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BIOTECH OUTSOURCING STRATEGIES

DISCOVERY, EARLY DEVELOPMENT AND CLINICAL OPERATIONS OUTSOURCING

LONDON 2017

3rd October,
Royal College of Physicians, London, UK,

Insight from expert speakers, including;

Dr Simon Cruwys — Head Innovative Medicines Unit, Grunenthal

Dr Arnaud Tiberghien — Senior Scientist, Spirogen (AstraZeneca Group)

Dr Simon Pointon — Associate Principal Scientist, Product Technical Expert, AstraZeneca

Anthony Hall — Therapeutic Area head, Orphan Drugs, Mereo Biopharma

Dr Yaa Adjei — Senior Project Manager, BTG plc

Dr Paul Quinn — Director Clinical Operations, Vectura

What You Can Expect From BOS 2017

- Update Technical Operations Skill Sets
- Build Specialist Outsourcing Knowledge
- Refine Outsourcing Business Process
- Meet New CMO and CRO Partners
- Make Efficient Use Of Limited Travel Budgets By Meeting Your Suppliers All Under 1 Roof
- Network with Peers from Biotech, Pharma and CMO/CRO Community
- Strengthen Existing CMO/ CRO Supplier Relationships
- A Friendly, Welcoming Event Which Fosters Networking & Partnering

Introduction to BOS 2017 and to the BOS Events Formula

Biotech Outsourcing Strategies (BOS) takes place on the 3rd October at the Royal College of Physicians in London. Established in 2006, BOS is unique in offering 2 parallel tracks in discovery/early development outsourcing and clinical outsourcing. As an attendee at BOS 2017 you will learn new perspectives and approaches to tackling shared challenges in R&D outsourcing, delivered through our programme of speakers. You will touch base with your CRO and CMO network, facilitated by our 1 to 1 meeting planner software. Finally, you will be able to build new networks with partners in R&D outsourcing in a relaxed and friendly environment, tried and tested over 10 years of BOS Events.

Who should attend BOS ? London 2017

From Biotech & Pharma: Executives involved in the following disciplines: Discovery biology, discovery chemistry, pharmacology, DMPK, lead validation, lead optimisation, in vitro ADME, early scale up, scale up, pre-formulation, formulation, CMC, regulatory affairs, clinical development, clinical operations, project managers, programme managers, clinical research, outsourcing managers, contracts managers.

Featured speaker profiles

Paul Quinn
Director Clinical Operations, Vectura

Paul Quinn has 20 years Clinical Development experience with a recent focus on Clinical Operations, currently Director – Clinical Operations, at Vectura an SME pharmaceutical company specialising in inhaled therapies. Paul has worked in the Pharma industry previously at Pfizer and Shire where he lead new initiatives in electronic capture of patient data and more recently novel approaches in patient recruitment in and engagement with clinical trials, these included eConsents and trial websites. Paul has also lead effective changes in clinical outsourcing strategy at Shire and Vectura.

Dr Simon Cruwys
Head of Innovative Medicines Unit, Grunenthal

Simon Cruwys Ph.D is head of the Innovative Medicines Unit (IMU) with Grunenthal R&D. Based in Aachen, Germany but with recently opened Innovation Hubs in Leiden and Boston, the IMU is responsible for search and development activities in pain, new technologies and niche diseases, including fibrosis. The IMU fosters a collaborative, cluster-based, approach to building disease knowledge and improve probability of success via a network of external providers.

He was previously a Team Leader in Bioscience at AstraZeneca R&D Charnwood. His team provided in vitro and in vivo pre-clinical support for a number of projects within the Respiratory and Inflammation area. As a Project Leader, he co-ordinated the progression of candidate drugs from early Discovery through to early stage Development (First Time in Man).

Dr Sandra Hirschberg
Project Leader, Centre for Drug Development, Cancer Research UK

Sandra leads cross functional teams to develop cutting edge drugs to contribute to Cancer Research UK's vision "to bring forward the day when all cancers are cured". To contribute to this goal Sandra leads science-based decision making and accelerated development of drugs from the early exploratory phase through to phase II clinical trials, with extensive collaboration with commercial and academic partners.

Sandra graduated from the University of Edinburgh and has a PhD in Immunology from Imperial College. She has more than 16 years experience in drug development and prior to her current role spent several years as a project manager within the pharma industry.

Anthony Fuller MCIPS

Anthony Fuller is Global Head of Sourcing at Mitsubishi Tanabe, a Japanese pharmaceutical company. He is based at their New Jersey office. Prior to joining Mitsubishi, Anthony worked at Eli Lilly and Bristol-Myers Squibb, following some years spent on the supplier side.

In his tenure with Mitsubishi, Anthony has developed what was a largely administrative vendor management department into a strategic function supporting end to end sourcing activities. He re-organized the US team on a category basis and focused their work on high-touch, high value projects. More recently, Anthony was asked to create a global Sourcing function for Mitsubishi, aligning people and processes worldwide.

Anthony is recognized as a strong line manager who invests heavily in coaching as well as supporting more formal training to develop his team. He himself is a graduate of the Universities of Oxford, Sheffield and Northumbria, with postgraduate studies in business, politics and commercial law. He holds Six Sigma Greenbelt certification, CPSM from the Institute for Supply Management, and MCIPS. He lives near Princeton with his wife and two children.

Yaa Adjei,
Senior Project Manager, BTG plc

Yaa is currently working as a Senior Projects and Programme Manager at BTG International; a global specialist healthcare company bringing to market innovative products in specialist areas of medicine to better serve doctors and their patients. Yaa joined BTG International 11 years ago and has provided project management leadership to a variety of projects in early phase clinical development, through to late stage, commercial launches and marked product life cycle management.

Prior to BTG, Yaa worked in projects & programme management roles at other scientific / non-scientific organisations including the Wellcome Trust, DEFRA and FSA, developing expertise in all stages of project oversight from initiating projects, planning, monitoring and controlling, risk and budget management through to successful delivery and benefits realisation. Yaa has a BSc in Biological Sciences from University of Westminster, an MSc in Science Communication from Imperial College London and holds a Six Sigma Lean Green belt. She is member of the Project Management Institute (PMi) and utilises best practice project management methodology for in person and virtual team management with internal cross functional teams and CRO relationship maintenance.

Simon Pointon
Associate Principal Scientist , Chemical Development, AstraZeneca

Simon Pointon is an Associate Principal Scientist within Chemical Development at AstraZeneca. He is currently working as API Technical Lead for the on-market support of two major oncology medicines. Technical management of APIs for marketed products is a diverse role, collaborating closely with contract manufacturing organisations. Typically, areas such as technical transfer of processes, change and deviation management, and process optimisation identification and implementation are covered.

Prior to his current role, Simon led the technical development and commercial implementation of API processes for an oncology medicine that followed a significantly accelerated development path. Simon has a BSc in Chemistry from the University of Birmingham and is currently studying for the APICS Certified Supply Chain Professional qualification. He lives in Macclesfield with his wife and three children.

Dr Brian Dickie
Director Research and Development, Motor Neurone Disease Association

Brian Dickie graduated in 1991 with a Ph.D in Neuropharmacology from the University of Wales College of Medicine. He then took up a research fellowship in the Department of Pharmacology, University of Oxford, where his research on the mechanisms of cell death in Parkinson's disease was combined with medical teaching at Lincoln College, Oxford.

He has worked for the UK Motor Neurone Disease Association as Director of Research Development for 20 years. His role includes providing strategic guidance to the Association's research activities, raising the Association's profile within the biomedical and clinical research communities, increasing the quantity and quality of Association-sponsored and collaborative research, organising the annual International Symposium on Amyotrophic Lateral Sclerosis/Motor Neuron Disease and communicating advances in MND research to lay and specialist audiences.

Here are some comments from past attendees...

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

Following BOS 2014, 23rd September, 2014

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

BOS 2017, 3rd October, 2017 Discovery/Early Development Track

BOS 2017, 3rd October, 2017 Clinical Operations Track

08.00
Registration and Partnering

Discovery/Early Development Track

Chair: Prof Brian Cox, Professor of Pharmaceutical Chemistry, University of Sussex & Director, Photodiversity

10.00 **LAB282 - a new collaborative model to transform academic discovery.**
Dr Mark Slack, VP In Vitro Pharmacology, Evotec AG & Dr Richard Reschen, Senior Technology Transfer Manager, Oxford University Innovation Ltd

10.30 **Utilising a networked R&D approach to harness innovation and drive drug discovery - case studies from Grunenthal IMU.**
Dr Simon Cruwys, Head Innovative Medicines Unit, Grunenthal

11.00 **Navigating the challenges and complexity in sourcing ADC capabilities.**
Dr Arnaud Tiberghien Senior Scientist, Spirogen (AstraZeneca Group)

11.30 **Innovative solutions for immuno-oncology drug discovery.**
Mr Stephen Anderton, Chief Scientific Officer, Aquila BioMedical

12.00 **Lunch and partnering.**

Outsourcing Early Development Module

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

13.30 **Accelerated API development for a breakthrough therapy - Tagrisso Case Study.**
Dr Simon Pointon, Associate Principal Scientist, Product Technical Expert, AstraZeneca

14.00 **The importance of dose prediction in early drug development.**
Dr Rob Harris – CTO, Juniper Pharma Services
Dr Richard Weaver, Managing Director, XenoGesis Ltd

14.30 **Project managing effective outsourced relationships' – CroFab® reconstitution project case study.**
Dr Yaa Adjei, Senior Project Manager, BTG plc

15.00 **Smoothing the development path from early development through commercialization when Working with a CDMO.**
Kasper van den Dries, Senior Director and Principal Scientist, Solid Dose Development, Europe, Patheon

15.15 **Refreshments and partnering**

Clinical Operations Track

Chair: Keith Borkett, Independent Consult

10.00 **Optimal trial design strategies for phase I and proof of principle/concept.**
Dr Robert M Miller, Chief Medical Officer and Managing Partner, Artemida Pharma Limited..

10.30 **Working in alliance with the patient and external partners to transform clinical development in an SME.**
Anthony Hall, Therapeutic Area head, Orphan Drugs, Mereo Biopharma

11.00 **New models of collaborative research: a case study of the transfer of a live clinical trial to new sponsors and stakeholders.**
Sandra Hirschberg, Project Leader, Centre for Drug Development, Cancer Research UK

11.30 **Working in partnership with hospital sites to achieve rapid, efficient and cost effective delivery of early phase clinical trials.**
Dr Peter MacLennan, Chief Operating Officer, Tailored Clinical Research Solutions

12.00 **Lunch and partnering**

Clinical Operations Outsourcing

Chair: Stephen Greentree, Senior Director Development Team Leader, Kyowa Kirin

13.30 **Evaluating sourcing models: costs, benefits, risks and rewards.**
Anthony Fuller, Global Head of Sourcing, Mitsubishi Tanabe Pharma

14.00 **Implementation of a new outsourcing strategy: successes and challenges .**
Dr Paul Quinn, Director Clinical Operations, Vectura

14.30 **Vendor Governance Strategies from an SME perspective.**
Dr Ian Hodgson, Head of Clnical Operations, Mereo BioPharma

15.00 **The politics of utilising a mobile research nursing in clinical trials.**
Helen Springford, Vice President of Strategic Development, Illingworth Resarch

15.15 **Refreshments and partnering**

16.00 **The evolving landscape of the charitable research sector and how stakeholders in R&D can collaborate to maximize opportunities.**

This interactive plenary will explore the following:

- Charitable Research Operational models
- Case Study showcasing opportunities in R&D
- What Charitable Research organisations need from industry
- Role to be played by the CRO sector

Chair: Duncan Judd, CEO, Awridian Ltd.
Speaker1: Dr Madhu Madhusadhan, Senior Business Manager, LifeArc
Speaker 2: Dr Brian Dickie, Director Research & Development, Motor Neurone Disease Association
Speaker 3: Dr Richard Thompson, CEO, Findacure
Speaker 4: Dr Roger Legtenberg, CEO, PSR Group

17.00 **Conference Close – Drinks Reception.**

"For those involved with outsourcing, either as a customer or as a supplier, I can recommend this as one of the truly focused events to explore and find new partners."

Following BOS 2014, 23rd September, 2014

Dr Hans Lindner, Head of Global Pharma Development, Bayer Schering Pharma AG (BOS cmc 16th June 2011)

"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."

Following BOS 2014, 23rd September, 2014

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

Correct at date of print