



BIO 2 BUSINESS

EVENT MANAGEMENT

BIOTECH OUTSOURCING STRATEGIES 2018

Speaker Programme and Event Content 2018



BASEL2018



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

Discovery & CMC Outsourcing
for Small Molecules &
Biopharmaceuticals

OUTSOURCING PARTNERING EVENTS FOR
THE PHARMACEUTICAL R&D OUTSOURCING
COMMUNITY



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

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 opportunity to engage with innovator companies at an earlier stage in the R&D continuum.

PRINCIPAL PROGRAMME BLOCKS



WHO SHOULD ATTEND BOS 2018, BASEL

DISCOVERY R&D PROFESSIONALS THOSE INVOLVED IN THE FOLLOWING FUNCTIONS:	CMC R&D PROFESSIONALS THOSE INVOLVED IN THE FOLLOWING FUNCTIONS:
<p>Biotech & Pharma: Target site identification & validation, discovery biology, discovery chemistry, pharmacology, DMPK, lead validation, lead optimisation, in vitro ADME,</p> <p>From CROs and CMO: Business development, sales, marketing and corporate management functions</p>	<p>Biotech & Pharma: PR&D, scale up, drug substance manufacturing, analytical method development, drug product manufacturing, pre-formulation, formulation, outsourcing project managers, external manufacturing, programme managers, contracts managers, CMC procurement</p> <p>From CROs and CMO: Business development, sales, marketing and corporate management functions</p>

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

Discovery

Use of a collaborative tool to simplify the outsourcing of preclinical safety studies: an insight into the AstraZeneca-Charles River Labs strategic relationship.



In 2012, AstraZeneca entered into a strategic relationship with Charles River Laboratories whereby preclinical safety packages comprising safety pharmacology, toxicology, formulation analysis, 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. Here, we describe in more detail the AstraZeneca preclinical safety outsourcing model and the way in which a chosen collaborative tool, iTraX, has helped to translate the processes in AstraZeneca and Charles River Laboratories into simpler integrated workflows that are efficient and visible across the two companies.

Frederic Martin, Senior Externalisation Specialist (Drug Safety & Metabolism), AstraZeneca

Oral BPP4 antagonists as a treatment for atrophic age-related macular degeneration – NIH Blueprint Neurotherapeutics Network (BPN) sponsored research.



The National Institutes of Health (NIH) Blueprint Neurotherapeutics Network (BPN) provides support for small molecule drug discovery and development to companies and academic researchers to develop new medicines to treat nervous system disorders by providing neuroscience researchers a "virtual pharma" including consultants with extensive pharma experience and industry-standard contract services. Since 2011, AMRI has been providing medicinal chemistry support to the BPN including compound design, synthesis, computational chemistry and ADMET services. This presentation will cover the efforts within one of the BPN programs to identify BPP4 antagonists as potential therapeutics for the treatment of atrophic age-related macular degeneration. The development of a conformationally restricted analog with a unique isostere of the anthranilic acid moiety of the lead molecule will be described.

Dr Keith Barnes, Assistant Director, Medicinal Chemistry, AMRI

Creating transformative business partnerships in drug discovery.



Innovation and success rates are major challenges in drug discovery. In order to improve these in Sanofi's pipeline we have introduced new business models which leverage the value of internal Sanofi research, while risk-sharing with a wide variety of external partners, and searching for innovation in new ways. The result should be value generation: increasing the successful translation of exciting biology into commercial projects.

Dr Peter Hamley, Global Head, External Innovation Drug Discovery, Sanofi

Orally bioavailable and in vivo active macrocycles for idiopathic pulmonary fibrosis.



The last decade was marked by an increased interest in intractable targets not amenable to traditional small molecules. Diseases that need a single 'hard target' interaction are known, however, a polypharmacology that attains many interactions is an alternative and perhaps less well exploited approach.

Macrocycles belong to an alternative chemical space with properties between small molecules and biologicals, and although they do not follow Lipinski rule of 5, they do have druggable PhysChem properties¹. Macrolides are an interesting class of macrocyclic molecules used clinically.

We will present our recent in vivo data of our compound at 5 mpk po bid with comparable activity to Nintendanib at 60 mpk qd in a model of idiopathic pulmonary fibrosis. It will include the latest in vitro Fibroblast to Myofibroblast Transition (FMT) results and pharmacokinetic data

Dr Gordon Saxty, Head of Chemistry, Fidelta

FEATURED PRESENTATIONS

CMC (Small Molecules)

Accelerating 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 Time in Human supplies and where there are opportunities to accelerate this through an externalised network. This will consider the transition from Discovery into Development, describe levers for acceleration and how they are reflected in GSK's oversight model as we seek to develop mutually-beneficial relationships with external partners.

Dr Andy Walker, Head of API, Global External Development, GlaxoSmithKline

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 statistical model was built using experimentally obtained stability data and the physicochemical properties of the 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 new drug. In this presentation Ms Fridgeirsdottir will outline the findings of this study.

Ms Gudrun Fridgeirsdottir, Senior Formulation Scientist, Juniper Pharma Services

ZP4207: selection of a late stage API vendor.



The topic will be the selection process of an API vendor for late stage and commercial manufacturing and the following process set-up, qualification and process validation carried out at Bachem.

Dr Frederik Barfoed Beck, Senior Outsourcing Manager, Zealand Pharma & Dr Frank Dettner, Director R&D, Bachem

Complex chemistry, simply delivered: co-crystal design, development and scale-up.



The physicochemical properties of many functional industrial materials including that of active pharmaceutical ingredients, APIs, are dependent upon the crystal structure of that material. Along with polymorph screening and salt selection, the emerging area of cocrystallisation offers a further unique and exciting opportunity for solid form development to enhance or change deficient properties that may be inherent within a particular development candidate, e.g. hygroscopicity, melting point, dissolution rate and processability by modification of the crystal structure. This presentation will highlight aspects of the design, development and scale-up for a specific example of the weakly basic agrochemical active Pyrimethanil.

Prof Chris Frampton, JM Scientific Adviser, Johnson Matthey

CMC (Biologics)

CMO considerations and technology transfer in support of a dynamic biologics portfolio.



Pfizer possesses a diverse biologics portfolio with sustained growth from both internal discovery efforts as well as from business development activity. Acquisitions, in-licensing of individual assets or innovative technology platforms enables Pfizer to supplement its pipeline, but places burden onto the CMC development organization which is responsible for internalization and adaptation of new technologies. In most cases, this must be done quickly to maintain timelines and progress clinical trials. In such a dynamic situation, Pfizer has become adept at the intake process and has enhanced its absorptive capacity. Critical to successful intake, during due diligence, External Supply (aka Outsourcing) makes an evaluation of the reliability of manufacture and controls at the asset's contractor(s). The evaluation includes analysis of outsourcing effectiveness, testing, and importantly process maturity in preparation for technology transfer. A judicious risk-based process has evolved that allows decisions to be made, such as whether to fully internalize, proceed in a collaboration or alliance, versus allowing current manufacturing and testing to continue. We will discuss representative case studies of the internalization and technology transfer of biological therapeutics at various stages of clinical development, from preclinical, up to and including late stage, post-proof of concept

Dr Vincent Turula, Director, External Supply BioTherapeutics, Pfizer

Recent examples in outsourcing of microbial process development and manufacturing.



Capua BioServices is a global provider of services for microbial custom development and manufacturing for the Pharma and Food industry. Microbial fermentation has its opportunities and challenges for biopharmaceutical manufacturing: from lab to pilot to commercial scale. During this short presentation, Capua BioServices would like to highlight recent successes from outsourcing of microbial projects.

Mrs Elise Mous, Director Sales & Marketing/Business Development, Capua Bioservices

Preparing for potential commercialisation: 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 against immune related diseases and cancer. For one monoclonal antibody product, Novimmune has recently undertook process validation activities in partnership with a fill & finish manufacturer. This presentation will share our experience and lessons learned in order to manage process validation activities as well when performing such complex activities in partnership with a CMO.

Dr Aiala Lorente-Trigos, CMC Manager, Novimmune SA

Deliver products faster with the Solvias solution.



The pressure to produce robust analytical data increases year on year. Ever increasing Regulatory & Industry expectations alongside a growing pipeline of Monoclonal and Biosimilar candidates places huge demands on CMC control strategies.

The Solvias Solution consistently delivers successful Protein characterisation, Stability and Comparability studies. The Solvias solution comprises a centralised Analytical laboratory stocked with all necessary techniques, industry Expert support and professional Project 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 while 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

Programme BOS 2018 - Day 1

Time	DISCOVERY OUTSOURCING	CMC OUTSOURCING SMALL MOLECULE	CMC OUTSOURCING BIOLOGICS
08.00 - 09.00	Registration & Partnering		
09.00 - 10.30	Outsourcing Process & Strategy		
09.00	Chair: Dr Guido Koch, COO, Topadur Pharma AG Principles and processes - building a robust, process driven discovery outsourcing operation at BAYER. Dr Jan Huebner, Alliance Manager Technology, Bayer	Chair: Prof. Dr. Tudor Arvinte, Chairman and CEO, Therapeomics Inc/University of Geneva Integrating a CDMO strategy in complex manufacturing environment. Alina Bugajewska, Specialist BioProcess Science, Project Coordinator, Ipsen	
09.30	Outsourcing strategy to support discovery – a PDP perspective. Dr Brice Campo, Director Drug Discovery, Medicines for Malaria Venture	Analyze from a methodological perspective SAP “purchase to pay” cycle in CMC R&D for continuous improvement purposes. Lidia Cappellina, Head of R&D Outsourcing Management, & Massimo Giossi, In/Outsourcing governance & Neo & Special Care Technical Leadership Head, CHIESI FARMACEUTICI S.p.A	
10.00	Creating transformative business partnerships in Drug Discovery. Dr Peter Hamley, Global Head, External Innovation Drug Discovery, Sanofi	The pharmaceutical world of tomorrow: how to get a personalized medication...only by innovative solutions in technology and by innovative way of working. Dr Edith Norrant, Researcher, Innovations Technology Sciences, Université libre de Bruxelles	
10.30 - 11.00	Coffee & Partnering		
11.00	BOS Outsourcing Showcase – Poster Presentations showcasing innovation and excellence in Discovery Outsourcing Services & Technologies. Chair: Dr Matthew Konneh, Director, Konnsult Life Sciences	BOS Outsourcing Showcase – Poster Presentations showcasing innovation and excellence in Small Molecule CMC Services & Technologies Chair: Dr Paul Madeley, Managing Director, Synth-Isis Ltd.	BOS Outsourcing Showcase – Poster Presentations showcasing innovation and excellence in Biologics CMC Services & Technologies Chair: Dr Edith Norrant, Researcher, Innovations Technology Sciences, Université libre de Bruxelles
12.00 - 13.30	Lunch & Partnering		
13.30 - 15.30	Technical Operations Outsourcing – Target ID & Validation to Hit Identification Chair: Dr. Sergio Lociuo, CSO, BioVersys AG	Technical Operations Outsourcing – Early Phase, Small Molecule Chair: Dr David Elder, Principal Consultant, David P Elder Consulting	Technical Operations Outsourcing – Early Phase, Biologics Chair: Dr Alain Bernard, Director, Independent Biopharma Advisor
13.30	Drugging the undruggable – integrated discovery with a chemical biology mindset Dr Ulrich Schopfer, Head, Integrated Target and Lead Discovery, Novartis Pharma AG	Accelerating early API development and manufacture – challenges and opportunities for externalisation. Dr Andy Walker, Head of API, Global External Development, GlaxoSmithKline	CMO considerations and technology transfer in support of a dynamic biologics portfolio. Dr Vincent Turula, Director, External Supply BioTherapeutics, Pfizer
14.00	Collaborative virtual screening to boost neglected tropical disease drug discovery. Dr Ben Perry, Senior Discovery Manager, Drugs for Neglected Disease initiative (DNDi)	Building a robust formulation strategy for phase 1 and beyond. Dr Susanne Ziffels, Group Head Formulation Research & Development, Roche	Implementing an effective manufacturing strategy for biosimilars. Dr Andreas Herrmann, CEO, Valerius Biopharma
14.30	New Chemistry technologies driving early discovery chemistry & sourcing external innovation. Dr Thomas Woltering, Section Head, Therapeutic Modalities, Medicinal Chemistry, Roche Pharmaceuticals Ltd	RNA therapeutics drug product development and experiences of outsourcing for ultra orphan indications. Maarten Van Geffen, Senior Director, Clinical Supplies & Logistics, ProQR Therapeutics	CMO Selection and Management: Creating the fundamentals for successful outsourcing partnerships. Carole Mainguet, Senior Site Manager, External Manufacturing, Roche.
15.00	Partnering for discovery- target to IND capability overview Dr Vikas Shirsath, Senior Vice President, Global Operations, Jubilant Biosys (30 minute presentation)	All aboard: analytical insights fast track your time to market. Joke De Gelder, Project Manager, Anacura – anaRIC biologics	Formulation and development of biologics for oral drug delivery. Mr Jo Vercammen, Director Operational Excellence, Eurofins Amatsigroup (30 minute presentation)
15.15		Accelerating drug development by automation. Dr Edwin Aret, Principal Scientist, Solid State Chemistry, Alcamì	
15.30 - 16.00	Coffee & Partnering		
16.00 - 17.30	Outsourcing Case Studies: Contract Giver and Contract Acceptors Showcase Effective Outsourcing Case Studies. Chair: Laura Millichamp, Consultant, Regulatory & CMC, Independent	Outsourcing Case Studies: Contract Giver and Contract Acceptors Showcase Effective Outsourcing Case Studies. Chair: Dr Rudolf Hausmann, VP Technical Development & Operations, Santhera Pharmaceuticals	Outsourcing Case Studies: Contract Giver and Contract Acceptors Showcase Effective Outsourcing Case Studies. Chair: Karlheinz Landauer, Managing Director, Quality Biotech Development & Cells GMBH
16.00	Advancing assets in drug discovery and early development: building a platform of evidence using networked R&D. Dr Darcey Black, Director, TherapeutAix	Dancing in the dark: development of a scalable synthesis of a novel CXCR3 antagonist through strategic outsourcing. Dr Simone Tortoioli, Senior Chemist, Chemical Development, Idorsia Pharmaceuticals	Small virtual biotech company: CMC outsourcing for antigen-specific cancer immunotherapy. Dr Einar Jonsbu, Director Biopharmaceutical CMC Development, Targovax
16.20	Use of a collaborative tool to simplify the outsourcing of preclinical safety studies: an insight into the AstraZeneca-Charles River Laboratories strategic relationship. Frederic Martin, Senior Externalisation Specialist (Drug Safety & Metabolism), AstraZeneca	Predicting solid dispersion stability - using multiple linear regression models. Ms Gudrun Fridgeirsdottir, Senior Formulation Scientist, Juniper Pharma Services	Role of Advanced Analytics - Mass Spectrometry in Monoclonal Antibody (mAb) Stability Assessment. Dr Ravi Krovidi, Lead Investigator, Biologics, Syngene International
16.40	VBio: The Virtual Bioincubator “pay as you go” therapeutics discovery. Dr Joann Rhodes, Translation and Early Development Support, The Research Network & Dr Andy McElroy, CEO, The Research Network	Complex chemistry, simply delivered: co-crystals design, development and scale-up Prof Chris Frampton, JM Scientific Adviser, Johnson Matthey	Manufacturability of Viral Therapeutics, an emerging field for CDMOs. Prof Rolf G Werner, Professorship for Industrial Biotechnology, Eberhard Karls University of Tuebingen, Germany
17.00	Antibody Assisted Drug Discovery – an industry-academia partnership. Dr Andy Merritt, Associate Director and Head of Chemistry, LifeArc	ZP4207: Selection of a late stage API vendor. Dr Frederik Barfoed Beck, Senior Outsourcing Manager, Zealand Pharma & Dr Frank Dettner, Director R&D, Bachem	Importance of formulation and orthogonal methods for the success of new protein drugs and biosimilars. Prof. Dr. Tudor Arvinte, Chairman and CEO, Therapeomics Inc/University of Geneva
17.30 - 19.30	Drinks Reception		

Programme BOS 2018 - Day 2

Time	DISCOVERY OUTSOURCING	CMC OUTSOURCING SMALL MOLECULE	CMC OUTSOURCING BIOLOGICS
08.00 - 09.00	Refreshments & Partnering		
09.00 - 11.00	Technical Operations Outsourcing – Lead Generation to Lead Optimization Chair: Dr Brian Cox, Professor of Chemistry, University of Sussex, & Director, Photodiversity	Technical Operations Outsourcing – Late Phase, Small Molecule Chair: Dr Alexander Bausch, CEO, Strekin AG	Technical Operations Outsourcing – Late Phase, Biologics Chair: Prof Rolf G Werner, Professorship for Industrial Biotechnology, Eberhard Karls University of Tuebingen, Germany
09.00	New Synthetic Modalities – How to tackle the increasing complexity of a rapidly changing drug discovery environment. Dr Werngard Czechtizky, Senior Director, Head Medicinal Chemistry, IMED RIA, AstraZeneca	Setting specifications in the early Development Phases (Phase I/II). Dr David Elder, Principal Consultant, David P Elder Consulting	Outsourcing late stage development and bio-manufacturing for fast track projects with accelerated timeline – the challenges and needs. Ensuring your external collaboration is fit for purpose. Dr Ulrich Rumenapp, Head of Launch Preparation and Coordination, Bayer AG
09.30	Enabling diverse drug discovery organisations. Dr Dave Madge, Vice President Research	Managing the scale up of drug product development and how to ensure effective CMO selection. Dr Hanu Ramchandruni, Senior Director Technical Product Development, Medicines for Malaria Venture	Integration of hybrid models for next generation manufacturing of biologics into clinical and commercial facilities. Dr Nripen Singh, Associate Director, Manufacturing Sciences and Technology, Bristol-Myers Squibb
10.00	Establishing an effective chemistry / research outsourcing strategy between large pharma and CROs. Lessons learned from 14 years at Pfizer. Dr Richard D Connell, Head of External Research Solutions, Pfizer Inc	Development of complex parenteral formulations. Dr Yogeshwar Bachhav, Associate Director, Pharmaceutical Development, Aicurus GmbH	Preparing for potential commercialisation: Managing Fill & Finish process validation in collaboration with your CMO partner. Dr Aiala Lorente-Trigos, CMC Manager, Novimmune SA
10.30	Oral RBP4 antagonists as a treatment for atrophic age-related macular degeneration – NIH Blueprint Neurotherapeutics Network (BPN) sponsored research. Dr Keith Barnes, Assistant Director, Medicinal Chemistry, AMRI (30 minute presentation)	Continuous flow chemistry for APIs and intermediates. Dr Wolfgang Schiek, Director, Business Development and Sales, Cambrex	Deliver products faster with the Solvias solution. Dr Ray Sexton, Business Development Manager Biopharma, Solvias AG
10.45		API development, production and biocatalysis. Mr François Besselièvre, Account Manager, PCAS, & Audrey Robic, R&D Manager, Proteus	Spray drying - a viable alternative to biopharmaceuticals. Dr Márcio Temtem, Director, PD & Pharmaceutical Development, Hovione, Researcher, Innovations Technology Sciences
11.00 - 11.30	Refreshments & Partnering		
11.30-12.30	PANEL SESSION Chair: Duncan Judd, CEO, Awridian Ltd How will drug pipelines evolve in the future and how best to adapt your outsourcing strategy to meet the challenges presented by new technologies and new therapeutic modalities (NTM)? Speaker 1: Maarten Van Geffen, Senior Director, Clinical Supplies & Logistics, ProQR Therapeutics Speaker 2: Dr Jeremy Parker, Principal Scientist, New Modalities & Tissue Targeting, AstraZeneca Speaker 3: Elmar Zurbruggen, Executive Vice President and Head of Biopharmaceuticals, Solvias AG Speaker 4: Neil Jones, Director Business Development, Europe, Oral Drug Delivery, Catalent Pharma Solutions		
12.30 - 14.00	Lunch & Partnering		
14.00 - 15.30	Outsourcing Case Studies: Contract Giver and Contract Acceptors Showcase Effective Outsourcing Case Studies		
14.00	Chair: Dr Chris Hill, Executive Director of Chemistry & DMPK in Early Discovery, Charles River Laboratories Unlocking drug discovery power through collaborative efforts between academia and CRO : bringing novel Tankyrase inhibitors towards the clinic. Dr Anita Wegert, Director Medicinal Chemistry, Mercachem & Professor Stefan Kraus, Research Team Leader, University of Oslo Hospital	Chair: Amer Alghabban, Managing Director, GXP Compliance & Training Partners Limited Making Magic Bullets; Development and Manufacture of Antibody-Drug Conjugates. Dr Jeremy Parker, Principal Scientist, New Modalities & Tissue Targeting, AstraZeneca	
14.30	Discovery and development of the OMPTA class of antibiotics- impact of CROs. Dr Anatol Luther, Head of Chemistry, Polyphor Ltd	From Complexity to Flexibility: Manufacturing Unique Drug Products. Sean Ramsden, Director, Business Management, Patheon, part of Thermo Fisher Scientific	
15.00	Mouse Clinical Trials: Large Scale in vivo Screening Predicts Drug Response in Cancer Patients. Dr Michael Rugaard Jensen, Director Head of Onc Discovery Pharmacology, Novartis	Can Enzymes Make the Magic in Manufacturing the Magic Bullet? Dr Xiaona Jing, Director Global CMC & Pharmaceutical Development, NBE-Therapeutics Ltd	
Conference Close & Drinks Reception			



Featured Presentation:

Fast track late phase development for Orphan Drugs – Ensuring your supply chain is fit for purpose.

Dr Ulrich Rumenapp
Head of Launch Preparation and Coordination, Bayer.

Accelerated programs to expedite the development and approval of innovative drugs for indications of high unmet medical need (supported by e.g. Breakthrough Therapy Designation of US FDA or the EMA Priority Medicines, PRIME scheme) raise numerous challenges to CMC developers and manufacturers incl. their outsourcing partners. Common goal of the pharmaceutical / biotech industry, patients and regulatory health authorities

is early access for patients to these drugs – of course with product quality and compliance uncompromised, and with sustainable supply. CMC development incl. any outsourcing and technology transfer needs to keep pace with much faster clinical development, causing the need for a well thought through development plan and strategy towards initial submission and for life-cycle management. In the presentation, the drivers, approaches and risks & mitigations related to such accelerated projects, esp. when outsourcing bio-manufacturing, will be reviewed.



Featured Presentation: Making Magic Bullets; Development and Manufacture of Antibody Drug Conjugates

Dr Jeremy Parker, Principal Scientist – New Modalities & Tissue Targeting, AstraZeneca

The preparation of Antibody Drug Conjugates (ADCs) presents significant challenges, requiring the preparation of specific antibodies and cytotoxic small-molecule payloads; conjugation of the two species and finally fill-finish. These projects pose significant development and manufacturing challenges, and typically require close collaboration with a range of CMOs. This talk presents key learning obtained by AstraZeneca/MedImmune in their ADC program which includes a Biparatopic HER2-Targeting Antibody Drug Conjugate currently in Phase I clinical trials.



Poster Presentation Scheduled for 19th June, 11.00 to 12.00

TIME	Discovery Poster Presentations Chair: Dr Matthew Konneh, Director, Konnsult Life Sciences	CMC (Small Molecule) Poster Presentations: Chair: Dr Paul Madeley, Managing Director, Synth-Isis Ltd	CMC (Biologics) Poster Presentations Chair: Dr Edith Norrant, Researcher, Innovations Technology Sciences, Université libre de Bruxelles
11.00 - 11.10	Orally bioavailable and in vivo active macrocycles for idiopathic pulmonary fibrosis. Dr Gordon Saxty, Head of Chemistry, Fidelta	Application and advantages of hazardous chemistry in API development and manufacturing. Dr Andrew Henderson, Sales and Marketing Director, Sterling Pharma Solutions Ltd.	3S Guojian an integrated global player and leading CDMO for biologics. Prof Rolf G Werner, Professor for Industrial Biotechnology, University of Tübingen
11.12 - 11.22	An efficient link from « Small quantity » commercial c-GMP API manufacture to clinical needs. Pierre Charrier, CEO, Diverchim	Automated drug-in-capsule dosing - overcoming the challenges for GMP clinical supply. Ms Lisa Burns, Clinical Development Manager, Custom Pharma Services.	Recent examples in outsourcing of microbial process development and manufacturing. Mrs Elise Mous, Director Sales & Marketing/ Business Development, Capua Bioservices
11.24 - 11.34	Assessing compound efficacy in age-related hearing loss model. Dr Wahid Awad, Business Development Manager, CILcare	Isomeric purity analysis to Kg. Dr Brian Freer, Sales and Marketing Manager, Chiral Technologies Europe	Biopharma manufacturing facility design and operations, integrated with advanced analytics; from a CMO perspective. Dr Jogi Amit, Associate Director, Head, Biologics Manufacturing Operation, Syngene International Ltd
11.36 - 11.46	“Putting Science to Work” – a journey of CRO with a virtual pharma company. Dr Jeyaprakashnarayanan Seenisamy, Associate Research Director, Discovery Chemistry, Syngene International Ltd	Recipharm Pathway to Clinic® - from formulation to clinical trial. Dr Mikael Bisrat, Development & Technology Sales Director, Recipharm	A cutting-edge improvement for biologics manufacturing. Pearl Fong, Vice-president, Mycenax
11.48 - 11.58	ALS Screening assays that track and monitor Zebrafish behaviour. Dr. Karl Ågär Karlsson, CSO, 3Z	Free flowing API powders through spherical agglomeration. Dr Massimiliano Forcato, R&D Director, Zach Systems SA	Process-related impurities – how to control host cell proteins. Dr Marcus Mreyen, Director Business Development, Protagen Protein Services GmbH

FEATURED POSTERS

Screening Assays that track and monitor Zebrafish behaviour

3Z

Discovery

Characterisation of Materials from an Alternative Supplier for a Modified Release Capsule Drug Product

CUSTOM PHARMA SERVICES

Small Molecule, Analytical

A cutting-edge improvement for biologics manufacturing

MYCENAX BIOTECH INC.

Category: Biologics, Drug Substance

3Z developed zebrafish screening assays. Recording up to 2300 larvae in parallel the throughput is immense while gaining high-content information from a whole behaving animal. We specialize in CNS, offering various assays. Currently, we present specifics of our ALS assay. By extended analysis of behavioral parameters we utilize behavior as the ultimate readout of the central nervous system to probe effects of small molecules on CNS activity.



A new API supplier was identified for a modified release broad spectrum antibacterial capsule drug product. Samples from three separate batches of each material were provided for assessment. A series of both solid state and chemical tests were conducted in order to allow a comparison to be made, and determine whether the material from the new supplier would be suitable for routine use in commercial manufacturing.



Mycenax Biotech Inc. (MBI) equips with CMC based platform, disposable technology, and PIC/S GMP manufacturing system, we dedicate to deliver satisfactory results by providing a high quality, cost-competitive and full line solution to manufacture biological products. Aiming to provide better services to our clients, we keep upgrading our technical capacity to meet the world manufacturing trend. Two highlights on recent MBI technology platforms are MBI JUMP and Mycenax Continuous Processing.



BOS CMC 2017 was a very informative congress which allows one 2 one meeting with CMOs and other collaborators, which is quite unique compared to other congresses. The topics covered in this congress were also very interesting and provided insight to all the relevant challenges regularly faced by biotech companies during outsourcing activities. Overall the event was organized meticulously by the organizers.

Yogeshwar Bachhav, Associate Director Pharmaceutical Development, Aicurus GmbH

I would like to thank you again for the opportunity of joining this exciting event. BOS cmc is the place where Analytical CROs meet CMOs together with outsourcing professionals! Because of its relatively small size, you can have the opportunity of knowing more providers experiencing their approach on the main CRO/CMO activities.

Gabriele Sassi, Non Clinical Outsourcing Manager, R&D Outsourcing Management, CHIESI FARMACEUTICI S.p.A.

Very interesting event for specific networking and selective information sourcing on CROs and CMOs. Very informative talks from experts with many relevant case studies Good size and venue.

Mario Amacker, PhD, Head of Quality & Manufacturing, Mymetics BV

The conference was an excellent opportunity to meet a variety of CMOs in the DS/DP field and have sufficient time for discussion. The timetables available prior to the meeting were a very helpful tool in setting the meetings. The talks I attended during the sessions were informative and the diversity of attendees and presenters represented a wide cross section of the industry.

Mirjam Sax, PhD, Principal Site Manager, External Development Collaborations, PTDMX Small Molecules, F Hoffmann-La Roche Ltd

Biotech Outsourcing Strategies: Facilitating partnering between Contract Giver and Contract Acceptor



BOS Event Components Delivering Partnering & Matchmaking

BOS PARTNERING SOFTWARE	CRO & CMO EXHIBITION
<p>All attendees will have access to the BOS Partnering Software. This platform allows participants to contact one another prior to the event to arrange 1-to-1 meetings. Confirmed meeting will then be scheduled into your agenda during the event. Further details describing this process are provided below:</p> <p>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 aseptic fill and finish capabilities.</p> <p>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</p> <p>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.</p> <p>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.</p> <p>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</p>	<p>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 full breadth of their capabilities to the attending biotech and pharma community. See details of the floor plan below.</p> <p>BOS OUTSOURCING SHOWCASE (POSTERS)</p> <p>Showcasing break-through technologies and innovations BOS 2018 will highlight the best of innovation in the CRO/CMO sector and in turn allow you to keep fully abreast of technology developments shaping the future of discovery and CMC outsourcing.</p> <p>Posters on Display at BOS cmc 2017, Basel.</p>



Key CRO Sponsors

Gold Sponsors



Exhibition Sponsors



Silver Sponsors



Host Sponsors

Events Partners

