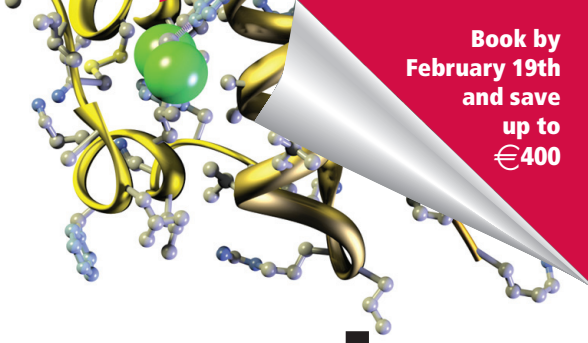
Workshops: 20th April 2010 | **Meeting:** 21st and 22nd April 2010
Location: Radisson Blu Hotel, Frankfurt, Germany



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Advancing Protein Therapeutics

Optimising Therapeutic Potential During Research and Development

Advancing Protein Therapeutics focuses on overcoming the key challenges in optimising therapeutic and drug-like qualities, and will help you to maximise the commercial potential of your protein therapeutic pipeline.

- Learn the latest techniques for **engineering protein therapeutics** to improve PK/PD and immunogenicity, with an overview from **Dr Graham Molineux,** Executive Director of Research at **Amgen**.
- Get an update on the latest methodologies for **expression and production of therapeutic proteins** with presentations from **Dr Tom Kost,** Director of Biological Reagents and Assay Development for **GSK** and **Dr Trevor Wilkinson,** Associate Director of Protein Sciences at **MedImmune**
- **Dr Michael Doyle,** Group Leader of Protein Therapeutics Discovery at **Bristol-Myers Squibb**, outlines the application of a **thermodynamic solubility assay during lead selection**
- Understand how **Medimmune** are **developing novel biologics to target less accessible cell surface antigens,** with a detailed description from **Dr Lutz Jermutus,** their Senior Director of Technology.
- **Dr Scott Glaser,** Director of Antibody Therapeutics at **Biogen Idec**, outlines the very latest developments in the **construction of bispecific antibodies**, including preclinical examples
- Discover how **Centocor (Johnson & Johnson)** are using **Fc-Fusion proteins** to enhance therapeutic potential and extend half-life

INTERACTIVE WORKSHOPS — Tuesday 20th April

Intellectual Property in Therapeutic Proteins — 9.30 - 12.30
Dr Antonio Maschio, Partner
Edwards Angell Palmer & Dodge Innovations LLP

Challenges in the Clinical Development of Biological Medicines — 13.30 - 16.30
Cecil Nick, Vice President (Biotechnology), PAREXEL Consulting

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Hear 24 world leading protein therapeutic experts

- **Dr Graham Molineux,** Executive Director, Research, Amgen
- **Dr Tom Kost,** Director, Biological Reagents and Assay Development, GlaxoSmithKline
- **Dr Lutz Jermutus,** Senior Director, Technology, MedImmune
- **Dr Scott Glaser,** Director of Antibody Therapeutics, Biogen Idec
- **Dr Michael Doyle,** Group Leader, Protein Therapeutics Discovery Biochemistry and Biophysics, Bristol-Myers Squibb Research and Development
- **Dr Chichi Huang,** Research Fellow, Centocor (Johnson & Johnson)
- **Dr Andy Nixon,** Vice President, Lead Discovery and Biochemistry, Dyax Corp
- **Dr Trevor Wilkinson,** Associate Director of Protein Sciences, MedImmune
- **Prof Arne Skerra,** Professor of Biological Chemistry, Technische Universitat Munchen
- **Dr Josi Holz,** Chief Medical Officer, Ablynx
- **Dr Lars Abrahmsen,** Chief Scientific Officer, Affibody
- **Dr Julian Bertschinger,** Co-founder and Chief Executive Officer, Covagen
- **Dr Arnd Steuernagel,** Chief Scientific Officer, SciIProtein
- **Dr Christian Zahnd,** Chief Executive Officer, Molecular Partners
- **Dr Christina Furebring,** Vice President Research & Development, Alligator Bioscience
- **Dr Samantha Cobb,** Chief Executive Officer, AdAlta
- **Dr Jeffrey Cleland,** Chief Executive Officer, Versartis
- **Dr Kendall Mohler,** Senior Vice President, Research & Development, Trubion
- **Dr Nico Mertens,** Senior Director of Antibody Engineering, Biotecnol
- **Prof Christian Heinis,** Group Head, EPFL
- **Dr Kevin FitzGerald,** Chief Executive Officer, f-star GmbH
- **Dr Andreas Hohlbaum,** Chief Technology Officer, Pieris AG
- **Dr Dominik Escher,** Managing Director and Vice President R&D, ESBATech
- **Dr Karyn O'Neil,** Chief Scientific Officer, Centyrex, Johnson & Johnson Ventures

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Workshops: 20th April 2010 | **Meeting:** 21st and 22nd April 2010 | **Location:** Radisson Blu Hotel, Frankfurt, Germany

Optimising Therapeutic Potential During Research and Development

Enhancing Protein Therapeutics to Deliver Business Growth

Advancing protein therapeutics through the clinic and into the market is fraught with difficulties. So why make it any tougher?

The agenda for this meeting has been designed with direct input from most of the successful innovative companies developing protein drugs today. Companies like **Pfizer**, **Merck**, **MedImmune**, **Biogen Idec**, **Amgen**, **GSK**, **Johnson & Johnson**, **Bristol-Myers Squibb and Roche**, have all given frank and honest assessments of principle challenges facing protein therapeutic developers.

We've collated this information into an agenda, and collected some of the world's leading experts in the field, to provide you with valuable knowledge and first-hand experiences that you simply cannot get elsewhere.

Hear the world's brightest minds talking about:

- Improving the **PK/PD characteristics** of your protein therapeutics, including **modulation of half–life** and matching of pharmacokinetics to clinical requirements.
- Enhancing production of proteins for therapeutic application and for preclinical studies using **novel expression systems**.
- Improving the therapeutic effectiveness of protein therapeutics, including **efficacy** and **tissue penetration**.
- Expanding the **alternative scaffold portfolio** to include completely novel antibody-alternatives.
- The very latest developments in **advancing multivalent protein therapeutics** towards the clinic
- How to design protein therapeutics that **target less accessible cell surface antigens**
- An interactive panel discussion addressing the **future of protein therapeutics**, including overcoming challenges in progressing to the clinic and an assessment of the most promising alternative scaffolds.

Invaluable feedback on your protein therapeutics

The quality and rate of innovative research and development in the proteins therapeutics sector has increased dramatically in the last few years. As part of the Biorbis mission to accelerate progress and encourage dialogue, **we encourage attendees to present a poster.**

Presenting a poster is free of charge to all registered delegates. Please note that poster displays may not be used for sales or marketing purposes, and all poster abstracts are subject to approval by the conference organisers.

Just tick on the booking form or inform us when registering.

Contact Richard Lumb at **richard.lumb@hansonwade.com** for more details

Who Should Attend

Advancing Protein Therapeutics is an elite meeting of international scientists and research leaders from the major pharmaceutical companies and large, medium and small biotechs. **Directors and Heads of Biologics, Protein Engineering, R&D, Chief Executive and Scientific Officers, research leaders and scientists** will all benefit and have the opportunity to debate issues at the cutting edge of the sector.

Register now and speak to the most innovative biotechs in the sector and forward-thinking research establishments. Make the most of opportunities for face-to-face dialogue during our interactive and networking sessions and converse with the other attendees as well as the skilled speaker faculty. Just be ready to talk about your work and don't forget to bring plenty of business cards.

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Biorbis in on an unrelenting mission to deliver scientific meetings to the business and research community that will accelerate progress and ultimately benefit patients.

Our focus is on discovering what makes a difference to your research or business, and working with you to design highly relevant, cutting-edge agendas with content delivered by globally recognised experts and leaders in the field.

We create an environment that encourages open dialogue, frank discussion, generation of ideas and exchange of information that will help to advance medical science and improve your research or grow your business.

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CONFERENCE DAY ONE: 21st April 2010

08.30 Registration, coffee and networking

09.00 **Chairman's Opening Remarks**
Dr Scott Glaser, Director, Antibody Therapeutics, **Biogen Idec**

IMPROVING PHARMACODYNAMICS / PHARMACOKINETICS

09.05 **KEYNOTE ADDRESS: Engineering Protein Therapeutics to Improve PK/PD and Immunogenicity**
- Evolution of protein therapeutics to enhance pharmacology profiles
- Addressing safety concerns during protein development

Dr Graham Molineux, Executive Director, Research, **Amgen Inc**

09.35 **Engineering Kunitz Domains to Extend Plasma Half-Life using PEGylation and Protein Fusions**
- Overview of the design features of a human Kunitz domain scaffold library
- Identification of engineered potent and selective serine protease inhibitors using a human Kunitz domain scaffold library
- Examples of engineering and labeling strategies to extend half-life

Dr Andy Nixon, Vice President, Lead Discovery & Biochemistry, **Dyax Corp**

10.05 *** SPEED NETWORKING SESSION ***
Meet other attendees early and make the most your networking opportunities

11.00 Morning Refreshments

11.15 **Application of a Thermodynamic Solubility Assay during Lead Selection of EGFR-IGF1R Bispecific Adnectins**
- Perspective on impact of solubility during protein therapeutic lead selection and optimization
- Strengths and weaknesses of existing methods to measure protein solubility
- Low-consumption, precise method applied to measure solubilities of PEGylated bispecific Adnectin and its constituent unPEGylated mono-Adnectins

Dr Michael L. Doyle, Group Leader, Protein Therapeutics Discovery Biochemistry and Biophysics, **Bristol-Myers Squibb Research and Development**

11.45 **XTEN Products: Matching Pharmacokinetics to Clinical Requirements - Monthly to daily dosing**
- XTEN Technology: Tunable PK, low manufacturing costs and lack of immunogenicity
- VRS-859: monthly dosed GLP-1 analog for type 2 diabetes
- VRS-317: monthly dosed hGH for growth hormone deficiency

Dr Jeffrey Cleland, Chief Executive Officer, **Versartis**

12.15 **Development and Application of a Serum Albumin Binding Protein for Increased Potency**
- Design and construction of an albumin-binding protein working across species
- Half-life extension and increased efficacy of albumin-bound biopharmaceuticals in rodents and primates.
- An albumin bound G-CSF fusion protein is equipotent with the clinically used PEG-ylated biopharmaceutical
- Future applications of an albumin binding domain

Dr Lars Abrahmsen, Chief Scientific Officer, **Affibody**

12.45 Lunch and Poster Session

PRODUCING PROTEINS FOR THERAPEUTIC APPLICATION

13.45 **BacMam Transduction: A Versatile Approach for Protein Expression**
- Utilising BacMam viruses for gene delivery and protein expression as an alternative to transient transfection
- Flexibility of BacMam virus gene delivery system in assay development and potential in protein production for pre-clinical studies.

Dr Tom Kost, Director, Biological Reagents & Assay Development **GlaxoSmithKline**

14.15 **Transient Production of Recombinant Proteins in Mammalian Cells and its Role in Supporting Drug Discovery Programs**
- Applications of transient mammalian expression systems
- Expression of recombinant antigens and antibodies
- Case studies describing support of Drug Discovery Programs

Dr Trevor Wilkinson, Associate Director, Protein Sciences **MedImmune**

OPTIMISING EFFICACY – MINIMISING COMPROMISE

14.45 **Enhanced Signaling and Pharmacologic Properties of SMIP™ Therapeutics**
- What are the constituent parts of Small Modular ImmunoPharmaceutical (SMIP) drugs?
- Clinically validation in autoimmune and oncologic diseases
- Binding domains in SMIP format can induce increased signaling and pharmacologic effects
- Developing novel, anti-CD3 specific immunomodulators

Dr Kendall Mohler, Senior Vice President, Research & Development, **Trubion Pharmaceuticals**

15.15 Afternoon refreshments

15.45 **Latest Clinical Results using Modular Designed Nanobodies**
- Formatting of Nanobodies for clinical activity
- Pre-clinical development and pharmacological modeling for clinical development
- Demonstrating biological activity in the clinic with biomarkers

Dr Josi Holz, Chief Medical Officer, **Ablynx NV**

16.15 **Topical Protein Drug Delivery: Latest Clinical Developments of ESBA105**
- A topical single-chain antibody fragment
- High stability and solubility of the product
- Preclinical and clinical evidence of good pharmacokinetics

Dr Dominik Escher, Managing Director and Vice President, Research & Development, **ESBATech, an Alcon Biomedical Research Unit**

16.45 **DARPins – a Strong Platform to Deliver Novel Differentiated Therapeutics**
- Introduction to the DARPin platform as a robust compound engine
- Approaching clinical validation: Update on the lead DARPin (MP0112, a VEGF antagonist in ophthalmology) in clinical Phase One
- Novel administration opportunities including topical administration and pulmonary delivery of biologics
- Immunogenicity risk assessment

Dr Christian Zahnd, Chief Executive Officer, **Molecular Partners**

17.15 Chairman's Closing Remarks

17.20 Poster Session and Networking

CONFERENCE DAY TWO: 22nd April 2010

08.30 Registration, coffee and networking

09.00 **Chairman's Opening Remarks**
Dr Tom Kost, Director, Biological Reagents & Assay Development
GlaxoSmithKline

09.05 **KEYNOTE ADDRESS: Engineering Alternative Non-Antibody Scaffolds for Molecular Recognition and Clinical Application**
- Principles of molecular recognition by antibodies and other protein scaffolds
- PASylation as a method to extend the plasma half-life

Prof Arne Skerra, Department of Biological Chemistry
Technische Universitat Munchen

EXPANDING THE ALTERNATIVE SCAFFOLD PORTFOLIO

09.35 **Fc-fusion Protein Therapeutics—Designs, Applications and Challenges**
- The successes of Fc-fusion proteins as biopharmaceuticals
- Overview of current Fc-fusion protein based technologies
- Examining the design, optimization and challenges associated with Fc-fusion protein development

Dr Chichi Huang, Research Fellow, Centocor, Johnson & Johnson

10.05 **Engineering Antigen Binding Sites into the Fc Region of IgG**
- Novel antibody formats: Fcab and mAb2
- Retaining antibody functionalities (antigen binding, effector functions and long half life) in small therapeutic antibody fragments
- Creating bispecific antibodies (mAb2) from minimally altered IgG

Dr Kevin FitzGerald, Chief Executive Officer, f-star GmbH

10.35 Morning Refreshments

ADVANCING MULTIVALENT PROTEIN THERAPEUTICS

11.00 **Bispecific Antibodies: Delivering Combination Therapy in a Single Agent**
- Platform technology for stabilizing scFvs
- Stabilized scFvs as building blocks for constructing bispecific antibodies
- Preclinical examples

Dr Scott Glaser, Director, Antibody Therapeutics, Biogen Idec

11.30 **IL-17 Neutralising Fynomers: Making Use of Multivalent Formatting Opportunities**
- Development of human Fyn SH3 library and functional variety in Fynomer formats (dimers, trimers, bi-specifics)
- In vitro and in vivo effects of Fynomer blocking IL-17A, a pro-inflammatory cytokine
- Engineering Fynomer-Fc fusion proteins for more desirable biophysical properties for clinical development

Dr Julian Bertschinger, Co-founder & Chief Executive Officer
Covagen

12.00 **Tribodies: Diverse Targeting through Modular Trispecific Protein Drugs**
- Modular design benefits of Tribody molecules
- Examining recent results obtained in mouse lymphoma model
- Utilising the Tribody generation platform for clinical development

Dr Nico Mertens, Director, Antibody Engineering, Biotecnol

12.30 Lunch

TARGETING LESS ACCESSIBLE ANTIGENS

13.30 **Targeting GPCRs and Ion Channels with Biologics**
- Monoclonal antibodies and peptides as potent biopharmaceutical GPCR and ion channel modulators
- Cysteine-knot peptides: Potential and challenges of a novel drug class
- Combining protein display and peptide chemistry to generate novel biologics

Dr Lutz Jermutus, Senior Director, Technology, MedImmune

14.00 **Shark Antibodies and their Human Analogues: Alternative Scaffolds as Potential Therapeutics**
- Size and stability biophysical advantages of shark antibodies
- Targeting cleft-type epitopes (enzyme active sites and surface receptors) through the elongated CDR3 loop which are otherwise inaccessible to conventional antibodies

Dr Samantha Cobb, Chief Executive Officer, AdAlta

14.30 **Targeting the areas Antibodies can't go: How the Affilin Scaffold can address this**
- Introducing Ubiquitin based Affilin® molecule libraries
- Affilin® molecules as a complimentary approach to antibody platforms
- Preclinical development of an alternative scaffold protein which is 100% conserved across species

Dr Arnd Steuernagel, Chief Scientific Officer, ScilProteins

ENHANCING DRUG-LIKE QUALITIES

15.00 Afternoon Refreshments

15.30 **ADC-1004, Removal of B Cell Epitopes from the Anti-Inflammatory Bacterial Protein CHIPS using FIND® Technology**
- Immunogenicity characterisation of original compound and removal of B cell epitopes
- In vitro findings and efficacy studies in a porcine AMI model

Dr Christina Furebring, Vice President, Research & Development
Alligator Bioscience

16.00 **Expanded Therapeutic Potential with Formulation and Formatting Flexibility for Alternative Delivery: Latest Anticalin Developments**
- Modified human lipocalins as unique scaffold
- Accessing novel targets and validation of PRS-050 (VEGF antagonist) entering human studies
- Examples of where formulation and formatting flexibility matter

Dr Andreas Hohlbaum, Chief Technology Officer, Pieris AG

16.30 **PANEL DISCUSSION: Where are protein therapeutics heading?**
- What are the challenges involved in progressing protein therapeutics through the clinic more effectively?
- How do non-antibody and antibody development programmes compare?
- Where does the most promise lie in current alternative scaffold research efforts?

Dr Scott Glaser, Director, Antibody Therapeutics, Biogen Idec
Dr Karyn O'Neil, Chief Scientific Officer, Centyrex
Johnson & Johnson Ventures
Prof Arne Skerra, Department of Biological Chemistry
Technische Universitat Munchen

17.00 Chairman's Closing Remarks

INTERACTIVE WORKSHOPS TUESDAY 20TH APRIL

WORKSHOP A 09.30-12.30
Intellectual Property in Therapeutic Proteins

This workshop will address the role of intellectual property in the development of biotherapeutics, both from the perspective of research into antibody-like and non-antibody protein drugs. Using case studies we will explore the steps involved in the creation of portfolios of intellectual property rights in the commercialisation of proteins for therapeutic applications. Specifically, the workshop will facilitate an active discussion covering:

IP IN OLDER PROTEINS: MODIFICATIONS, HALF LIVES, AND PEPTIDE TECHNOLOGY

Just because a protein is "off patent" doesn't mean it cannot be the subject of patent protection. The leading technologies for protein modification and how they relate to commercialisation of proteins for therapeutic application will be discussed. Examples such as serum albumin complexes, PEGylation, production technologies are all subject to IP today and we will look at the IP that may be necessary to access the market with a therapeutic protein.

WHY IS IP IN THERAPEUTIC PROTEINS VALUABLE? AN OVERVIEW OF THE ISSUES INVOLVED IN GENERIC COMPETITION AND BIOSIMILARS

Discussing the considerations involved in generic competition, and why generic biologicals ("biosimilars") present a very different target for generic competition. Case studies in biosimilar registration, highlighting some of the difficulties.

EXPLORING NEW FIELDS: SCAFFOLDS, POLYPEPTIDES AND NOVEL STRUCTURES.

Many have sought alternatives to antibodies using different scaffolds. We will examine this growing IP sector and identify key companies and patent portfolios.

ANTIBODIES AND FRAGMENTS; CHANGE AND OPPORTUNITY AS EARLY IP EXPIRES

Antibodies are still the most important class of therapeutic protein, by far. The key technologies which enabled the antibody revolution are passing into the public domain in the next few years, or have already done so. The workshop will identify opportunities for antibody development around the world as key patents expire.

Workshop Leader: Dr Antonio Maschio, Partner, Edwards Angell Palmer & Dodge Innovations LLP

Antonio Maschio is a Partner at Edwards Angell Palmer & Dodge Innovations LLP. He has extensive experience in patenting biotechnology inventions and has advised many start-up companies in value generation using Intellectual Property Rights. Antonio specialises in Biotechnology and Immunology. Antonio's list of high-technology Life Sciences clients has included the Medical Research Council, Domantis, Sirna Therapeutics, The Wellcome Trust, University of Cambridge, Isis Innovation, Covidien, Astra Zeneca and Argenta Discovery.

WORKSHOP B 13.30-16.30
Challenges in the Clinical Development of Biological Medicines

This workshop will focus on the challenges faced in the clinical development of biological medicines. Many of these are the same as for small molecules e.g. geographic and ethnic considerations, recruitment and safety.

However, for biological medicines there is far greater focus on immunogenicity, the effects of which can be variable, ranging from serious adverse events such as the pure red cell aplasia that has been associated with epoetin to no effect at all; this will impact program designs and target populations.

Other key challenges that will be considered include:

- **Generating relevant non-clinical data**
- **Pharmacokinetic studies** (biologicals often have long half-lives)
- **Placebo use** (as biologicals often target serious diseases)
- Dealing with **non-inferiority trials**, particularly in the development of so called biobetters
- The issue of **comparability and aligning process and formulation development** with the clinical program
- **Regulatory precedence**

Active participation by the attendees is encouraged and we welcome specific questions, either in advance (to cecil.nick@parexel.com) or on the day.

The workshop will provide an introduction to this complex field for those who are new to the subject, as well as critical debate for those who are more experienced.

Workshop Leader: Cecil Nick, Vice President (Biotechnology), PAREXEL Consulting, UK

Cecil holds a BSc (Hons) in biochemistry from the University of Cape Town and is a regulatory professional with over 30 years experience specializing in biological and biotech products.

Cecil joined PAREXEL in 2001 from Novo Nordisk Ltd. where he gained considerable experience in the development and registration of biotechnological products and NCE's.

In addition he has knowledge of health economic assessments, quality assurance, pharmaceutical distribution and clinical research. He has authored many articles published in GCP Journal and Regulatory affairs Journal.

Cecil has particular expertise in biotech and orphan drug submissions and is a well known expert on comparability and biosimilarity.

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

How long does your team spend cold calling? It's not easy to get productive call time with the most successful drug developers. And even if you manage to engage with your target market, call-time is no substitute for face-time. Advancing Protein Therapeutics is **guaranteed to get you in front of an audience of prospective customers** – not just for a few minutes on the phone – but for 48 hours. You'll have plenty of **time to cement relationships** with informal networking breaks and interactive panel discussions, as well as over lunch and at the bar in the evening. Don't miss this opportunity. **Sponsor** or **Exhibit** at Europe's most influential vaccine innovation meeting. Your next partners, prospects and clients will be there. **Will you?** Why wait? The earlier we confirm your involvement, the sooner we can include you in our marketing campaign and expose your company to our extensive database of vaccine business and research contacts.

Contact **Miles Harley** on **+ 44 (0)203 141 8701** or email **miles.harley@hansonwade.com**

Advancing Protein Therapeutics

Workshops: 20th April 2010 | **Meeting:** 21st and 22nd April 2010
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Mail: Hanson Wade
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