD, MBA, CQA**, Independent Consultant, *Evalue Consulting LLC*

15:30 – 15:50

Technology Transfer Fundamentals for Building Successful Products with CDMO Partnerships

**Presenter: Beth J. Haas, MChE**, Owner/Consultant, *Haas Pharma Consulting*

15:50 – 16:10

Navigating Standard and Custom Technology Transfer Workflow

**Presenter: Brandon Haigh**, Associate Director, Cell Therapy Process Development, *WuXi Advanced Therapies*

16:00 – 16:40

Case Studies of Tech Transfer Challenges

16:40 – 17:00

Q&A with Additional Panelist

**Panelist: Steven S. Oh, PhD**, Deputy Office Director, OCTHT, CBER, *U.S. FDA*



# Agenda

## 2024 PDA CDMO Partnership Workshop

17:00 – 18:00

Networking Reception in the Exhibit Area  
Room 104B

### Friday, 29 March

08:00 – 09:00

Continental Breakfast  
Room 104B

08:00 – 12:30

Registration Open  
Promenade Lobby

09:00 – 10:30

P4: Strategic Alliances: A Playbook for Effective Partnerships  
Room 104A

There are several key elements essential for successful CDMO collaborations, including crafting effective quality agreements, comprehensive documentation, aligned expectations, ensuring regulatory compliance, and fostering a transparent relationship. Following the presentations, participants will explore the practical dynamics of managing deviations and implementing corrective and preventive actions (CAPAs) using a case study. This real-world scenario will serve as a focal point for discussion, offering valuable insights into how transparency plays a pivotal role in navigating challenges and fostering successful collaborations.

**Moderator: Maria Amaya, PhD**, Lead External Advocacy North America (Quality Policy), *Genentech*

09:00 – 09:20

Execution and Governance of an Outsourcing Relationship: The Client Perspective

**Presenter: Dimpy Gupta, MASc, PMP, CAAM**, Director, Partnerships & External Supply, *Johnson & Johnson Innovative Medicine*

09:20 – 09:40

Execution and Governance of an Outsourcing Relationship: The CDMO Perspective

**Presenter: Morten Munk**, Director, Global Alliance Management, *FUJIFILM Diosynth Biotechnologies*

09:40 – 10:15

Case Studies on the Deployment of an Effective Quality Management System in an Outsourcing Relationship

10:15 – 10:30

Q&A

10:30 – 11:00



# Agenda

## 2024 PDA CDMO Partnership Workshop

### Networking Break in the Exhibit Area

Room 104B

11:00 – 12:30

### P5: How to Get the Most Out of a CDMO Relationship

Room 104A

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.

**Moderator: Jennifer Cheung, MS**, Vice President, Quality Assurance and Regulatory Affairs, *WuXi Advanced Therapies*

11:00 – 11:20

#### The Good, the Bad, and the Ugly of Conflict Management

**Presenter: Jo Anne Valentino, MS**, Vice President, Quality and Regulatory Affairs, *New York Blood Center Enterprises*

**Presenter: Salvatore DelloBuono, MBA**, Director, Quality External Manufacturing, NA EXM Quality Operations, *Bristol Myers Squibb*

11:20 – 12:00

#### Role Play: How to Resolve Conflicts Between CDMOs and a Sponsor Company

**Presenter: Jo Anne Valentino, MS**, Vice President, Quality and Regulatory Affairs, *New York Blood Center Enterprises*

**Presenter: Salvatore DelloBuono, MBA**, Director, Quality External Manufacturing, NA EXM Quality Operations, *Bristol Myers Squibb*

12:00 – 12:25

#### Report Out and Discussion

12:25 – 12:30

#### Closing Remarks from Workshop Chair

**Chair: Jackie Veivia-Panter**, *Consultant*