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Biotech & Pharma Package

£545 + VAT
Available to biotech and pharma delegates (non service providers only)

Package	Price	Features/Conditions
CRO Sponsor	£2850	Full access to the BOS event for 1 delegate Full utilisation of partnering software 4 weeks prior to event
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EARLY AND LATE STAGE CMC
OUTSOURCING FOR SMALL MOLECULES
AND BIOPHARMACEUTICALS

BASEL 2017

27th & 28th June, Basel, Switzerland

Insight from expert speakers, including;

- **Dr Ulrich Rümenapp** – Head of Launch Preparation and Coordination, Bayer
- **Firelli Alonso** – Senior Director, External Supply (BioTherapeutics), Pfizer
- **Jesper Valbjørn** – VP CMC, Genmab A/S
- **Rudolf Hausmann** – VP Technical Development & Operations, Santhera Pharmaceuticals
- **Andrea Calenne** – Senior Manager External Manufacturing, Biogen
- **Joan Herbert** – Director – Business Development, Medicines for Malaria Venture

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

PRINCIPAL PROGRAMME BLOCKS

- Outsourcing Business Process & Strategy
- Early Development Outsourcing
- Late Stage Outsourcing
- Outsourcing Drug Delivery & Packaging (NEW for 2017)
- BOS Outsourcing Showcase (New for 2017 + Posters)

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 phase CMC space
- Informal Networking: Open and friendly, the BOS ethos encourages networking

BOS cmc 2017 Programme Format: 2 Days of high quality presentations, consisting of 2 separate tracks for Small Molecule and Biologics CMC outsourcing respectively.

Who should attend BOS *cmc* ?

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 - 27th June 2017

Times	BOS *cmc* 2017 **Small Molecule Programme**	BOS *cmc* 2017 **Biologics Programme**
08.00 – 10.00	**Registration & 1to1 Partnering**	
10.00 – 12.00	**Effective Outsourcing Process & Strategy** Chair: Dr Alain Bernard, Independent Advisor & Former VP Process Development, UCB	
10.00	Moving Beyond APIs - The Promise of Contract Development and Manufacturing. Dr Unmesh Lal, Programme Manager, Frost & Sullivan	
10.30	Evaluating costs, benefit, risks and rewards of CMC outsourcing strategies. Lidia Cappellina Head of Outsourcing Management, CHIESI FARMACEUTICI	
11.00	Designing and executing a biologics outsourcing process. Dr Ulrich Ruemenapp, Head of Launch Preparation and Coordination, Bayer	
11.30	Managing a tripartite outsourcing collaboration. A case study resulting in improved bio-availability using RapidScreen. Dr Ian Barker, Principle Scientist, Juniper Pharma Services Dr Graham Trevitt – Director, Xenogesis Dr Karen Van de Wal, Senior Lead CMC Drug Product, Galapagos	
12.00 – 13.30	**Lunch & 1to1 Partnering**	
13.30 - 15.30	**Early Development Outsourcing – Small Molecules.** Chair: Dr Paul Deutsch, Head, Chemical Process Development, UCB Pharma	**Early Development Outsourcing – Biologics.** Chair: Dr Richard Dennett, Director, CMC & Quality, Voisin Consulting Life Sciences
13.30	Early Phase Drug Substance Outsourcing Strategy. Dr Chris Davies, Sourcing Project Manager, AstraZeneca.	Cell and Gene Therapy Supply Chain: Not Mission Impossible? Dr Firelli Alonso, Senior Director, External Supply (BioTherapeutics), Pfizer
14.00	Developing a risk based analytical outsourcing strategy for virtual biotech. Dr Mette Husbyn, CMC Manager, Lytix Biopharma	Moving from ´proof of principle´ to first in human trials: an action plan for successful early stage technology transfer. Dr Richard Dennett, Director CMC and Quality, Voisin Consulting Life Sciences
14.30	Phase I formulation strategies - selecting the appropriate oral dosage forms in early stage clinical trials. Dr Rudolf Hausmann, VP Technical Development & Operations, Santhera Pharmaceuticals	Case studies in analytical outsourcing for biologics. Dr Sachin Dubey, Head of Formulation and Analytical Development, Glenmark Pharma
15.00 - 15.15	**Developing paediatric formulations.** Dr Alison Foster, Technical Manager, Quay Pharma	**Successful outsourcing: a CRO perspective.** John Todd, Business Development Manager – Biopharmaceutical Services, Intertek Pharmaceutical Services
15.15 - 15.30	**Integrated early stage outsourcing with CMOs: balancing the benefit of speed, with the potential for risk concentration.** Dr Michel Bulliard, Business Development Manager, Piramal Healthcare	**Managing risks effectively – how to deal with E&L in your biologics.** Dr Karl Abele, Project Manager Extractables and Leachables, Solvias AG I
15.30 – 16.00	**Coffee & 1to1 Partnering**	
16.00 – 18.00	**Building Effective Outsourcing Partnerships (Plenary)** Chair: Dr Roxana Timmermans, Associate Director Global Procurement Biologics, Bristol Myers Squibb	
16.00	How to survive someone else's FDA inspection. Dr Joan Herbert, Director – Business Development, Medicines for Malaria Venture	
16.30	Establishing a framework to support handling of strategic R&D collaborations. Dr Signe Maria Christensen, Strategic Alliance Manager, Leo Pharma A/S	
16.50	Two Sides to Every Coin: Experiences of a Contract Acceptor. Dr Vikki Renwick, Director Commercial Services & David Scott, Senior Director, Tepnel Pharma Services	
18.00 – 20.00	**Drinks Reception**	

Day 2 - 28th June 2017

Times	BOS *cmc* 2017 **Small Molecule Programme**	BOS *cmc* 2017 **Biologics Programme**
08.00 – 09.00	**Registration & 1to1 Partnering**	
09.00 – 10.30	**Late Stage Outsourcing – Small Molecules.** Chair: Frederik Barfoed Beck, Senior Outsourcing Manager, Zealand Pharma	**Late Stage Outsourcing – Biologics.** Chair: Prof Rolf G Werner, Professorship for Industrial Biotechnology, Eberhard Karls University of Tuebingen, Germany
09.00	Key considerations when evaluating your CMO capabilities for the journey to commercialisation. Dr Xiaoyong Fu, VP, Head of process R&D and Commercialization, STA, Antonio Toto, Director of Process Engineering, Pharmaceutical Sciences, Tesaro	Managing communication within tech transfer: balancing effectiveness, quality of deliverables and stakeholder objectives. Dr Andrea Calenne, Senior Manager External Manufacturing,Biogen
09.30	Developing a robust, agile, operating model to support external research collaborations contract lifecycle management. Dr Gabriella Gentile, Global Head of Organizational Effectiveness Pharma Research and Early Development, Hoffmann-La Roche Ltd	How to use QbD/CPV to guide process strategy for late phase outsourced biomanufacturing – a practical example. Jorgen Wittendorff, Senior Director, CMC Manufacturing & Supply, Ablynx nv
10.00	Enabling technologies to improve solubility and stability of portly soluble and labile NCEs. Dr Yogeshwar Bachhav, Associate Director, Pharmaceutical Development, Aicuris GmbH	Preparing for potential commercialisation: Managing Fill & Finish process validation in collaboration with your CMO partner. Dr Aiala Lorente-Trigos, CMC Project Co-ordinator, Novimmune SA
10.30 - 10.45	**Considerations for paediatric outsourcing.** Brian Eastwood, Head of Business Development (EU), Almac	**GE's flexible and fully integrated solutions to support customer's biomanufacturing challenges.** Fabrice Gachot, Solution Modality Leader, GE Healthcare Life Sciences
10.45 - 11.00	**Development by design.** Dr Marco Gil, Senior Director, Commercial Services, Hovione PharmaScience Ltd	**Presentation TBC**
11.00 – 11.30	**Coffee & Partnering**	
11.30 – 12.30	**Drug Delivery & Packaging – Oral Dose Innovations.** Chair: Dr Laura Millichamp, Director, CMC & Quality, Voisin Consultancy Life Sciences	**Drug Delivery & Packaging – Parenteral Drug Delivery Innovations.** Chair: Dr Alexander Bausch, CEO, Strekin
11.30	Constructing an outsourcing collaboration from development to commercial supply of new generation allergy immunotherapy. Dr Annette R Lundegaard, Director of Product Supply SLIT Tablet, Drug Product, ALK & Dr Andrea Cusack, Business Development & Licensing ADT, Catalent Pharma Solutions	Covering all the bases - A contemporary manufacturing strategy is key to strategic drug development. Johannes Clemens, Director Business Development Europe, Vetter
12.00	Mini-tablets for paediatric & geriatric administration. Dr Michael Wilkins, Head of formulation & process development, Almac Group	Driving the external manufacturing for a complex, multi-component, drug product - lessons learnt. Dr. Niko Klan, Director CMO Operations Marketed Products, Merck
12.30 – 14.00	**Lunch & 1to1 Partnering**	
14.00 – 15.30	**Evolving Regulatory Landscape: Managing comparability in outsourced biologics manufacturing.** Chair: Dr Amer Alghabban, VP GxP, Quality Assurance, Compliance & Training, Karyopharm Therapeuitics	
14.00	**Regulatory recommendations re: sub-visible particle thresholds in biological drug products.** Dr Abbas Razvi, Principal Group Leader, Drug Product Services, Lonza	
14.30	**Managing M7 in CMC strategy - challenges faced by innovator and CMO.** Dr David Elder, Consultant and former Director Due Diligence (PQRM), GlaxoSmithKline	
15.00	**FDA recommendations for comparability studies to support manufacturing changes.** Dr Joslyn Brunelle, Product Quality Team Leader, FDA (Office of Biotechnology Products OBP)	
15.45	**Speaker Q&A**	
16.00	**Conference Close & Drinks Reception**	