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Biotech Outsourcing Strategies *cmc* 2015

10th and 11th of June, Hilton Park Hotel, Munich

Early and late stage CMC outsourcing for small molecules and biopharmaceuticals

Insight from expert speakers, including;

Signe Maria Christensen
R&D Outsourcing Manager, Leo Pharma A/S

Pepijn Bink
Snr Site Manager, Development CMO's, Roche

Dr Walter Cabri
VP I&D Region Generic API, Fresenius Kabi Anti-Infectives

Dr Ulrich Rümenapp
Head of Biotech Projects, Bayer Pharma AG

Dr Shahid Uddin
Head of Formulation, Medimmune UK

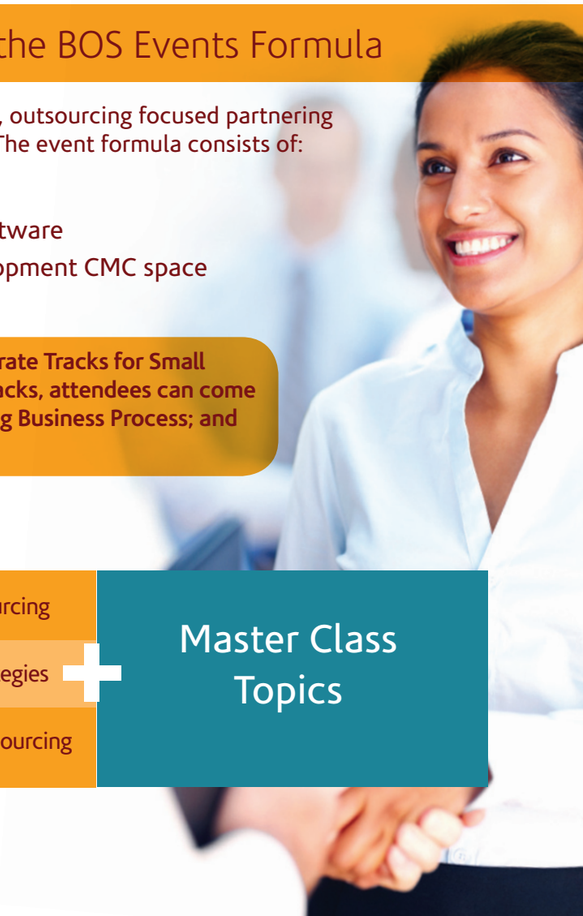
Dr Mary Reilly
VP Pharmaceutical Development &Operations, Opsona Therapeutics

Introduction to BOS *cmc* Munich and to the BOS Events Formula

Launched in 2006 Biotech Outsourcing Strategies Events are niche, outsourcing focused partnering events for the biotech, pharma and contract services community. The event formula consists of:

- Presentations: From thought leaders in the industry
- 1 to 1 Partnering: Delivered by BOS Events Partnering Software
- Exhibition: Meet leading international CMOs in the development CMC space
- Informal Networking: Open and friendly, the BOS ethos

New for BOS *cmc* 2015: a new 2-day format consisting of 2 separate Tracks for Small Molecule and Biologics CMC outsourcing. In addition to these Tracks, attendees can come together: for plenary sessions that explore themes in Outsourcing Business Process; and for Master Class modules.



Principal Programme Blocks

Outsourcing Technical Ops
Drug Substance
Drug Product
Regulatory/QA

+

Business Process in Outsourcing
Supplier Relationship Strategies
Managing Innovation in Outsourcing

+

Master Class Topics

Who should attend BOS *cmc* Munich?

From Biotech & Pharma: Executives involved in the following disciplines: lead optimisation, early scale up, scale up, pre-clinical development, pre-formulation, formulation, CMC, regulatory affairs, clinical CMC development, drug product, drug substance, drug analytics, project managers, programme managers, outsourcing managers, contracts managers.

From CROs and CMO – business development, sales, marketing and corporate management functions.

Here are some comments from past attendees...

"Good size meeting with a good mixture of presentations and opportunities to meet customers and vendors".

Dr Rudolf Hausmann, VP Technical Development & Operations, Santhera Pharma Ltd

"BOS 2014 is always a pleasure to attend. It is well organized, the talks are usually of high quality and the number of suppliers is suitable for an event of this size. I can only recommend attending BOS".

Frederik Barfoed Beck, CMC outsourcing Manager Zealand Pharma A/S

"BOS cmc has become the single most important partnering event of the year. In one day in a well organized and well crafted fashion we enjoyed great presentations and touched base with our most important partners and started the process of finding new experts who can make our future possible".

Paul Little, Director of CMC, 7TM Pharma (now Senior Vice President, CMC, Insusense Therapeutics

Day 1

BOS *cmc* 2015 Small Molecule Programme

09.00 Registration Opens

Outsourcing Business Process – Outsourcing Relationship Strategies

Chair: Dr. Petra Wicklandt, Vice President, Global Head of Chemical & Pharmaceutical Development, Merck KGaA

10.00 **Vested outsourcing: five rules that will transform outsourcing.** Kate Vitasek, Faculty, University of Tennessee, College of Business Administration

10.30 **KPI's to build sustainable outsourcing relationships - A Case study at Actelion for the manufacturing of API.** Dr Jacques-Alexis Funel, Technical Project Leader, Drug Substance Operations, Actelion Pharmaceutical Ltd

11.00 **Communication: a key tool in building a collaborative outsourcing culture.** Dr Signe Maria Christensen, R&D Outsourcing Manager, Leo Pharma A/S

11.30 **Dealing with Agency Theory in Outsourced Projects.** Prof David Bryde, Professor in Project Management, Liverpool John Moores University

12.00 Lunch and partnering

Small Molecule Drug Substance Outsourcing Module

Chair: Dr Paul Madeley, Managing Director, Synth-Isis Ltd

13.30 **Challenges of Placing High Potent and "Cytotoxic" APIs at CMOs.** Pepijn Bink, Snr Site Manager, Development CMO's, Roche

14.00 **Regulatory Strategy for applying the QbD principle in the development of an API/Parental Drug Product.** Dr Richard Dennett, Director, Voisin Consulting Life Sciences

14.30 **Creating a development path for peptide drugs;** ***a biotech case study outlining the development and outsourcing approaches for a clinical development candidate.*** Dr Frederik Barfoed Beck, CMC Outsourcing Manager, Zealand Pharma

15.00 **Quality, Speed, Flexibility and Customer Focus - An Introduction to Cambrex.** Alexandra Pichard Nielsen, Sales & Business Development Director, Cambrex

15.15 **Small Molecule and Synthetic Peptide API development and manufacturing at Almac.** Dr Simon Hamilton, Snr Business Development Manager, API & Chemical Development, Almac Group

BOS *cmc* 2015 Biologics Programme

Biologics Drug Substance Outsourcing Module

Chair: Prof Rolf G Werner, Professorship for Industrial Biotechnology, Eberhard Karls University of Tuebingen, Germany

13.30 **In house manufacturing or outsourcing: best practices in converting an in-house manufacturing set-up into a successful CMO partnership.** Dr Ulrich Rümenapp, Head of Biotech Projects, Bayer Pharma AG

14.00 **Outsourcing partnerships to meet the challenge of innovative therapeutic platforms.** Aiala Lorente-Trigos, Bioprocess R&D Project Coordinator, NovImmune SA

14.30 **Managing outsourcing stability studies for early phase biopharmaceutical drug substance.** Dr Andrew Splevins, Group Leader for Analytical Sciences Group, Ipsen Bioinnovation Ltd

15.00 **Particle identification in sterile products,** Pierre Barratt, Head of CMC, Drug Development Services, LGC

15.15 **Towards the ideal one stop shop.** Andrew Carver, Senior Commercial Development Manager, FUJIFILM Diosynth Biotechnologies

15.30 Coffee Break

Quality and Regulatory Module

Chair: Dr Richard Dennett, Director, Voisin Consulting Life Sciences

16.30 **Outsourcing strategies in the current GMP and Regulatory environment.** Dr Walter Cabri, VP I&D Region Generic API, Fresenius Kabi Anti-Infectives

17.00 **Strategies to enhance quality compliance in outsourced CMC development.** Dawn Toronto, Regulatory Compliance and CMC consultant, CMCPLUS

17.30 **The story of a new biopharmaceutical orphan drug in development Regulatory Challenges and support for SMEs.** Dr Mary Reilly, VP Pharmaceutical Development & Operations, Opsona Therapeutics

18.00 Drinks Reception

Day 2

BOS *cmc* 2015 Small Molecule Programme

Small Molecule Drug Product Outsourcing Module

Chair: Dr Ian Hayter , Principal Consultant, IPHarmaConsult Ltd

08.30 **Strategies to ensure successful CMO selection in drug product sourcing.** Miriam McCloskey, Pharma External Sourcing Specialist (formerly Director, External Manufacturing, Europe Africa Asia, Lilly)

09.00 **External partnering to meet the challenges of neglected disease CMC development.** Dr Joan Herbert, Director of Business Development, Medicines for Malaria Venture

09.30 **"Rapid Screen™ – identifying the best formulation strategy for poorly soluble compounds.** Dr Rob Harris, Chief Technical Officer, Juniper Pharma Services

09.45 **Elemental impurities: multi-element analysis to ICH Q3D and USP** Andrew Maitland, Business Development Manager, Drug Development Services, LGC

BOS *cmc* 2015 Biologics Programme

Biologics Drug Product Outsourcing Module

Chair: Dr Paul Little, Senior Vice President, CMC, Insusense Therapeutics

08.30 **Outsourcing (bio-)manufacture – ensuring IP protection and effective contract making to prevent pitfalls.** Dr Ulrich Rümenapp, Head of Biotech Projects, Bayer Pharma AG

09.00 **Formulation strategies in biopharmaceutical development.** Dr Shahid Uddin, Head of Formulation, Medimmune UK

09.30 **Fast and accurate quantification of mAbs by ICP/MS without a reference substancet.** Dr Colas Swalus, Key Account Manager, Business Development, Quality Assistance SA

09.45 **Patheons OneSource Solutions for Biologics – The efficient way of reducing supply chain complexity.** Nico Faerber, Account Executive, Patheon

10.00 Coffee Break

11.00 Master Class Module

MasterClass 1	MasterClass 2	MasterClass 3
Preformulation and Formulation Considerations for Oral Dose Development James Hurst, Head of Analytical Development & Noel Hamill, Investigator Physical Sciences, Almac Group	**Building a blueprint for successful Tech Transfer** Dr Richard Dennett, Director, Voisin Consulting Life Sciences	**How to structure a Vested Agreement** Kate Vitasek, Faculty, University of Tennessee, College of Business Administration

12.30 Lunch and partnering

Outsourcing Business Process – Innovation in Outsourcing Process

Chair: Kate Vitasek, Kate Vitasek, Faculty, University of Tennessee, College of Business Administration

14.00 **Vested outsourcing in healthcare: unlocking value from strategic partnerships.** Emmanuel Cambresy, Global Supplier Performance & Innovation Manager – Warehousing & Distribution Novartis Business Services

14.40 **Innovative sourcing models for SME sponsors. Global Health Clinical Consortium case study in co-operative sourcing.** Dr Joan Herbert, Director of Business Development, Medicines for Malaria Venture

15.10 **Partnership - A road to increase success and decrease confusion.** Dr Nicolaas Schipper, Section Manager, SP Process Development

15.30 **Speaker/Audience Open Forum.**

16.00 Conference Close and Drinks Reception

Featured speaker profiles

Dr Signe Maria Christensen, R&D Outsourcing Manager, Leo Pharma A/S

Signe Maria Christensen, Ph.D. has more than 13 years of experience with outsourcing of R&D work for the pharmaceutical industry and biotech companies. Signe joined LEO Pharma in April 2011, and in her position as R&D Outsourcing Manager she is responsible for outsourcing of CMC activities up until phase III. Before joining LEO Pharma, Signe has held a position as CMC Coordinator at NeuroSearch and as Development Chemist at Novo Nordisk. Signe received a Master of Chemical Engineering and a Ph.D. in Organic Chemistry from the Technical University of Denmark.

Dr Mary Reilly, VP Pharmaceutical Development &Operations, Opsona Therapeutics

Mary Reilly joined the Opsona management team in March 2005 to head up the pharmaceutical development of its pre-clinical candidates.

Her role is to direct the development of lead compounds from discovery through pharmaceutical development including chemistry, manufacturing and controls (CMC) and their progression into the clinic.

She has extensive experience in drug development from late-stage discovery to registration and approval of products at all stages of the development cycle within Europe and the USA.

Before joining Opsona she worked for 15 years with Elan Pharmaceuticals where she was Associate Director and Project Leader for development projects. She also has experience in parenteral sterile drug development, manufacture and registration.

Mary Reilly currently oversees programme management, pharmaceutical and clinical development and operational activities. She has QP qualifications in line with EU clinical directive 2001/20/EC.

Dr Ulrich Rümenapp, Head of Biotech Projects, Bayer Pharma AG

Dr. Rümenapp is based in Berlin, Germany and working within the Product Supply Biotech division of Bayer Pharma AG, where he is responsible for external manufacturing cooperations in the field of biotechnological APIs and finished products.

In his current position as Head of Biotech Projects in Contract Manufacturing, he provides expertise in team leadership, manufacturing processes, and project management to both current and planned external cooperations, with the goal to ensure reliability in supply, quality, and economy of costs.

Before it was acquired by Bayer, Dr. Rümenapp hold a similar position at Schering AG, and before that, he worked in the production & logistics department of Schering, where he was responsible for production aspects of in- and out-licensing deals, due diligences, and product acquisitions for small molecules and biologics.

Dr. Rümenapp studied chemistry and holds a Ph.D. in biosciences. He worked several years in academic research in the field of signal transduction and as an assistant teacher in the field of general pharmacology.

Pepijn Bink, Snr Site Manager, Development CMO's, Roche

Pepijn Bink is part of Roche's pharma technical development organization and is managing the external development and manufacturing of its small molecule clinical pipeline.

He has 18 years of experience in the pharmaceutical development and supply, leading process development, transfer and scale-up activities in all phases between phase 1 and commercial product launch. He worked for MSD, Xendo, Actelion and in between as a consultant for biotech start-ups and bigger innovator companies, gaining ample experience in working with technical partners, like CMO's and medical device companies, before moving to Roche.

He received his MSc in pharmaceutical technology from the University of Groningen (NL) and has an MBA from Melbourne business school (AUS) & UCLA Anderson (USA).