

# Outsourcing, Technology Transfer, and CMO-Client Relationships

Please  
Bring Your  
Laptop

## Overview

A large part of biopharmaceutical companies now rely on outsourcing partners for the development and manufacture of biological drug substance and drug product for clinical studies and commercial supply.

The CMC section of a biopharmaceutical project is typically on the time critical path and this can prove a challenge for both the Client (contract giver) and the Contract Manufacturing Organization or CMO (contract acceptor). To ensure a successful collaboration and outcome, client expectations must be aligned with the contracted CMO. A mutual understanding of risk is a prerequisite for designing the right development and manufacturing program. In addition, a sense of “co-ownership” of the project adds value in facilitating a seamless contract execution and completion.

Topics to be covered:

- This workshop will discuss the lessons learned from a broad range of biopharmaceutical projects developed successfully by the workshop instructors, who represent both the Client and the CMO sides.
- The focus of the workshop will be on the key elements to develop a partnership between the parties, covering all phases, from the CMO selection activity, technology transfer of processes and test methods, to project execution including production, testing, and delivery of Clinical Trial Materials (CTM).
- Additionally, the workshop will include an interactive case study, offering the participants hands-on experience with different CMO selection, risk assessment and mitigation, as well as vendor management tools developed to facilitate cost effective and successful transfer and development of biopharmaceuticals in partnership between the Client and the CMO.

## Who Should Attend:

This workshop is designed for all persons involved in outsourcing activities -- either your job function is on the receiving side (the CMO) or you are representing the contract giver (the Client). Relevant job functions include: Project Management, Process and Analytical Development, Production / Manufacturing, Sourcing, Procurement, Quality Assurance and Control, Business Development, and Senior Management.

## Learning Objectives:

Wear the “Hat” of a Big Pharma Sponsor in a safe, educational and entertaining environment, allowing you to explore key outsourcing situations in one day, which normally take years to develop. Experience how applying Risk Assessment tools supports the different elements of the process, including: Choose the right CMO, guide you through the contractual agreement, perform technology transfer and produce a clinical batch of monoclonal antibody while keeping within budget and time constraints!

## Trainers

**Firelli Alonso**, PhD, Senior Director External Supply, Pfizer

**Jon Crate**, Chief Technical Officer, FAI Testing Services

**Kim Hejnaes**, CEO, Hejnaes Consult

**Morten Munk**, Global Technology Partner, NNE

**Thursday, 17 November 2016****9:00 – 18:00**

<b>9:00</b>	<b>Introduction to the Workshop</b> <ul style="list-style-type: none"> <li>• Welcome and introductions – instructors &amp; participants</li> <li>• Expectations from the workshop</li> <li>• Client-CMO relationships</li> </ul>	Morten Munk
<b>9:30</b>	<b>CMO Selection Process and Tools</b> <ul style="list-style-type: none"> <li>• Selection process parameters</li> <li>• Introduction to the CMO selection exercise</li> </ul>	Firelli Alonso
<b>10:30</b>	<b>Coffee Break</b>	
<b>11:00</b>	<b>Group Breakout and Discussion I</b> <ul style="list-style-type: none"> <li>• CMO selection process (50 min)</li> <li>• Justification of CMO choice (20 min)</li> </ul>	
<b>12:30</b>	<b>Lunch Break</b>	
<b>13:30</b>	<b>Technology Transfer and Outsourcing Tools – Part 1</b> <ul style="list-style-type: none"> <li>• Process transfer</li> <li>• Risk assessment and FMEA</li> <li>• Introduction to the FMEA exercise based on CMO choice</li> </ul>	Kim Hejnaes
<b>14:30</b>	<b>Group Breakout and Discussion II</b> <ul style="list-style-type: none"> <li>• Technology transfer FMEA (45 min)</li> <li>• Discussion (15 min)</li> </ul>	
<b>16:00</b>	<b>Coffee Break</b>	
<b>16:30</b>	<b>Closing Remarks – Day 1</b> <ul style="list-style-type: none"> <li>• Lessons learned</li> <li>• Participants' and instructors' feedback</li> </ul>	
<b>18:00</b>	<b>End of Day 1</b>	

**Friday, 18 November 2016****9:00 – 17:00**

<b>9:00</b>	<b>Recap of Day 1</b>	Firelli Alonso, Kim Hejnaes
<b>9:30</b>	<b>Technology Transfer and Outsourcing Tools – Part 2</b> <ul style="list-style-type: none"> <li>• Analytical test methods transfer</li> <li>• Introduction to the exercise based on CMO choice</li> </ul>	Jon Crate
<b>10:30</b>	<b>Coffee Break</b>	
<b>11:00</b>	<b>Group Breakout and Discussion III</b> <ul style="list-style-type: none"> <li>• Analytical methods transfer interactive exercise</li> <li>• Discussion</li> </ul>	
<b>12:00</b>	<b>Lunch Break</b>	
<b>13:00</b>	<b>Production, Testing, and Delivery of Phase I CTM</b> <ul style="list-style-type: none"> <li>• Project execution and management</li> <li>• Introduction to the exercise based on CMO choice</li> </ul>	Morten Munk
<b>14:00</b>	<b>Group Breakout and Discussion IV</b> <ul style="list-style-type: none"> <li>• Production, testing, and delivery of Phase I CTM</li> <li>• Discussion</li> </ul>	
<b>15:00</b>	<b>Coffee Break</b>	
<b>15:30</b>	<b>CMO Performance Management Tools</b> <ul style="list-style-type: none"> <li>• Vendor performance management metrics</li> </ul>	Firelli Alonso
<b>16:15</b>	<b>Closing Remarks – Day 2</b> <ul style="list-style-type: none"> <li>• Lessons learned</li> </ul>	
<b>17:00</b>	<b>End of Workshop</b>	