BIOTECH OUTSOURCING STRATEGIES 2018

Speaker Programme and Event Content 2018

BASEL 2018

19th & 20th June,
Congress Centre Basel, Switzerland.

Discovery & CMC Outsourcing for Small Molecules & Biopharmaceuticals

OUTSOURCING PARTNERING EVENTS FOR THE PHARMACEUTICAL R&D OUTSOURCING COMMUNITY
In a new and exciting development, BOS 2018 will comprise the existing CMC focused event but in addition, will add a new discovery outsourcing component, creating an enlarged 2 day conference in Basel, Switzerland.

The new format will allow discovery and development teams the opportunity to come together to share experience and knowledge from discovery into development. For our CRO and CMO partners the addition of the discovery component to our existing CMC focused event will present an earlier stage in the R&D continuum.

All the above to be explored in the context of outsourcing and R&D contract giver/contract acceptor collaboration

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 CROs and CMOs active in discovery and development stage CMC outsourcing (for both small molecules and biologics)
- Informal Networking: Open and friendly, the BOS ethos encourages networking

**Discovery**

**Use of a collaborative tool to simplify the outsourcing of preclinical study: an insight into the AstaZenea-Charles River Labs strategy.**

In 2012, AstraZeneca entered into a strategic relationship with Charles River Laboratories whereby preclinical safety packages comprising safety pharmacology, toxicology and formulation studies, in vivo ADME, bioanalysis and pharmacokinetics studies are outsourced. New processes were put in place to ensure seamless workflows with the aim of accelerating the delivery of new medicines to patients. AstraZeneca recently engaged Charles River Laboratories for a specific preclinical safety study and the model in which it has been collaboratively rolled out. This talk will highlight the processes in place at AstraZeneca and Charles River Laboratories to ensure integrated workflows that are efficient and visible across the two companies.

**Frederic Martin, Senior Outsourcing Specialist, Drug Safety & Metabolism, AstraZeneca**

**Predicting solid dispersion stability—using multiple linear regression models.**

The aim of this study was to produce a support tool for the formulation development of solid dispersions. A predictive statistic model was built using experimentally obtained stability data of dispersed solid dispersions of APIs used. The model is intended to provide an indication of which polymer and manufacturing method is most likely to give a stable solid dispersion for a certain drug substance. This presentation will outline the findings of the study.

**Ms. Gustave Frondelindt, Senior Scientist, Formulation Science, Janssen Pharma Services**

**CMC (Small Molecules)**

**UAccelerating early API development and manufacture—challenges and opportunities for externalisation.**

This talk will explore the challenges faced in early phase API development and manufacture to provide first in human supplies and where there are opportunities to accelerate this through an externalised network. This will consider the transition from the GSK Discovery+Discovery organisation, describe levers for acceleration and how these are reflected internally as we seek to develop mutually-beneficial relationships with external partners.

**Dr. Andy Walker, Head API, Global External Development, GSK/Scievate**

**CMC (Biologics)**

**Biologics and biologics outsourcing: challenges and opportunities for externalisation.**

Pfizer possesses a diverse biologics portfolio with sustained growth from both internal discovery efforts as well as through external development activity. Acquisitions, in-licensing of individual biologics and investment in technology platforms enables Pfizer to supplement its pipeline, but places huge demands on our internal processes. In such a dynamic situation, Pfizer has become adept at the use of partner models and exploitation of biologics outsourcing. Critical to successful intake, during due diligence, external manufacturing (BioServices) provides an evaluation of the reliability of manufacture and control at the vendor’s contract site. The evaluation includes analyses of outsourcing effectiveness, testing, and importantly process capability in preparation for the facility transfer. A judicious risk-based process has evolved that allows decisions to be made as to whether fully to internalise, proceed in a collaboration in alliance, or allow volume manufacturing and control to continue. We will discuss representative case studies of the internal and external manufacturing of biologics at various stages of clinical development, from preclinical, up to and including late stage post-proof of concept.

**Dr. Vincent Xionu, Director, External Supply, BioTherapeutics, Pfizer**

**Recent examples in outsourcing of microbial process development and manufacturing.**

CapaBioservices is a global provider of downstream process development and manufacturing for the Pharma and Food industry. Microbial fermentation has its opportunities and challenges for tech transfer and manufacturing from lab to pilot to commercial scale. During this short presentation, CapaBioservices would like to highlight recent success from outsourcing of microbial projects.

**Mr. Anis More, Director Sales & Marketing, BioServices, CapaBioservices**

**Preparing for post-commercialization: managing fill and finish process validation in collaboration with your CMO partner.**

Novimmune is a company dedicated to the discovery and development of therapeutic monoclonal antibodies and targeting, rare or orphan diseases and cancer. For one monoclonal antibody product, Novimmune has recently undertaken process validation activities in partnership with a U.S. based manufacturer. This presentation will share our experience and lessons learned in order to manage process validation activities as well as performing such complex activities in partnership with a CMO.

**Dr. Alaa Gueret-Trigo, CMO Manager, Novimmune SA**

**Deliver products faster with the Solvias solution.**

The pressure to produce robust data at increasing rates of growth year on year in a rapidly increasing Regulatory & industry expectation alongside a sharing pipeline of Monoclonal and Biosimilar candidates places huge demands on CMC control strategies.

The Solvias Solution consistently delivers successful Product to Manufacturing, Stability and Comparability studies. The Solvias solution comprises a centralised Analytical and laboratory childhood with all necessary technologies, industry expert support and professional Program management. This unique hub concept means all analysis is performed in-house under the same Quality system, thus allowing optimal laboratory scheduling to deliver the fastest possible outcome. Project management ensures communication excellence with a team of experts are on hand to address all your study design, troubleshooting and data interpretation needs.

**Dr. Ray Sexton, Business Development Manager, Biopharma, Solvias AG”**
BOS Outsourcing Partnering Dynamic

**BOS Outsourcing Dynamic**

- **Supply of Outsourcing Services & Technologies**
- **New Technology & Innovation Development**
- **Account Management**

**BOS Outsourcing Strategies: Facilitating partnering between Contract Giver and Contact Acceptor**

**CONTRACT GIVER**

- **Outsourcing Requirements**
- **Technology/Capabilities Scouting**
- **Relationship Management**

**CONTRACT ACCEPTOR**

(CMO/CRO)

- **Outsourcing Requirements**
- **Technology/Capabilities Scouting**
- **Relationship Management**

**BOS Event Components Delivering Partnering & Matchmaking**

**BOS PARTNERING SOFTWARE**

**CRO & CMO EXHIBITION**

- **Scouting**
- **Technology/Capabilities Scouting**
- **Contract Giver and Contact Acceptor**

**BOS Events are built around the exhibition space. Our venue has been carefully selected to offer an “open plan” space, which allows exhibiting CROs and CMOs the opportunity to present the breadth of their capabilities to the attending biotech and pharma community. See details of the floor plan below.**

**Step 1**

4 weeks prior to the event, Biotech & Pharma participants (Contract Giver) invited to access the Partnering Software and outline outsourcing requirements e.g. looking for a specific FI and finish capabilities.

**Step 2**

3 weeks prior to the event, CRO and CMO participants receive credentials to access the partnering and are invited to outline outsourcing capabilities and 1-to-1 meeting objectives.

**Step 3**

3 weeks – 1 day prior to event. Partnering software fully operational. Delegates can use the software to send meeting requests, based on a specific timeslot, to a fellow delegate who can then accept or decline the meeting request.

**Step 4**

Accepted meeting requests will be scheduled in your agenda at the requested timeslot. You will be able to view your finalised 1-to-1 meeting agenda electronically.

**Step 5**

Go to the allocated partnering table (as shown on your agenda) or exhibitor stand at the specified time to conduct your 1-to-1 meeting.
Go to http://www.bio2bevents.com/registration to complete your registration enquiry online

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