Workshop: Outsourcing, Technology Transfer, and CMO-Client Relationships

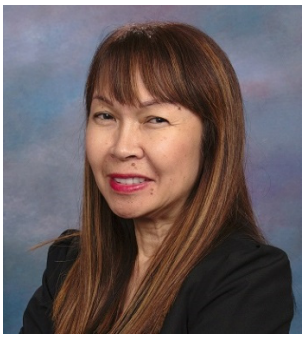
Agenda	
Date / Time	23-24-Nov-2017 / 0900 – 1700 **N.B. Bring your laptops!**
Introduction	A large part of biopharmaceutical companies now rely on outsourcing partners for the development and manufacture of biological drug substance and drug product for clinical studies and commercial supply. The CMC 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 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 stages, 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 a 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.
Why Should You Attend?	Wear the "Hat" of a Big Pharma Sponsor in a safe, educational and entertaining environment, allowing you to explore key outsourcing situations in two days, which normally takes 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!

AGENDA – Day 1 (0900-1700)		
Time	**Leader**	**Topic**
0900 - 0930	Morten Munk	**Introduction to the workshop:** • Welcome and introductions – instructors & participants • Expectations from the workshop • Client-CMO relationships
0930 - 1030	Fi Alonso	**CMO selection process and tools:** • Selection process parameters • Introduction to the CMO selection exercise
1030 - 1100	All	**Coffee / Networking / E-mail Break**
1100 - 1230	All	**GROUP BREAKOUT AND DISCUSSION I** • CMO selection process (60 min) • Justification of CMO choice / Group presentations (30 min)
1230 - 1330	All	**Lunch / Networking Break**
1330 - 1430	Kim Hejnaes	**Technology transfer and outsourcing tools – Part 1:** • Process transfer • Risk assessment and FMEA • Introduction to the FMEA exercise based on CMO choice
1430 - 1600	All	**GROUP BREAKOUT AND DISCUSSION II** • Technology transfer FMEA (60 min) • Discussion (30 min)
1600 - 1630	All	**Coffee / Networking / E-mail Break**
1630 - 1700	Fi Alonso / Kim Hejnaes	**Closing remarks – Day 1:** • Lessons learned • Participants' and instructors' feedback
1700	All	**End of Day 1**

AGENDA – Day 2 (0900-1700)		
Time	**Leader**	**Topic**
0900 - 0930	Fi Alonso / Kim Hejnaes	**Recap of Day 1**
0930 - 1030	Jon Crate	**Technology transfer and outsourcing tools – Part 2:** • Analytical test methods transfer • Introduction to the exercise based on CMO choice
1030 - 1100	All	**Coffee / Networking / E-mail Break**
1100 - 1200	All	**GROUP BREAKOUT AND DISCUSSION III** • Analytical methods transfer interactive exercise (40 min) • Discussion (20 min)
1200 - 1300	All	**Lunch / Networking Break**
1300 - 1400	Morten Munk	**Production, testing, and delivery of Phase I CTM** • Project execution and management • Introduction to the exercise based on CMO choice
1400 - 1500	All	**GROUP BREAKOUT AND DISCUSSION IV** • Production, testing, and delivery of Phase I CTM (30 min) • Discussion (15 min)
1500 - 1530	All	**Coffee / Networking / E-mail Break**
1530 - 1615	Fi Alonso	**CMO performance management tools:** • Vendor performance management metrics
1615 - 1700	Morten Munk / Jon Crate	**Closing remarks – Day 2:** • Lessons learned • Participants' and instructors' feedback
1700	All	**End of Workshop**

Workshop Instructors	Dr. Firelli Alonso Senior Director, External Supply Pfizer, Inc., USA Mr. Jon Crate Chief Technical Officer Advantage Analytical, USA Mr. Kim Hejnaes Partner Hejnaes Consult AB, Sweden Mr. Morten Munk Global Technology Partner NNE, Denmark

WORKSHOP INSTRUCTORS – BRIEF BIOS:



Firelli Alonso, Ph.D.
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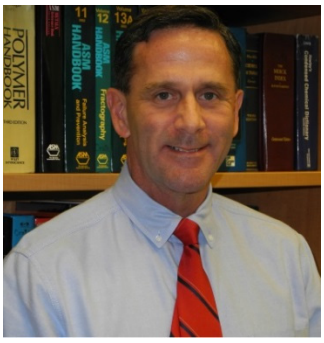
Dr. Firelli Alonso is a Senior Director at Pfizer, Inc. She heads the BioTherapeutics and Vaccines Outsourcing group in Worldwide Research and Development. Fi has more than 33 years of combined experience in research, development, and cGMP production of biological products and vaccines, and more than 13 years of experience in outsourcing, project / contract management, and technology transfer to qualified third parties. Her areas of expertise include viral vectors and vaccine development, biotherapeutics and vaccine process development and cGMP production, project management, technology transfer, outsourcing, and budgets and operations.

She obtained her Ph.D. in Microbiology from the University of Alabama in Birmingham, followed by postdoctoral research at the U.S. Army Medical Research Institute for Infectious Diseases, Sloan-Kettering Institute for Cancer Research, and Rutgers University Center for Advanced Biotechnology and Medicine. Prior to working for Wyeth / Pfizer in 1996, Fi was at The Salk Institute (Government Services Division), a vaccine contract manufacturer for the U.S. Army.



FAI Testing Services
The analysis experts

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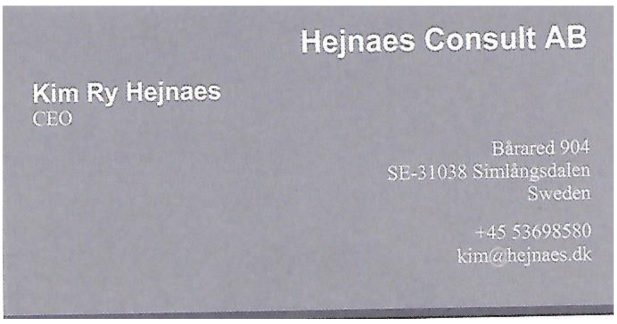
Jon Crate is the Chief Technical Officer at FAI Testing Services which he helped found. He has over 25 years of experience in independent CTO and CRO services, overseeing projects in every phase of medical device and pharmaceutical production from basic and applied research, in-depth characterization of proteins including enzymes and monoclonal antibodies, characterization of glycosylation, comparison of biosimilars, method validation, validation of cleanliness protocols, stability, compatibility, and the testing and evaluation of packaging systems. A significant portion of FAI's work involves failure analysis, and independently conducted investigations of root cause.

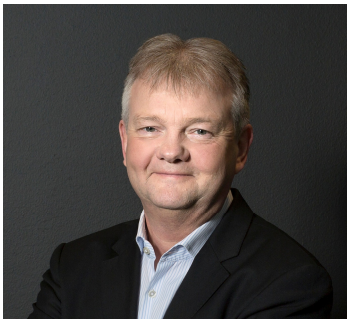
Jon holds a Bachelor of Science degree in Chemistry from the University of Central Florida, a Master of Science in Polymers and Materials Science and Engineering from the Georgia Institute of Technology, and three years of graduate level work in Molecular Cell Biology at the University of Alabama in Birmingham.



KIM RY HEJNAES (M. Sc. in Biochemistry from University of Copenhagen) has worked in the biopharmaceutical industry for more than 35 years as a protein chemistry principal scientist, project director, chief operating officer and chief executive officer hereof 20 years with Novo Nordisk and 5 years with CMC Biologics. Kim Hejnaes is the co- founder of L&K Biosciences, SMC Biotech, Hejnaes Consult, help4biotech and invest4biotech and serves as an adjunct professor in Biotechnology at University of Aalborg, Denmark.

Since 1998, Kim Hejnaes has focused on outsourcing aspects of Chemistry, Manufacturing and Control (CMC) operations with involvement in a substantial number of international biotech projects over the years.

Morten Munk



Position:	Global Technology Partner
Department:	Global Best Practice
Company:	NNE
Education and graduation year:	B.Sc. Hon (Chem. Eng., 1986) Engineering Technology Management (ETM) (2001)
Languages:	Danish and English

Experience:

- 30 years of industry experience in biopharmaceutical development and manufacturing
- Experience areas: Process Development, Facility Design, Single Use Systems, Process Validation, QbD, Tech Transfer, Post Approval Changes, Regulatory Affairs and International Business Development
- Authored or co-authored of technical articles and guidelines
- Frequent presenter at international conferences
- Active in international industry organizations, including ISPE and PDA

Resume:

- Global Technology Partner NNE since 2015
- Vice President for Manufacturing, Downstream Development and finally for Business Development at CMC Biologics A/S in the period from 2001 to 2015
- Co-founded of CMC Biologics A/S 2001
- Principal scientist and other positions at Novo Nordisk A/S from 1986 to 2001