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 Chief Quality and Compliance Officer BioCentriq

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<th>Time</th>
<th>Session</th>
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<tr>
<td>09:00 – 09:10</td>
<td>Welcome and Opening Remarks from Workshop Chair</td>
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<td>09:00 – 09:10</td>
<td>Chair: Jackie Veivia-Panter Chief Quality and Compliance Officer BioCentriq</td>
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<tr>
<td>09:10 – 09:35</td>
<td>Regulatory Perspective on Sponsor-CDMO Partnerships</td>
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<td>09:10 – 09:35</td>
<td>Presenter: Steven S. Oh PhD Deputy Office Director, OCHHT, CBER U.S. FDA</td>
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<td>09:35 – 09:55</td>
<td>“Should I Stay or Should I Go?” Insourcing vs. Outsourcing</td>
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<td>09:35 – 09:55</td>
<td>Presenter: Zeke Johnston MS Senior Director, External Manufacturing and Supply Chain Avenge Bio</td>
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<td>09:55 – 10:15</td>
<td>&quot;Hello, Is It Me You're Looking For&quot;: How to Determine Search Criteria and Evaluate CDMOs</td>
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<td>10:15 – 10:45</td>
<td>Presenter: Apneet Hayer Principal Quality Site Mgr GxP Supplier Quality Roche Genentech</td>
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10:15 – 10:45
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

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.

11:40 – 12:05

CDMO Selection and Performance Management

Presenter: Firelli Alonso PhD Senior Director, External Supply (Retired) Pfizer

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 – 13:45

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 Independent Consultant Elevalue 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

16:10 – 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

17:00 – 18:00
# Agenda

## 2024 PDA CDMO Partnership Workshop

### Networking Reception in the Exhibit Area

**Room 104B**

**Friday, 29 March**

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<th>Time</th>
<th>Event</th>
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| 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 |

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| 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 |

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

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 Chief Quality and Compliance Officer BioCentriq