Thursday, 28 March

08:00 – 09:00
Continental Breakfast

08:00 – 17:30
Registration Open

09:00 – 10:45
P1: “The Climb”: The Start of CDMO Journey

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter Details</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Welcome and Opening Remarks from Workshop Chair</td>
<td>Chair: Jackie Veivia-Panter Chief Quality and Compliance Officer BioCentriq</td>
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<tr>
<td>09:10</td>
<td>Regulatory Perspective on CDMO Partnerships: Past, Present, and Future</td>
<td>Presenter: Steven Oh PhD Deputy Office Director, OTP, CBER U.S. FDA</td>
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<td>09:35</td>
<td>“Should I Stay or Should I Go?” Insourcing vs. Outsourcing</td>
<td>Presenter: Zeke Johnston MS Senior Director, External Manufacturing and Supply Chain Avenge Bio</td>
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<td>10:15</td>
<td>Hello, Is It Me You're Looking For?: How to Determine Search Criteria and Evaluate CDMOs</td>
<td>Presenter: Apneet Hayer Principal Quality Site Manager GxP Supplier Quality North America Roche Genentech</td>
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<tr>
<td>10:45</td>
<td>Q&amp;A</td>
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10:45 – 11:15
## Agenda

### 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 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*

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| 11:15  | 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  | CDMO Selection and Performance Management  
**Presenter:** Firelli Alonso PhD  
Senior Director, External Supply (Retired)  
*Pfizer* |
| 12:05  | Q&A                                              |

### Networking Lunch in the Exhibit Area

12:30 – 13:30

### 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  
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<tbody>
<tr>
<td>13:30</td>
<td>Case Study Introduction</td>
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<tr>
<td>13:40</td>
<td>RFP Drafting Exercise</td>
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14:30 – 15:00

Report Out and Discussion

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 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 Oh PhD Deputy Office Director, OTP, CBER U.S. FDA

17:00 – 18:00

Networking Reception in the Exhibit Area
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, 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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<tr>
<td>09:00</td>
<td>Execution and Governance of an Outsourcing Relationship: The Client Perspective</td>
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<td>Presenter: Dimpy Gupta MASc, PMP, CAAM Director, Partnerships &amp; External Supply Johnson &amp; Johnson Innovative Medicine</td>
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<tr>
<td>09:20</td>
<td>Execution and Governance of an Outsourcing Relationship: The CDMO Perspective</td>
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<tr>
<td></td>
<td>Presenter: Morten Munk Director, Global Alliance Management FUJIFILM Diosynth Biotechnologies</td>
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<tr>
<td>09:40</td>
<td>Case Studies on the Deployment of an Effective Quality Management System in an Outsourcing Relationship</td>
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<td>10:15</td>
<td>Q&amp;A</td>
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10:30 – 11:00

Networking Break in the Exhibit Area

11:00 – 12:30

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
## Agenda

### 2024 PDA CDMO Partnership Workshop

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<thead>
<tr>
<th>Time</th>
<th>Topic</th>
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<th>Duration</th>
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<tr>
<td>11:00 – 11:20</td>
<td>The Good, the Bad, and the Ugly of Conflict Management</td>
<td>Presenter: Jo Anne Valentino MS&lt;br&gt;Vice President, Quality and Regulatory Affairs&lt;br&gt;New York Blood Center Enterprises&lt;br&gt;Presenter: Salvatore DelloBuono MBA&lt;br&gt;Director, Quality External Manufacturing, NA EXM Quality Operations&lt;br&gt;Bristol Myers Squibb</td>
<td>20 minutes</td>
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<td>11:20 – 12:00</td>
<td>Role Play: How to Resolve Conflicts Between CDMOs and a Sponsor Company</td>
<td>Presenter: Jo Anne Valentino MS&lt;br&gt;Vice President, Quality and Regulatory Affairs&lt;br&gt;New York Blood Center Enterprises&lt;br&gt;Presenter: Salvatore DelloBuono MBA&lt;br&gt;Director, Quality External Manufacturing, NA EXM Quality Operations&lt;br&gt;Bristol Myers Squibb</td>
<td>40 minutes</td>
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<td>12:00 – 12:25</td>
<td>Report Out and Discussion</td>
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<td>25 minutes</td>
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<td>12:25 – 12:30</td>
<td>Closing Remarks from Workshop Chair</td>
<td>Chair: Jackie Veivia-Panter&lt;br&gt;Chief Quality and Compliance Officer&lt;br&gt;BioCentriq</td>
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