08:00 – 09:00

Continental Breakfast

08:00 – 17:30

Registration Open

09:00 – 10:45

P1: Should I Stay or Should I Go? Insourcing vs. Outsourcing

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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<tbody>
<tr>
<td>09:00 – 09:10</td>
<td><strong>Welcome and Opening Remarks from Workshop Chair</strong></td>
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|           | **Chair:** Jackie Veivia-Panter  
Chief Quality and Compliance Officer  
*BioCentriq* |
| 09:10 – 09:35 | **Title to be Announced** |
|           | **Presenter:** Steven Oh PhD  
Deputy Office Director, OTP, CBER  
*U.S. FDA* |
| 09:35 – 09:55 | **Title to be Announced** |
|           | **Presenter:** Zeke Johnston MS  
Senior Director, External Manufacturing and Supply Chain  
*Avenge Bio* |
| 09:55 – 10:15 | **Title to be Announced** |
|           | **Presenter:** Apneet Hayer  
Principal Quality Site Manager  
*GxP Supplier Quality North America  
Roche Genentech* |
| 10:15 – 10:45 | **Q&A** |
| 10:45 – 11:15 | **Moderator:** Jackie Veivia-Panter  
Chief Quality and Compliance Officer  
*BioCentriq* |

Networking Break in the Exhibit Area

11:15 – 12:30

P2: It All Starts with Selecting the Right Collaboration Partner

Outsourcing of a pharmaceutical project is a strategic decision and 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

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<th>Time</th>
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<tr>
<td>11:15</td>
<td>Lessons Large and Small: CDMO Interactions from the Big Pharma and Start-up Perspectives</td>
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|        | **Presenter:** Jay Howlett MSc, PEang
Director, External Manufacturing
Vir Biotechnology, Inc.                             |
| 11:40  | CDMO Selection and Performance Management                                 |
|        | **Presenter:** Firelli Alonso PhD
Senior Director, External Supply (Retired)
Pfizer                                            |
| 12:05  | Q&A                                                                      |

12:30 – 13:30

Networking Lunch in the Exhibit Area

13:30 – 15:00

Small Group Work: Hands on RFP Drafting Exercise

This session will give participants hands-on experience with the RFP drafting process. With the support of experienced instructors, each table will work as a group 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.

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

15:00 – 15:30

Networking Break in the Exhibit Area

15:30 – 17:00

P3: Walking the Technology Transfer Tightrope
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 Elevale 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

17:00 – 18:00  
Networking Reception in the Exhibit Area

**Friday, 29 March**

08:00 – 09:00  
Continental Breakfast

08:00 – 12:30  
Registration Open

09:00 – 10:30  
P4: Strategic Alliances: A Playbook for Effective Partnerships

There are several key elements essential for successful CDMO collaborations, including crafting effective quality agreements, comprehensive documentation and 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.
### Agenda

**2024 PDA CDMO Partnership Workshop**

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

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<tr>
<td>09:00 – 09:20</td>
<td>Execution and Governance of an Outsourcing Relationship: The Client Perspective</td>
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<td><strong>Presenter:</strong> Dimpy Gupta MASc, PMP, CAAM  Director, Partnerships &amp; External Supply Johnson &amp; Johnson Innovative Medicine</td>
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<tr>
<td>09:20 – 09:40</td>
<td>Execution and Governance of an Outsourcing Relationship: The CDMO Perspective</td>
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<td><strong>Presenter:</strong> Morten Munk  Director, Global Alliance Management FUJIFILM Diosynth Biotechnologies</td>
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<td>09:40 – 10:10</td>
<td>Case Studies on the Deployment of an Effective Quality Management System in an Outsourcing Relationship</td>
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<td>10:10 – 10:30</td>
<td>Q&amp;A</td>
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<td>10:30 – 11:00</td>
<td>Networking Break in the Exhibit Area</td>
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<td>11:00 – 12:30</td>
<td><strong>P5: How to Get the Most Out of a CDMO Relationship</strong></td>
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<td>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 shared goals.</td>
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<td><strong>Moderator:</strong> Jennifer Cheung MS  Vice President, Quality Assurance and Regulatory Affairs WuXi Advanced Therapies</td>
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<td>11:00 – 11:20</td>
<td>Conflict Management</td>
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<td><strong>Presenter:</strong> Jo Anne Valentino MS  Vice President, Quality and Regulatory Affairs New York Blood Center Enterprises</td>
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<td><strong>Presenter:</strong> Sal DelloBuono MBA  Director, Quality External Manufacturing, NA EXM Quality Operations Bristol Myers Squibb</td>
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<td>11:20 – 12:00</td>
<td>Role Play: How to Resolve Conflicts Between CDMO’s and a Sponsor Company</td>
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<tr>
<td>12:00 – 12:25</td>
<td>Table Read Out and Q&amp;A</td>
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12:25 – 12:30

Closing Remarks from Workshop Chair

Chair: Jackie Veivia-Panter Chief Quality and Compliance Officer BioCentriq