

TRAINING SEMINARS

- Protein Expression Technologies
- Introduction to Protein Engineering

ENGINEERING

- Display of Antibodies
- Engineering Antibodies
- Engineering Bispecifics
- Engineering Next-Generation ADCs

THERAPEUTICS

- Novel Immunotherapy Strategies
- Advancing Bispecifics
- Novel Therapies for Cancer

ANALYTICAL

- Optimisation & Developability
- Analytical Characterisation
- Aggregates & Particles

EXPRESSION

- Protein Expression Technologies
- Optimising Expression Platforms
- Protein Purification Technologies

Sponsor & Exhibit Opportunities

Hotel & Travel Information

Registration Information

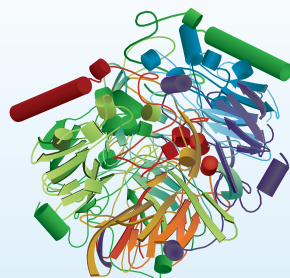
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Register by 30 September**

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Eighth Annual

PEGS EUROPE

Protein & Antibody Engineering Summit

31 October – 4 November 2016 | EPIC SANA Lisboa Hotel | Lisbon, Portugal

Plenary Keynotes



Paul Adam, Ph.D.,
Boehringer Ingelheim



Christian Klein, Ph.D.,
Roche Pharmaceutical Research and Early Development



Sandra S. Diebold, Ph.D.,
National Institute for Biological Standards and Control

Be part of a growing event - attendance has increased more than 60% since 2013

Network with 700 colleagues from 30+ countries at Europe's largest protein engineering event

See unpublished data and case studies from industry leaders

Learn from 200 speakers and 125 poster presenters



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T W I S T
BIOSCIENCE

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CONFERENCE-AT-A-GLANCE

	Monday - Tuesday 31 October - 1 November	Wednesday - Thursday (am) 2-3 November	Thursday (pm) - Friday 3-4 November
TRAINING SEMINARS	TS1: Basic Technologies in a Core Protein Expression Lab TS2: Introduction to Protein Engineering		
ENGINEERING STREAM	1A: Display of Antibodies 4A: Engineering Next-Generation Antibody-Drug Conjugates	1B: Engineering Antibodies	1C: Engineering Bispecifics
THERAPEUTICS STREAM	2A: Novel Immunotherapy Strategies	2B: Advancing Bispecifics and Combination Therapy to the Clinic	2C: Novel Therapies for Cancer and Emerging Targets
ANALYTICAL STREAM	3A: Optimisation & Developability	3B: Analytical Characterisation of Biotherapeutics	3C: Protein Aggregates & Particles
EXPRESSION STREAM	TS1: Basic Technologies in a Core Protein Expression Lab	4B: Optimising Expression Platforms	4C: Protein Purification Technologies

Pre-Conference Short Courses*

Dinner Short Courses*

* Separate registration required for short courses

“The best biologics technology meeting in Europe: a must-attend conference for novel biologics.”

- Rakesh D., Ph.D., Vice President, R&D, MedImmune



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Make the Most of Your Time in Lisbon!

Maximize your educational and networking opportunities by adding a short course.

MONDAY, 31 OCTOBER | 09:00 – 12:00

SC1: Cancer Immunotherapy

Fred Arce, Ph.D., University College London Cancer Institute
Andrea van Elsas, Ph.D., CSO, BioNovion B.V.

Distinct from other paradigms in medical oncology, cancer immunotherapy aims to treat the patient's immune system. During the past few years, antibodies targeting T cell checkpoint proteins have demonstrated unprecedented clinical responses and long-term benefit in patients diagnosed with melanoma and other advanced cancers. Beyond anti-PD-1 and anti-CTLA-4, other pathways and therapeutic agents are rapidly being translated to clinical practice alone or in combination approaches.

SC2: Mutation and Selection Strategies beyond Affinity Optimisation

Orla Cunningham, Ph.D., Associate Director, Global Biotherapeutic Technologies, Pfizer, Inc.
Matthew Lambert, Ph.D., Principal Scientist, Global Biotherapeutic Technologies, Pfizer, Inc.

This course will begin with an introduction to the multiple display technology platforms, mutagenesis strategies and library generation options that exist to enable antibody optimization. In the simplest application, generated libraries can be selected for improved antigen binding. However, increasingly these strategies are being used for more complex applications from humanization to ortholog cross-reactivity, stability, solubility and specificity optimizations. This workshop will use case studies to help attendees navigate the complex workflows and technological options available to ensure success.

SC3: Designing Antibodies for Function and Low Risk of Immunogenicity

George Octavian Badescu, Ph.D., Senior Director Scientific Affairs, Abzena plc
Maria Gonzalez-Pajuelo, Ph.D., Chief Scientific Officer, FairJourney Biologics
Matthew Baker, Ph.D., Chief Scientific Officer, Abzena plc

Increased knowledge of elements that contribute to enhancing the immunogenicity of protein therapeutics has enabled the development of a preclinical 'toolkit' that can be used to assess and mitigate against the risk of immunogenicity during the early stages of drug development. For antibody therapeutics a variety of *in silico*, *in vitro* and *in vivo* immunogenicity selection/testing technologies are available and these can be used at various stages during antibody development from discovery through to lead optimisation. This workshop will provide an introduction to antibody immunogenicity, assessment of the technologies available for lead selection, rational sequence design through engineering, and a look at how these tools can be integrated with optimising antibodies for desired function.

SC4: Transient Protein Expression: A Key Tool to Enable Rapid Protein Engineering

Richard Altman, MS, Scientist, Protein Technologies, Amgen, Inc.
Henry C. Chiou, Ph.D., Associate Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific
Dominic Esposito, Ph.D., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc.

This short course introduces both the fundamental concepts and technologies needed to establish transient protein production in mammalian cells, which has become an essential tool to enable rapid protein engineering. Transient expression allows for the rapid generation, purification and characterization of milligram-to-gram quantities of secreted or intracellular recombinant proteins for therapeutic, functional and structural studies. The course combines instruction and case studies in an interactive environment.

THURSDAY, 3 NOVEMBER | 17:30 – 20:30 (DINNER)

SC5: Troubleshooting and Engineering of Antibody Constructs

Jonas Schaefer, Ph.D., Head, High-Throughput Binder Selection Facility, Biochemistry, University of Zurich
Julia Neugebauer, Ph.D., Associate Director, Leader Discovery Programs, MorphoSys AG

Recombinant antibodies vary widely in their biophysical characteristics. In particular, antibody variable domains differ in their intrinsic thermodynamic stability and may require labour-intensive engineering. It is essential to implement antibody engineering strategies in screening and initial characterisation project phases in order to avoid time and cost consuming optimisation strategies in later development. Moreover, it is critical to understand how poor stability of individual variable domains can limit the biophysical properties of small fragments, and also affect production yield, stability and homogeneity of full-length IgGs containing these domains.

SC6: Engineering of Bispecific Antibodies

Nicolas Fischer, Ph.D., Head, Research, Novimmune SA
Michaela Silacci, Ph.D., Director, Discovery Research, Covagen AG, part of J&J

By attending this interactive workshop, you will learn about the various approaches used for the engineering of bispecific antibodies and bispecific scaffold-based binding proteins. Different technologies will be compared, and examples for applications of bispecific antibodies in drug development will be presented with a focus on candidates that are currently being evaluated in clinical trials. Opportunities and challenges in the field of bispecific antibodies will be discussed.

SC7: Protein Purification Strategies: Dealing with Proteins that Are Prone to Aggregation

Mario Lebediker, Ph.D., Head, Protein Purification Facility, Wolfson Centre for Applied Structural Biology, Alexander Silberman Institute of Life Sciences, The Hebrew University of Jerusalem

This course will provide a comprehensive and detailed outline of hands-on issues for purifying proteins. We will first address general considerations about the protein we want to produce, including issues of activity, solubility, homogeneity, purity, and proper oligomeric conformation. Aggregation is one of the main obstacles in protein production, so we will look at how to monitor for aggregation and comprehend its mechanism. We will also discuss how to check for the optimal solubility conditions at the expression level, and our comprehensive approach for optimizing solubility during purification. We will also discuss expression screening methodology, environmental factors to consider during purification, families of additives, and screening for additives. Lastly, we will address ways to avoid aggregation, as well as setting up protein concentration and storage.

SC8: Protein Aggregation: Mechanism, Characterisation and Consequences

Thomas Laue, Ph.D., Professor, Molecular, Cellular & Biomedical Sciences, University of New Hampshire

Protein aggregation is recognized by regulatory agencies and industry as a key quality attribute of biotherapeutic products. Various aggregates hold the potential for adversely impacting production and patients. This in-depth workshop reviews origins and consequences of aggregation in biotherapeutics, and then examines strategies for predicting and quantifying it. It benefits scientists engaged in development, production, analytical characterization and approval of biotherapeutics and who require a good working knowledge of aggregation.

* Separate Registration required

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TRAINING SEMINAR

31 October – 1 November 2016

Introduction to Protein Engineering

Cambridge Healthtech
Training SEMINARS
Comprehensive and Practical Training

Day 1: 31 October 13:40 – 18:25**Day 2: 1 November 08:30 – 18:45****Instructor:**

David Bramhill, Ph.D.,
Founder, Bramhill Biological Consulting, LLC

CHI's Introduction to Protein Engineering training seminar offers a comprehensive tutorial in the concepts, strategies and tools of protein engineering – and explains the role of this discipline in the progression of biotherapeutic research and development. The class is directed at scientists new to the industry or working in support roles, academic scientists and career protein scientists wanting a detailed update on the current state of the field.

Today's wealth of knowledge of protein structures is reviewed, along with the genetics of diversity generation of antibodies, to give insights into the best strategies for improving protein function. There is particular emphasis on the selection of functional assays to monitor effectively the changes in desired properties.

Display technologies such as phage display and yeast display are described and the advantages and disadvantages of each compared. Design strategies are presented for constructing libraries of variant proteins for display, and panning strategies for enriching proteins with the desired properties considered.

The course details the engineering and enhancement of traditional antibodies and also cytokines, antibody fragments and emerging antibody-like scaffolds. Also included is a discussion of the roles of protein engineering in the discovery, design and development of new therapeutic modalities including antibody-drug conjugates (ADCs), bispecific antibodies and Chimeric Antigen Receptor (CAR) constructs.

This class will discuss the expression platforms used for producing proteins for testing and for manufacture, along with the rapidly emerging role of protein engineering in optimizing antibody and other protein therapeutics.

A background in biochemistry and molecular biology is useful, as the course is designed to progress rapidly from simple to advanced concepts. Links and references will be provided with the course materials to provide a glossary and other useful resources.

What is Protein Engineering?

- Functions amenable to engineering: Affinity, specificity, catalysis, stability, solubility, immunogenicity, serum half-life

Tools and Techniques

- The measure of success: Functional assays
- Engineering by design
- Engineering by random mutation
- Designed libraries
- Display technologies

Production and Manufacturing

- Evaluating biotherapeutic developability
- Improving manufacturing by protein engineering methods
- Glycosylation engineering – Function and homogeneity
- Other protein modifications
- Immunogenicity engineering
- Expression of antibodies and fragments for discovery and testing
- Manufacturing platforms for antibodies and fragment

Emerging Molecule and Product Formats

- Bispecific antibodies/binders
- Antibody-drug conjugates (ADCs)
- CAR T strategies
- Other emerging constructs

Each CHI Training Seminar offers 1.5 Days of instruction with start and stop times for each day shown above and on the Event-at-a-Glance published in the on-site Program & Event Guide. Training Seminars will include morning and afternoon refreshment breaks, as applicable, and lunch will be provided to all registered attendees on the full day of the class.

Each person registered specifically for the training seminar will be provided with a hard copy handbook for the seminar in which they are registered. A limited number of additional handbooks will be available for other delegates who wish to attend the seminar, but after these have been distributed no additional books will be available.

Though CHI encourages track hopping between conference programs, we ask that Training Seminars not be disturbed once they have begun. In the interest of maintaining the highest quality learning environment for Training Seminar attendees, and because Seminars are conducted differently than conference programming, we ask that attendees commit to attending the entire program, and NOT engaging in track hopping, as to not disturb the hands-on style instruction being offered to the other participants.

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3rd Annual

Display of Antibodies

Empowering Novel Biologics

Recommended Short Course*

SC2: Mutation and Selection Strategies beyond Affinity Optimisation

*Separate registration required, please see page 4 for details.

MONDAY 31 OCTOBER

12:00 Registration

PLENARY KEYNOTE SESSION

13:40 Welcome from PEGS Europe Team

13:45 Chairperson's Opening Remarks

Ana Barbas, Ph.D., Coordinator, Bayer Satellite Laboratory at iBET, iBET and Bayer Portugal SA

13:50 Biotherapeutic Programs that Re-Direct Cytotoxic Lymphocytes to Cancer Cells



Paul Adam, Ph.D., Executive Director, Immune Modulation and Biotherapeutics Discovery, Boehringer Ingelheim

Cytotoxic lymphocytes such as NK and T cells have the capability to control cancer development and progression. Harnessing this cytotoxic potential with biotherapeutic agents is predicted to become a future pillar of cancer therapy in light of recent clinical successes. This presentation will describe novel biotherapeutics whose mode of action involves the engagement and re-direction of NK and T cells to hematological tumors.

14:30 Antibody-Based Combination Cancer Immunotherapy at Roche pRED



Christian Klein, Ph.D., Distinguished Scientist, Head, Oncology Programs, Cancer Immunotherapy Discovery, Roche Pharmaceutical Research and Early Development, Roche Innovation Center Zurich

This presentation will introduce novel antibody cancer immunotherapies developed at Roche pRED including novel IL2 variant immunocytokines and T cell bispecifics as well as preclinical data for their optimal combination and scheduling.

15:10 Safety Concerns Associated with Immunotherapy and Novel Biotherapeutics and Challenges in Investigating Their Immunotoxicity



Sandra S. Diebold, Ph.D., Principal Scientist, Immunotoxicology, Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

The pre-clinical assessment of the risks associated with

immunotherapy and novel biotherapeutics is challenging since the bioassays have to be individually tailored to the investigated reagent. The immunotoxic activity and adverse responses that may be observed in patients are depending to a large degree on the mechanism of action of the biotherapeutic. The specific set-up of *in vitro* assays plus the identification of suitable animal models is critical for obtaining predictive pre-clinical data.

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

USING DISPLAY TO ADVANCE IMMUNOTHERAPY

16:50 Chairperson's Remarks

Kerry Chester, Ph.D., Professor, Molecular Medicine, University College London Cancer Institute

16:55 FEATURED PRESENTATION: Optimisation of Chimeric Antigen Receptors for T Cell Cancer Therapy

Martin Pule, Ph.D., Clinical Senior Lecturer, University College London

17:25 Combinatorial Display in Development of T Cell Vaccines

Andrew Sewell, Ph.D., Professor, Division of Infection and Immunity, Cardiff University School of Medicine

Several uses of combinatorial display will be described including: (1) Quantification of extremely high levels of T-cell cross-reactivity, (2) Definition of causal epitopes/pathogens during autoimmune disease, (3) Generation of optimal epitopes for given T-cell clonotypes, (4) Ligand discovery for dominant 'orphan' T-cell clones following successful tumour-infiltrating lymphocyte therapy for malignant melanoma and, (5) Generation of acid and protease stable non-biologic T-cell ligands that can be orally administered. These exciting studies are providing new ubiquitous targets for cancer vaccination and open up the possibility of oral vaccination and/or induction of tolerance.

17:55 Development and Validation of lIamdA, a Synthetic Domain Antibody Library

Guy Hermans, Ph.D., CSO, Isogenica Ltd.

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isogenica

lIamdA is a synthetic library design based on natural camelid antibody repertoire analysis, manufactured to the highest fidelity standards using Isogenica's COLIBRA library synthesis technology. The use of CIS cell-free display technology allows for the selection of libraries with orders of magnitude greater diversity than competing technologies. We will discuss various validation studies where a high diversity of low single digit nanomolar binders could be rapidly isolated to different therapeutically relevant targets.

18:25 Welcome Reception in the Exhibit Hall with Poster Viewing

19:25 End of Day

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TUESDAY 1 NOVEMBER

07:45 Registration and Morning Coffee

USING DISPLAY TO ADVANCE IMMUNOTHERAPY (CONT.)

08:30 Chairperson's Remarks

Kerry Chester, Ph.D., Professor, Molecular Medicine, University College London Cancer Institute

08:40 How Display and Signaling of CAR Molecules Can Be Used to Redirect the Specificity of Human T Cells

Hinrich Abken, Ph.D., Professor, Genetics & Immunology, Center for Molecular Medicine Cologne, University of Cologne

Adoptive therapy with engineered T-cells with an antigen-specific chimeric antigen receptor (CAR) is achieving impressive efficacy in early phase trials, in particular in hematologic malignancies, strongly supporting the notion that the immune system can control cancer. Such CAR T-cells can substantially reduce the tumor burden as long as the targeted antigen is present on the cancer cells and recognized by the antibody domain of the CAR.

09:10 Inclusion of Strep-Tag II in Design of Antigen Receptors

Stanley R. Riddell, M.D., Professor, Immunology & Clinical Research, Fred Hutchinson Cancer Institute

09:40 Problem-Solving Breakout Discussions*

**See website for details.*

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

ANTIBODIES TO GPCRS AND ION CHANNELS

11:15 Chairperson's Remarks

John McCafferty, Ph.D., Co-Founder, Director and CEO, IONTAS Ltd

11:20 Using Stabilised Receptors as Antigens to Generate Therapeutic Antibodies to GPCRs

Catherine Hutchings, Ph.D., Consultant, Antibody Alliance Management & Strategic Partnering, Heptares Therapeutics Ltd.

Stabilized receptors offer a breakthrough solution to the central challenge of reliably making pharmacologically active antibodies against GPCRs. They enable the production of purified, properly folded and functional protein when removed from the cell membrane for use as an antigen. This presentation provides several examples that provide important validation of this solution, including data from our MorphoSys and AstraZeneca collaborations, demonstrating that StaR antigens preserve biologically relevant epitopes. This enables the generation of diverse panels of functional antibodies directed to this important target class for use as therapeutics.

11:50 Pathological Autoantibodies to Ion Channels

Angela C. Vincent, Ph.D., Emeritus Professor of Neuroimmunology, Nuffield Department of Clinical Neurosciences, University of Oxford

For many years it was thought that the blood brain barrier prevented antibodies or B cells reaching the brain. Over the last 15 years it has become very clear that they can. The talk will show how many rare but treatable diseases of the nervous system are associated with autoantibodies to neuronal proteins, and emphasise the importance of testing for binding to extracellular domains on native proteins, or of establishing quicker and cheaper methods for routine testing and searching for new antibodies.

12:20 Deeper Profiling of Antibodies During High Throughput Antibody Discovery

Niccolo Pengo, Ph.D., Senior Scientist, UCB-Celltech

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12:35 Protein-Protein Docking with Sequential Coarse-Grained Minimization

Nels Thorsteinson, MSc, Scientific Services Manager, Biologics, Chemical Computing Group

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COMPUTING
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Protein-protein docking is an important tool for predicting affinity, optimizing properties and exploring druggable sites. This work presents a novel protein docking method for predicting protein-protein binding. The output protein poses are shown to produce high-quality structures. The applicability of the docking program to antibody optimization will also be discussed.

12:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

13:20 Session Break

14:00 Dessert Break in the Exhibit Hall with Poster Viewing

COMPETITIVE TECHNOLOGIES FOR IMMUNOTHERAPY AGAINST MAJOR AUTOIMMUNE DISEASE

14:30 Chairperson's Remarks

Ahuva Nissim, Ph.D., Reader, Molecular Targeting, Biochemical Pharmacology, William Harvey Research Institute, Queen Mary University of London

14:35 Disease Interception Approaches in Autoimmunity

Louise Jopling, Ph.D., Director, Immunology Scientific Innovation, Johnson & Johnson Innovation Centre

Biologic therapies are extremely effective at treating clinical signs and symptoms of chronic inflammatory diseases although there remains a significant unmet need. Understanding the pivotal mechanisms of disease initiation is critical for developing novel therapies with the potential to reset the immune system prior to the development of chronic inflammation. This presentation will outline novel antibody approaches with the potential for disease interception leading to long term remission.

15:05 Overview on the Current Antibody Treatment of Multiple Sclerosis

Gavin Giovannoni, MBBCh, Ph.D., FCP (Neurol., SA), FRCP, FRCPATH, Professor, Neurology, Centre for Neuroscience and Trauma, Barts and the London School of Medicine and Dentistry

Multiple sclerosis is a putative autoimmune disease of the central nervous system that is characterised pathologically by inflammation, demyelination and variable degrees of axonal loss. Numerous immunomodulatory therapies have been licensed, or are in late stage development, to treat multiple sclerosis including several monoclonal antibodies. Dissecting out the mode of action of the targeted monoclonal antibodies is providing interesting insights into the pathogenesis of MS.

15:35 Targeted-Cytokines for the Treatment of Rheumatoid Arthritis

Mattia Matasci, Ph.D., Head, Cell Line Development, Philochem

Antibody-cytokine fusion proteins (immunocytokines) are being mainly developed for cancer therapy applications. However, certain immunomodulatory cytokine payloads can also be considered for the treatment

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of patients with chronic inflammatory conditions. I will present work of the Philogen group, in collaboration with the Swiss Federal Institute of Technology (ETH Zürich), which has led to the development of potent immunocytokines for the treatment of rheumatoid arthritis.

15:50 Targeting Therapeutic and Regenerative Biomedicine Specifically to Arthritic Joints

Ahuva Nissim, Ph.D., Reader, Molecular Targeting, Biochemical Pharmacology, William Harvey Research Institute, Queen Mary University of London

We developed a panel of human scFv that bind specifically to collagen type II post-translationally modified by oxidants which: binds specifically to arthritic cartilage from patients with RA and OA or from murine models of inflammatory arthritis and OA, localises and target payload drug in the arthritic joints in a mouse model of arthritis (inflammatory and OA). Our development will have a significant impact on treatment of arthritic conditions.

16:05 F-star: Advancing Novel Bispecific Antibody Biologics using the iQue Screener Platform

Frederick Akele, Senior Research Associate, F-star Biotechnology Ltd

F-star develops novel bispecific antibodies (called mAb2) based on a unique modular approach. Using this cutting-edge technology, F-star is building a product pipeline focused on immuno-oncology. This talk will highlight the pivotal role the iQue Screener played in increasing the screening throughput of Fcab (antigen-binding Fc domain) candidates against several antigens.

16:35 Refreshment Break in the Exhibit Hall with Poster Viewing

ANTIBODY GENERATION

17:10 Chairperson's Remarks

Claire Dobson, Ph.D., Associate Director, Antibody Discovery & Protein Engineering, MedImmune Ltd.

17:15 CDR-Restricted Engineering beyond Affinity Maturation

Orla Cunningham, Ph.D., Director GBT, Pfizer

CDR mutagenesis has been used successfully for many years across multiple display platforms for antibody affinity maturation. However, approaches to other aspects of antibody engineering, such as humanization, stability and solubility, tend to maintain the CDR loops and their interaction with antigen as sacrosanct. This talk will use a number of case studies to demonstrate that CDR-restricted engineering can be used for multi-parameter optimization with the benefit of maintaining 100% germline framework content.

17:45 Nanobodies as a Versatile and Clinically Validated Drug Platform

Antonin de Fougères, Ph.D., CSO, Ablynx

An outline of the Nanobody platform and clinical experience will be

presented. The flexibility of Nanobody formatting is used to create differentiated drugs, and examples of mono-specific and multi-specific Nanobody drugs will be shared.

18:15 Toward Single Cell Proteome Analysis Using Phage Display of Recombinant Antibodies

Peter Kristensen, Ph.D., Associate Professor, Molecular Engineering, Aarhus University

In recent years the importance of cellular heterogeneity has become increasingly clear. In developing therapies for important diseases, such as cancer, the ability to isolate and characterize rare cell populations will be important. We have advanced the phage display technology, thus allowing the isolation of specific antibodies binding to one or few identified cells in a heterogeneous mixture such as blood or a tissue section.

18:45 End of Display Of Antibodies



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Inspiring Next-Generation Biologics Discovery and Development

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SC5: Troubleshooting and Engineering of Antibody Constructs

*Separate registration required, please see page 4 for details

WEDNESDAY 2 NOVEMBER

07:45 Registration and Morning Coffee

TECHNOLOGIES AND STRATEGIES TO IMPROVE TARGETING AND BIOACTIVITY OF THERAPEUTICS

08:30 Chairperson's Remarks

Claudio Sustmann, Ph.D., Head, Molecular Design & Engineering, Large Molecule Research, Roche Diagnostics GmbH

08:35 KEYNOTE PRESENTATION:

Using Nanobody Bi-Specifics to Improve the Targeting of Therapeutics

Antonin de Fougères, Ph.D., CSO, Ablynx

This presentation will provide an outline of the Nanobody® platform and will illustrate the flexibility of Nanobody formatting to rapidly make multi-specific drugs. Examples of multi-specific Nanobody drugs that improve targeting of therapeutics will be presented.

09:20 Protease-Activated Antibody Derivatives - Engineered bsAbs with Prodrug-Like Functionality

Ulrich Brinkmann, Ph.D., Expert Scientist, Large Molecule Research, Roche Pharma Research & Early Development

Bispecific and engineered antibody derivatives have been generated in a multitude of formats. Many of these are in preclinical stages for a variety of applications, some in clinical development, and a few are approved. The presentation will provide an overview of the concepts and status of engineered bispecific antibodies at Roche and cover novel formats and applications including bispecific antibody derivatives with prodrug-like functionalities.

09:50 Characterizing and Optimizing Glycostructures by Targeted Cell Engineering

Claus Kristensen, Ph.D., Associate Professor, Copenhagen Center for Glycomics, University of Copenhagen

Using targeted gene editing of mammalian cells we modify sugars on glycoproteins. The technology involves knock-out and/or knock-in of glycogenes to modify cellular glycosylation pathways and generate arrays of different glycans on glycoproteins produced by the cell. Application includes glycooptimization of biologics for improving bioactivity and/or obtain more homogeneous product.

10:20 A Deimmunised Form of the Ribotoxin, α-sarcin, Lacking CD4+ T Cell Epitopes and Its use as an Immunotoxin Warhead

Rob Holgate, Ph.D., Head, Protein Engineering, Abzena

Fungal ribotoxins that block protein synthesis are useful warheads. Peptide mapping using an ex-vivo human T cell assay determined that α-sarcin contained two T cell epitopes. Mutations within each epitope were designed, tested and combined to isolate deimmunised α-sarcin variants with the desired properties of silencing T cell epitopes whilst retaining the ability to inhibit protein synthesis. The results represent the first fully deimmunised fungal ribotoxin.

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Highly Efficient Elimination of High Concentration Soluble Antigen from Plasma by Novel Sweeping Antibody Technology

Meiri Shida-Kawazoe, Ph.D., Research Scientist, Biologics Discovery, Chugai Pharmaceutical Co., Ltd.

In this presentation, we will introduce novel sweeping antibody technology that enables highly efficient elimination of soluble antigen from plasma. The novel technology has been applied to various antigens, which are present at high concentration in plasma and therefore difficult to target by conventional antibodies, and we will show that these antibodies can efficiently eliminate various soluble antigens from plasma in cynomolgus monkey.

12:00 Antibody Engineering in Drug Discovery & Development at Roche

Claudio Sustmann, Ph.D., Head, Molecular Design & Engineering, Large Molecule Research, Roche Diagnostics GmbH

Bispecific antibodies are an important drug class in oncology but also beyond. Identification of the best candidates for a certain application is a challenging task. These aspects as well as selected examples of Roche development candidates will be the focus of the presentation. In particular, application of the IgG-like bispecific CrossMab technology in different disease areas will be addressed.

12:30 Rapid Affinity Measurements Using Gyrolab Immunoassay Platform

Johan Engström, Senior Scientist, Research & Development, Gyros AB

Real-time, surface-based analytical methods often have difficulty in analyzing the slow dissociation kinetics associated with high-affinity KD's. Gyrolab systems enable rapid determination of KD's down to low picomolar levels. This will be illustrated with the KD determination for three TNF-α antagonists and the active binding concentration of the antagonists.

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12:45 to Presentation to be Announced

Mingjie Xie, MSc, MBA, Co-Founder, CEO,
Rapid Novor Inc

13:00 Talk Title to be Announced

Marie Gagnaire, Research Scientist,
Protein Biochemistry, Biologics Research, Sanofi

13:30 Session Break

ANTIBODY DISCOVERY FOR EMERGING AND CHALLENGING TARGETS

14:00 Chairperson's Remarks

Claus Kristensen, Ph.D., Associate Professor, Copenhagen Center for
Glycomics, University of Copenhagen

14:05 Efficient Mining of the Natural Antibody Repertoire – Finding Rare Molecules with Desirable Characteristics

Dale Starkie, BSc., Research Scientist, Antibody Discovery, UCB Celltech
UCB's core antibody discovery technology combines high throughput B
cell culture screening and a proprietary technique called the "fluorescent
foci method" to identify and isolate single, antigen-specific, IgG-secreting
B cells from which variable region genes are isolated and cloned. The talk
will describe case studies on the application of the platform to a number of
antibody projects.

14:35 Discovering Antibodies to a Moving Target

Elizabeth England, Scientist I, Antibody Discovery and Protein Engineering,
MedImmune Ltd.

MedImmune has shown that IL-33 forms disulphide bonds, resulting in large
conformational changes. This occurs rapidly, posing a challenge in identifying
antibodies that inhibit the action of IL-33. Through innovative use of mutant
forms of IL-33 and appropriate design of screening campaigns, a highly potent
inhibitor of IL-33 was identified, a testament to how understanding of target
structure and biology is key to the identification of potential therapeutic
drug candidates.

15:05 Antibodies Targeting Peptide/HLA Complexes for Cancer Therapy

Julia Neugebauer, Ph.D., Associate Director/Leader, Discovery Programs,
Morphosys AG

Tumor-specific peptide / HLA complexes make intracellular targets accessible
to antibodies. However, the generation of therapeutic antibodies, which
recognize a particular peptide / HLA complex specifically, is highly challenging.
By identifying and applying appropriate counter-targets we generated fully
human, high affinity antibodies against a WT1 peptide / HLA complex. These
antibodies bind to target-positive cancer cell lines and outperform similar
state-of-the-art antibodies regarding target specificity and binding affinity.

15:35 Refreshment Break in the Exhibit Hall with Poster Viewing

16:15 Strategies to Identify High Potency Therapeutic Antibodies for Multi-TM Targets

Peter Ertl, Ph.D., Manager, Biopharm Molecular Discovery, GlaxoSmithKline
Cellular targets such as G-protein coupled receptors (GPCRs) are typically very
challenging for therapeutic antibody discovery due to their complex nature
and limited antigen availability. This presentation will describe the strategies
implemented by GSK to successfully identify high potency neutralising
antibodies for such targets, using both *in vitro* antibody presentation
technologies and *in vivo* immunisation approaches.

16:45 Integration of High Throughput Omic's Platforms into Antibody Discovery

John Castle, Ph.D., Senior Director, Bioinformatics, Agenus & 4-Antibody

In pursuit of lead structures, omic technologies are revolutionizing the
discovery and development of novel biological lead structures. However,
omic platforms are first and foremost data generation instruments that
require careful integration into workflows. Here, we demonstrate how
we have applied next-generation sequencing, big data, biostatistics, and
computational immunology to the discovery and development of novel
antibody lead structures.

17:15 Problem-Solving Breakout Discussions*

*See website for details.

18:15 Networking Reception in the Exhibit Hall with Poster Viewing

19:15 End of Day

THURSDAY 3 NOVEMBER

08:00 Registration and Morning Coffee

COMPUTATIONAL AND *IN SILICO* DESIGN AND ENGINEERING

08:30 Chairperson's Remarks

David Melvin, Ph.D., Director, Informatics, Kymab Limited

08:35 Engineering Protein-Protein Interactions *in silico*: Lessons from the Affibody Scaffold

Samuel Coulbourn Flores, Ph.D., Group Leader, Structural Bioinformatics and
Computational Structural Biology, Uppsala Universitet

Altering protein-protein interface properties is key to biologic design, but
experimental directed evolution introduces many mutations, leading to
immunogenicity and off-target effects. We have created an *in silico* method
which predicts single mutations with a clear mechanism, to modify charge
and binding properties and remove functionalization sites. We engineer
properties of the Affibody – IgG interaction. I briefly discuss how to apply this
to important oncology and autoimmune disease targets.



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09:05 Beyond Binding: How to Design Biologically Active, Developable Antibodies against Difficult Targets

Yanay Ofra, Ph.D., Founder & CEO, Biologic Design; Head, Lab of Systems Biology and Functional Genomics, Bar Ilan University

It is fairly straightforward to obtain antibodies that specifically bind almost any protein. However, further screenings and analyses typically reveal that most of these binders are not biologically active or not developable. This is because existing methods for antibody engineering select for binding, while drug development requires function and developability. We show how computational design and *in vitro* evolution can be combined to design developable antibodies with specific, predefined function.

09:35 Rational Design of Antibody Solubility and Complementarity Determining Regions

Pietro Sormanni, Ph.D., Researcher, Chemistry, Centre for Misfolding Diseases, University of Cambridge

I will present a computational strategy for the design of soluble binding proteins as well as experimental validations and applications. I will introduce the CamSol method of designing protein variants with improved solubility, and a method for the *de novo* design of protein-protein interactions, which we used to design domain antibodies and molecular-chaperones binding to linear epitopes and able to inhibit the disease-related aggregation of their target proteins.

10:05 Engineering Next-Generation Biotherapeutics: Developability & Manufacturability

Maria Wendt, Ph.D., Head, Science, Biologics, Genentech

Next-generation biotherapeutics, specifically bi- and multi-specifics, alternative scaffolds, and ADCs, provide significant advantages over traditional IgG-based molecules. However, as highly engineered molecules they pose new design, cloning, expression, purification, and analytics challenges. Our workflow platform automates engineering, production, and testing of large panels of these candidate therapeutic molecules. We demonstrate the platform's capability to explore the huge combinatorial space of novel molecule-specific designs, its high-throughput capability, and its built-in tools for developability and manufacturability assessments.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

HIGH THROUGHPUT SCREENING AND SELECTION

11:15 Advances in Kymab's Fully Integrated, B-Cell Repertoire Analysis and Hit Selection Capabilities

David Melvin, Ph.D., Director, Informatics, Kymab Limited

Kymab have developed an advanced technology to visualise and deeply explore the Kymouse™ antibody repertoire. We can identify candidate-quality molecules with exceptionally broad diversity and with the quality of fully human antibodies. Our platform allows rapid, detailed and efficient exploration of the B-cell response to immunisation as well as informing and supporting decision making process throughout our discovery program. We will present our work with the Bill and Melinda Gates foundation.

11:45 High-Throughput Screening of Monoclonal Antibodies to Multiplexed Antigens

Benjamin Hoffstrom, Ph.D., Director, Antibody Technology, Fred Hutch Cancer Research Center

We have a high-throughput platform for simultaneous screening of monoclonal antibodies to 5 different antigens. The target identification assay is 25-50 times more sensitive than traditional ELISA-based screens, which allows for rapid ranking of several thousand antibodies based on target affinity and isotype. We have validated the platform for modified peptide targets, small molecules, recombinant proteins, and cell surface receptors. A general overview of the workflow will be outlined and specific projects will be highlighted.

12:15 Enjoy Lunch on Your Own

13:00 Dessert Break in the Exhibit Hall with Poster Viewing

13:30 End of Engineering Antibodies



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8th Annual

Engineering Bispecifics

New Approaches and Platform Refinements

Recommended Short Course*

SC2: Mutation and Selection Strategies beyond Affinity Optimisation

*Separate registration required. Please see page 4 for details.

THURSDAY 3 NOVEMBER

12:30 Registration

13:00 Dessert Break in the Exhibit Hall with Poster Viewing

NEW MODES OF ACTION / T CELL ENGAGEMENT

13:30 Chairperson's Opening Remarks

Christoph Spiess, Ph.D., Senior Scientist, Antibody Engineering, Genentech, Inc.

13:35 KEYNOTE PRESENTATION:

Protein Engineering for New Modes of Action

Andreas Plückthun, Ph.D., Director and Professor, Biochemistry, University of Zurich

The engineering of very robust binding proteins gives new opportunities for achieving novel modes of action of biotherapeutics. These can exploit a very strict control of receptor geometries, the opportunity to attack intracellular targets and the opportunity to engineer cell-specific virus entry. The basis for these development is a reliable engine to generate high-affinity specific binding proteins.

14:20 Pfizer's T Cell Engaging Full Length Bispecific Antibody Platform: From Bench to NHS

Javier Chaparro-Riggers, Ph.D., Senior Director, Protein Engineering, Rinat Pfizer, Inc.

The recent clinical success of blinatumomab (anti-CD19/CD3) spurred the development of a variety of T cell engaging bispecific antibody architectures. Pfizer developed a T cell engaging antibody platform, which allows the formation of full length human IgG1 and IgG2 antibodies *in vitro* or *in vivo*. The effect of IgG isotype and affinities of the T cell- and tumor antigen-targeting arm were explored and optimized.

14:50 Computational Approaches in Antibody Design: Identifying and Reducing Liabilities early in the Discovery Process

David Pearlman, Ph.D., Senior Principle Scientist, Schrödinger

Computational tools that can be used in the optimization process for antibody drug candidates have greatly improved in the past. These tools are finding increasing acceptance for liability assessment and reduction in the discovery process. We describe how these calculations can be utilized for workflowed triage among multiple candidates, and how tools such as FFP are used to suggest sequence engineering that can ameliorate identity aggregation propensity while maintaining affinity and stability.

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

ENGINEERING BISPECIFICS FOR T CELL ENGAGEMENT

16:05 Engineering of CD3 Bispecific FynomAbs

Julian Bertschinger, Ph.D., Vice President, Janssen R&D, Managing Director, Covagen

I will describe the development of bispecific FynomAbs by fusing human Fynomer binding proteins to antibodies, resulting in bispecific protein therapeutics with novel modes-of-action and enhanced efficacy for the treatment of inflammatory diseases and cancer. We will present case studies demonstrating that FynomAbs with tailored architecture overcome limitations encountered with other therapeutic protein formats, such as suboptimal efficacy of lack of tumour selectivity.

16:35 High Affinity T Cell Receptor-Based Bifunctional Biologics for Redirected Tumour Killing

Milos Aleksic, Ph.D., Team Lead, Protein Engineering, Immunocore

ImmTACs are bispecific reagents that target tumours via a soluble monoclonal TCR with exceptionally high sensitivity and specificity and redirect host polyclonal T cells via an anti-CD3 antibody fragment. The selection and validation of appropriate target antigens and the testing of ImmTACs for specificity is critical. Using appropriate tumour and primary human cell lines, the *in vitro* pre-clinical package can be predictive of *in vivo* clinical observations.

17:05 End of Day

17:00 Dinner Short Course Registration

Recommended Dinner Short Course*

SC6: Engineering of Bispecific Antibodies

*Separate registration required. Please see page 4 for details.



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FRIDAY 4 NOVEMBER

08:00 Registration and Morning Coffee

FOCUS ON BISPECIFIC ENGINEERING FOR TARGETING

08:30 Chairperson's Remarks

Ulrich Brinkmann, Ph.D., Expert Scientist, Roche Innovation Center

08:35 Epitopes Matter: Strategies to Generate and Analyse Binders to Different Epitopes

Jonas Schaefer, Ph.D., Head, High-Throughput Binder Selection Facility, Biochemistry, University of Zurich

Several characteristics determine the true value and potential of affinity reagents for most applications. However, while amongst other the lead candidate's affinity can be matured after it has been identified, scientists still are not able to routinely and reliably design these binders for specific epitopes. Thus, special considerations have to be taken into consideration both in the selection and screening processes, which will be presented in this presentation.

09:05 Engineered Fab Domains Promote Efficient Production of Bispecific Antibodies in a Single Cell

Christoph Spiess, Ph.D., Senior Scientist, Antibody Engineering, Genentech, Inc.

Bispecific antibodies have gained increased relevance in research and therapeutic settings despite the complexities in their production and challenges in finding the right combination. The presentation will discuss strategies and consideration to screen for the best bispecific antibody pair. In addition, a novel approach to produce a bispecific antibody with natural surface architecture in a single cell will be discussed. The technology now simplifies bispecific production for research and development.

09:35 A Novel Highly Versatile Multi-Specific Antibody Format

David Urech, Ph.D., CSO and Co-CEO, Numab AG

We present the MATCH, a novel modular antibody format that utilises a pair of split variable domains to drive defined assembly of heterodimeric complexes with up to six specificities. This architecture offers the unique advantage of rapidly screening permutations of binder panels to identify ideal combinations of affinities, potencies and specificities in the final molecular format. This format offers unprecedented opportunities for fine-tuning binding properties for targeting complex pathologies.

10:05 Coffee Break in the Foyer with Poster Viewing

PLATFORM DEVELOPMENT AND REFINEMENT

10:35 CrossMAb Version 2: A Versatile Toolbox for Bispecific Antibody Engineering

Joerg Thomas Regula, Ph.D., Head, Functional Characterisation, Large Molecule Research, Roche Pharmaceutical Research and Early Development

The CrossMAb technology (Schäfer et al., 2011) can be used to generate a bispecific antibody from two independent parental antibodies by immunoglobulin domain exchange. Additional modifications can be introduced in these different CrossMAb designs. This enables their use as well suited building blocks for the generation of bispecific antibodies with 1+1, 2+1 or 2+2 target binding sites.

11:05 Efficient Generation of Bispecific Mouse Antibodies for Preclinical Investigations

Aran F. Labrijn, Ph.D., Principal Scientist, Antibody Sciences, Genmab BV

Complex therapeutic concepts are often studied using (surrogate) mouse antibodies in immunocompetent mice to ensure optimal interaction with tumour associated immune cells and the microenvironment. We recently described controlled Fab-arm exchange (cFAE) as a versatile and robust method for the generation of therapeutic human IgG1 bispecific antibodies (bsAb). To facilitate the study of dual-targeting concepts in immunocompetent mice, we have now applied and optimised our method for the efficient generation of murine bsAbs.

11:35 Platform Refinements for Bispecifics for Oncology Targets

John de Kruif, Ph.D., CTO, Merus

12:05 Sponsored Presentation (Opportunity Available)

12:35 Problem-Solving Breakout Discussions with a Light Snack in the Foyer*

*See website for more details.

13:35 Session Break

NOVEL APPROACHES

14:00 Chairperson's Remarks

Joseph Dukes, Ph.D., Head, Pre-Clinical Biology, Cell Biology, Immunocore

14:05 Using Alphanobodies to Generate Bispecifics with Optimal *in vitro* and *in vivo* Characteristics

Yvonne McGrath, Ph.D., CSO, Complix NV

CMPX-1023 is an Alphanobody that has been engineered to bind the p19 chain of IL-23, a cytokine of therapeutic importance in autoimmune disease. By fusing CMPX-1023 to different anti-TNF α antibodies at various positions, we have generated a panel of therapeutic bispecific proteins. CMC characteristics, *in vitro* potencies and *in vivo* pharmacokinetics of this panel of bispecifics will be presented.

14:35 Hapten-Bispecific Antibodies for Drug Discovery and Delivery Applications

Ulrich Brinkmann, Ph.D., Expert Scientist, Roche Innovation Center

Many bispecific and engineered antibody derivatives are in preclinical stages for a variety of applications, some in clinical development, and a few are approved. The presentation will provide an overview of the concepts and status of engineered bispecific antibodies at Roche with a focus on novel formats and bsAb-applications for discovery applications. This includes the application of Hapten-binding antibody derivatives for delivery of payloads to, into, as well as across tissues and cells.



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15:05 Cellular FRET Assay for the Determination of Simultaneous Binding of Bispecific Antibodies

Stefan Seeber, Ph.D., Principal Scientist, Cell Line and Molecule Development, Roche Innovation Center Munich/Large Molecule Research

To demonstrate simultaneous binding to two cell surface expressed receptor targets, we developed a robust, one-vial, FRET-based system, allowing for parallel testing of 2 independent pathways (not necessarily cross-talking). We engineered cell lines expressing the two receptors with FRET tags inserted proximal to the cell membrane. Possible applications as a screening tool or potency assay will be discussed.

15:35 Novel Strategy for a Bispecific Antibody: Induction of Dual Target Internalisation and Degradation

Ji Min Lee, Ph.D., Principal Scientist, Open Innovation Team, Samsung Bioepis

Cancers show well aligned multifaceted properties, and there is cross-talk and convergence of signaling pathways of RTKs. Consequently, many therapeutic interventions have been actively developed to overcome inherent or acquired resistance. To date, no BsAb have shown complete depletion of dual RTKs from the plasma membrane and efficient dual degradation. Leveraging the anti-Met mAb, we generated the BsAbs for Met/EGFR and Met/HER2 to induce an efficient EGFR or HER2 internalisation and degradation.

16:05 Engineering and Manufacturing of Bispecific Antibodies for T-Cell Redirection

Stanislas Blein, Ph.D., Senior Director, Antibody Engineering, Glenmark Pharmaceuticals

Over the past two decades various functional bispecific antibody formats have been designed with only few molecules reaching clinical trials due to an inherent lack of manufacturability. Herein we describe a versatile bispecific antibody format that fits industrial-scale manufacturing processes and enables the rapid design and making of T-cell redirecting molecules. Engineering, preclinical and phase-one manufacturing data will be presented.

16:35 End of Conference

"As in past years, PEGS Europe again proved to be a stimulating conference with distinguished speakers from both industry and academia, covering the hot topics of the field. A great source of food for thought"

*- Jonas S., Ph.D., Head, High-Throughput Binder Selection Facility,
Department of Biochemistry, University of Zurich*



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Engineering Next-Generation Antibody-Drug Conjugates

Into the Clinic and Beyond

Recommended Short Course*

SC3: Designing Antibodies for Function and Low Risk of Immunogenicity

*Separate registration required, please see page 4 for details.

MONDAY 31 OCTOBER

12:00 Registration

PLENARY KEYNOTE SESSION

13:40 Welcome from PEGS Europe Team

13:45 Chairperson's Opening Remarks

Ana Barbas, Ph.D., Coordinator, Bayer Satellite Laboratory at iBET, iBET and Bayer Portugal SA

13:50 Biotherapeutic Programs that Re-Direct Cytotoxic Lymphocytes to Cancer Cells



Paul Adam, Ph.D., Executive Director, Immune Modulation and Biotherapeutics Discovery, Boehringer Ingelheim

Cytotoxic lymphocytes such as NK and T cells have the capability to control cancer development and progression. Harnessing this cytotoxic potential with biotherapeutic agents is predicted to become a future pillar of cancer therapy in light of recent clinical successes. This presentation will describe novel biotherapeutics whose mode of action involves the engagement and re-direction of NK and T cells to hematological tumors.

14:30 Antibody-Based Combination Cancer Immunotherapy at Roche pRED



Christian Klein, Ph.D., Distinguished Scientist, Head, Oncology Programs, Cancer Immunotherapy Discovery, Roche Pharmaceutical Research and Early Development, Roche Innovation Center Zurich

This presentation will introduce novel antibody cancer immunotherapies developed at Roche pRED including novel IL2 variant immunocytokines and T cell bispecifics as well as preclinical data for their optimal combination and scheduling.

15:10 Safety Concerns Associated with Immunotherapy and Novel Biotherapeutics and Challenges in Investigating Their Immunotoxicity



Sandra S. Diebold, Ph.D., Principal Scientist, Immunotoxicology, Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

The pre-clinical assessment of the risks associated with immunotherapy and novel biotherapeutics is challenging since the bioassays have to be individually tailored to the investigated reagent. The immunotoxic activity and adverse responses that may be observed in patients are depending to a large degree on the mechanism of action of the biotherapeutic. The specific set-up of *in vitro* assays plus the identification of suitable animal models is critical for obtaining predictive pre-clinical data.

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

DEVELOPING EFFICACIOUS ADCs

16:50 Chairperson's Remarks

Jens Lohrmann, Ph.D., Senior Global Program Manager, Translational Clinical Oncology, Novartis Institutes for BioMedical Research

16:55 Chemical Pharmacology of Protein Conjugates

Gonçalo J.L. Bernardes, Ph.D., Principal Investigator, Chemistry, University of Cambridge

Our work centers on reaction engineering for site-selective chemical protein modification to provide insight into biology and for the development of protein therapeutics. This lecture addresses recent research in: (i) site-selective chemical modification of proteins and antibodies at cysteine and lysine, and (ii) the development of CO-releasing artificial metalloproteins that are able to deliver CO in a targeted and controlled manner to tumor tissues leading to potent CO-mediated immunomodulation.

17:25 Platform Technologies for Homogeneous and Versatile Full Antibody and Antibody Fragment Modification

Vijay Chudasama, Ph.D., Lecturer, Chemistry, University College London

There is clear demand for the construction of novel antibody-drug conjugate (ADC) platforms that offer greater stability, homogeneity and flexibility. A significant step towards the ideal platform for next generation antibody-based therapeutics is presented. Our technology provides decorated antibody constructs that are highly stable, with complete retention of antibody binding/structure post-modification. It combines site-specific functionalisation with exceptional versatility via the functional re-bridging of interchain disulfide bonds native to antibodies.



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17:55 Sponsored Presentation (*Opportunity Available*)

18:25 Welcome Reception in the Exhibit Hall with Poster Viewing

19:25 End of Day

TUESDAY 1 NOVEMBER

07:45 Registration and Morning Coffee

FULFILLING THE PROMISE OF ADCs

08:30 Chairperson's Remarks

João Tomé, Ph.D., Associate Professor, Chemical Engineering, Instituto Superior Técnico, University of Lisbon

08:40 KEYNOTE PRESENTATION:

Advancement in Antibody Drug Conjugates: A Step Closer to Creating Magic Bullets against Deadly Cancers

Rakesh Dixit, Ph.D., DABT, Vice President, Research & Development, and Global Head, Biologics Safety Assessment, Medimmune (A member of AstraZeneca Group)

- Discuss 5 Rights (target, antibody, linker, warhead and translational strategy) of ADCs
- How to improve and maximize the therapeutic effectiveness of ADCs
- Case studies of a biparatopic ADC for highly resistant low Her2 expressing cancers
- Recent developments in PBD-based ADCs
- Personalized biomarkers-dependent clinical ADC development

09:10 Design, Synthesis and Scale-Up of an ADC Tubulysin Payload

Jeremy S. Parker, Ph.D., Principal Scientist, New Modalities & Tissue Targeting, AstraZeneca

AstraZeneca has designed, synthesized, and manufactured a novel Tubulysin payload that has been successfully used in the production of MedImmune's Biparatopic HER2-Targeting Antibody Drug Conjugate which is currently in Phase I clinical trials.

09:40 Problem-Solving Breakout Discussions*

**See website for details.*

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

SITE-SPECIFIC TECHNOLOGY

11:20 Challenge ADC Therapeutic Index with TG-IPH Site-Specific Technology

Florence Lhospice, Director, Pharmaceutical Operations, Innate Pharma

Here, we describe the *in vitro* and *in vivo* characterization of four novel ADCs that are based on the anti-CD30 antibody cAC10, which has the same polypeptide backbone as ADCETRIS®, and compare the results with the latter. Overall, the results suggest that homogenous ADCs display improved pharmacokinetics and better therapeutic indexes compared to chemically modified ADCs with variable DARs. Of note, equivalent results were confirmed with a panel of drugs and targets as per our current collaborations and our own programs.

11:50 Tub-Tag Labeling – A Novel Chemoenzymatic Approach for the Generation of Site-Specific ADCs

Jonas Helma, Ph.D., Project Group Leader, Biology II, Ludwig-Maximilians University Ludwig-Maximilians Universität

A novel chemoenzymatic approach for simple and fast site-specific antibody conjugation is presented. We repurposed tubulin tyrosine ligase (TTL) to attach various unnatural tyrosine derivatives as small bioorthogonal handles to nanobodies and recombinant antibodies containing a short tubulin-derived recognition sequence (Tub-tag). This novel strategy enables a broad range of chemoselective C-terminal antibody modifications. We foresee a wide field of potential applications throughout the life sciences, including next-generation Antibody-Drug Conjugates.

12:20 Sponsored Presentation (*Opportunity Available*)

12:50 Luncheon Presentation (*Sponsorship Opportunity Available*) or **Enjoy Lunch on Your Own**

13:20 Session Break

14:00 Dessert Break in the Exhibit Hall with Poster Viewing

ADVANCING CONJUGATION CHEMISTRY

14:30 Chairperson's Remarks

Jeremy S. Parker, Ph.D., Principal Scientist, New Modalities & Tissue Targeting, AstraZeneca

14:35 Enhancing the Therapeutic Index of ADCs by Conjugation through Glycans with Improved Linkers

Floris Van Delft, Ph.D., Founder & CSO, SynAffix BV

The globally conserved N-glycan provides a superior, natural anchor point for antibody conjugation. By applying a two-stage process involving enzymatic glycan remodeling, and copper-free click attachment of cytotoxic payload, antibody-drug conjugates (ADCs) can be readily prepared from any mAb without protein reengineering. Conjugation of highly hydrophobic payloads is facilitated by applying a short and polar spacer technology, leading to ADCs with improved therapeutic index by increasing *in vivo* efficacy and tolerability.

15:05 Advances in Bio-Orthogonal and Bio-Specific Bond-Forming Reactions for Improved Antibody-Based Conjugates

Alain Wagner, Ph.D., Research Director, Functional ChemoSystem, Strasbourg University and CNRS

The recent development in the fields of bio therapeutics and chemical biology has shed light on the limitations of current bioconjugation and bio-de-conjugation reactions in terms of bio-stability bio-selectivity and biocompatibility. The presentation will focus on some methodological approaches we have implemented to discover novel efficient molecular systems to link and release bioactive compounds and biomolecules.

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15:35 Photo-Immunoconjugates for Targeted Cancer Photodynamic Therapy

João Tomé, Ph.D., Associate Professor, Chemical Engineering, Instituto Superior Técnico, University of Lisbon

The recent development of photo-immunoconjugates as photosensitizers (PSs, photoactive drugs) to target cancer cells open new perspectives for cancer photodynamic therapy (PDT). In this talk, some of our recent work on the synthesis of PSs and PS-antibody conjugates will be shown, as well as highlighting their biological potential against human bladder cancer cell lines.

16:05 Sponsored Presentation (Opportunity Available)

16:35 Refreshment Break in the Exhibit Hall with Poster Viewing

INNOVATING ADC DESIGNS AND PROCESSES

17:15 Novel Linker Chemistries for Antibody-Drug Conjugates

Thomas Pillow, Ph.D., Senior Scientist, Discovery Chemistry, Genentech, a member of the Roche Group

This presentation will focus on our development of a novel disulfide linker where we demonstrate for the first time the ability to decouple stability and release. This linker takes advantage of new sites on cysteine-engineered antibodies that stabilizes both the linker and the payload from metabolism. When applied to PBDs, the disulfide-linked ADC has an improved therapeutic index compared to a peptide-linked ADC.

17:45 Small is Beautiful – Humabodies Drug Conjugates, HDCs a Real Alternative to ADCs

Normann Goodwin, Ph.D., Senior Scientist, Preclinical Development, Crescendo Biologics, Ltd.

Humabodies enable plug and play engineering allowing simple exploration of limitless format options. HDCs demonstrate exceptionally fast tumor penetration. Half-life can be tailored facilitating low systemic and high tumor exposure. Different format of HDCs show high-impact on potency both *in vitro* and *in vivo*. Therefore the versatility of the Humabody™ format enables creation of optimal HDC format and half-life with improved Therapeutic Index.

18:15 Challenges & Lessons Learned in ADC CMC Development & Outsourcing

Jens Lohrmann, Ph.D., Senior Global Program Manager, Translational Clinical Oncology, Novartis Institutes for BioMedical Research

A key decision for achieving stable ADCs is whether to “buy or make” these highly active compounds. Leveraging the know-how of CMOs can be powerful; however, to ensure an effective relationship, communication is key. Technical challenges of site-transfers, especially with concomitant scale-up are to be expected. Case studies will be presented to discuss impact of conjugation process on key product quality attributes, as well as lessons learned from analytical transfers.

18:45 End of Engineering Next-Generation Antibody-Drug Conjugates



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31 October – 1 November 2016

Inaugural

Novel Immunotherapy Strategies

Exciting Developments with Promise in the Clinic

Recommended Short Course*

SC1: Cancer Immunotherapy

*Separate registration required, please see page 4 for details

MONDAY 31 OCTOBER

12:00 Registration

PLENARY KEYNOTE SESSION

13:40 Welcome from PEGS Europe Team

13:45 Chairperson's Opening Remarks

Ana Barbas, Ph.D., Coordinator, Bayer Satellite Laboratory at iBET, iBET and Bayer Portugal SA

13:50 Biotherapeutic Programs that Re-Direct Cytotoxic Lymphocytes to Cancer Cells



Paul Adam, Ph.D., Executive Director, Immune Modulation and Biotherapeutics Discovery, Boehringer Ingelheim

Cytotoxic lymphocytes such as NK and T cells have the capability to control cancer development and progression. Harnessing this cytotoxic potential with biotherapeutic agents is predicted to become a future pillar of cancer therapy in light of recent clinical successes. This presentation will describe novel biotherapeutics whose mode of action involves the engagement and re-direction of NK and T cells to hematological tumors.

14:30 Antibody-Based Combination Cancer Immunotherapy at Roche pRED



Christian Klein, Ph.D., Distinguished Scientist, Head, Oncology Programs, Cancer Immunotherapy Discovery, Roche Pharmaceutical Research and Early Development, Roche Innovation Center Zurich

This presentation will introduce novel antibody cancer immunotherapies developed at Roche pRED including novel IL2 variant immunocytokines and T cell bispecifics as well as preclinical data for their optimal combination and scheduling.

15:10 Safety Concerns Associated with Immunotherapy and Novel Biotherapeutics and Challenges in Investigating Their Immunotoxicity



Sandra S. Diebold, Ph.D., Principal Scientist, Immunotoxicology, Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

The pre-clinical assessment of the risks associated with immunotherapy and novel biotherapeutics is challenging since the bioassays have to be individually tailored to the investigated reagent. The immunotoxic activity and adverse responses that may be observed in

patients are depending to a large degree on the mechanism of action of the biotherapeutic. The specific set-up of *in vitro* assays plus the identification of suitable animal models is critical for obtaining predictive pre-clinical data.

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

KEYNOTE PRESENTATIONS

16:50 Chairperson's Remarks

Marie Kosco-Vilbois, Ph.D., CSO, Novimmune SA

16:55 Immunotherapy "From the Inside"

Stefan Dübel, Ph.D., Managing Director, Biochemistry, Biotechnology and Bioinformatics, Technische Universität Braunschweig

We present approaches for inhibition of cell surface receptors or signalling pathways by novel strategies "from the inside". We will inspire the biologics engineering community to start thinking out of the box by opening doors to targets which so far could not be reached inside the cell, and to add extra punch or extra safety to biologics by targeting a combination of two disease specific features.

17:25 Clinical Development of Adoptive T-Cell Therapy in Melanoma and Beyond

Rienk Offringa, Ph.D., Head, Molecular Oncology of Gastrointestinal Tumours, German Cancer Research Centre

Adoptive transfer of tumour-infiltrating T cells has shown striking efficacy in patients with metastatic melanoma, even in late stage patients. T cells targeting neo-epitopes encoded by the tumour mutanome play a dominant role in this respect. Based on this insight, adoptive T-cell therapy can now be further optimised and developed for the treatment of other cancer indications.

17:55 Quantitative Cell-Based Bioassays for Analysis of mAb Fc Effector and Immune Checkpoint Functions

Gopal Krishnan, Ph.D., Global Product Manager, Cellular Analysis & Proteomics, Promega

Immunotherapy is a promising therapeutic strategy to better fight cancer. We have developed many reporter bioassays for immune checkpoint, co-stimulatory and immunomodulatory receptors including combination bioassays (e.g., PD-1+TIGIT). The assays can quantitatively determine the potencies of candidate antibody drugs or ligand proteins and are valuable tools for antibody screening.

18:10 Sponsored Presentation (Opportunity Available)

18:25 Welcome Reception in the Exhibit Hall with Poster Viewing

19:25 End of Day

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THERAPEUTICS

31 October – 1 November 2016

TUESDAY 1 NOVEMBER

07:45 Registration and Morning Coffee

IMMUNE CHECKPOINT INHIBITORS

08:30 Chairperson's Remarks

Saar Gill, M.D., Ph.D., Assistant Professor, Medicine, Hematology- Oncology, University of Pennsylvania School of Medicine

08:40 Targeting Immune Regulation at the Tumour Site: Mechanistic Insights on Immune Modulatory Antibodies

Frederick Arce Vargas, Ph.D., Haematology, University College London Cancer Institute

By studying the mechanism of action of anti-CLTA-4 therapy in murine models, we have learned that the effectiveness of immune modulatory antibodies depends on the antibody isotype and not only on blocking or activating the signalling through their targets. Furthermore, a systematic characterisation of the immunological landscape of human cancers has provided more insight on how to translate findings in murine models into clinical application in a rational way.

09:10 Targeted Protein Therapeutics – Alone and in Combination with Immunotherapy

Gregory P. Adams, Ph.D., Chief Development Officer, Viventia Bio

TPTs mediate direct tumour killing and offer the ability to activate anti-tumour immunity. In early phase clinical studies, intra-tumoural injection of Proxinium mediated impressive effects directly on injected tumours and indirectly on uninjected tumours, suggesting the generation of an anti-tumour immune response. Clinical trial results and preclinical studies will be presented both examining the mechanisms underlying the indirect anti-tumour effect and evaluating the potential of combining Proxinium with checkpoint inhibitors.

09:40 Problem-Solving Breakout Discussions*

*See website for details.

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

PRECLINICAL AND CLINICAL DEVELOPMENTS

11:20 Therapeutic Targeting of B7-H3 in Solid Tumours through Immune Enhanced Abs and DART Molecules

Paul Moore, Ph.D., Vice President, Cell Biology and Immunology, MacroGenics, Inc.

Complementary strategies targeting B7-H3, a B7-family member expressed on solid tumours, are undergoing clinical development. Enoblituzumab, an Fc-enhanced humanized anti-B7H3 mAb, exhibits favorable safety with preliminary evidence of activity and T-cell modulation, supporting further development as monotherapy and combination with checkpoint inhibitors. To leverage the tumor lytic activity of T cells and drive their expansion, we have also developed MGD009, an Fc-bearing B7-H3xCD3 DART molecule, currently in Phase 1 testing.

11:50 FEATURED PRESENTATION: CART Cell Immunotherapy Approaches in the Clinic

Renier J. Brentjens, M.D., Ph.D., Director, Cellular Therapeutics, Memorial Sloan-Kettering Cancer

While chimeric antigen receptor (CAR) approaches have resulted in significant clinical benefit with some CD19-B cell malignancies, far more modest outcomes are seen in patients treated with chronic lymphocytic leukemia (CLL). I will present next generation CART cell approaches that directly target and kill tumour cells, modulate and overcome the immunosuppressive tumour microenvironment and recruit endogenous anti-tumour immune effector cells to avoid tumour immune escape.

12:20 Talk Title to be Announced

Amrik Basran, Ph.D., CSO, Therapeutics, Avacta Life Sciences

12:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

13:20 Session Break

14:00 Dessert Break in the Exhibit Hall with Poster Viewing

DEVELOPMENTS WITH CHIMERIC ANTIGEN RECEPTOR-T CELL THERAPY

14:30 Chairperson's Remarks

Kerry Chester, Ph.D., Professor, University College London, Cancer Institute

14:35 Clinical Advances in CART Cell Therapy with a Focus on Anti-CD19 CARs

Saar Gill, M.D., Ph.D., Assistant Professor, Medicine, Hematology- Oncology, University of Pennsylvania School of Medicine

Currently more than 70 clinical trials using CART cells, most of them targeting CD19, are open worldwide. Patients with B-cell malignancies are the first beneficiaries of an exciting and potent new treatment that harnesses the power of the immune system as never before. These patients represent the vanguard of enormous preclinical efforts to develop CART therapy into a procedure that hopefully will one day be routine and curative.

15:05 Tumour Models to Investigate CART Cell Potency, and Acute and Chronic Toxicity

David Gilham, Ph.D., Senior Lecturer, Clinical and Experimental Immunotherapy Group, Institute of Cancer Sciences, University of Manchester

Reports of objective clinical responses and tumour regression in patients receiving Chimeric Antigen Receptor (CAR) -T cell therapy are driving a major surge of interest in the field. CARs are artificial targeting proteins that exploit antibody-based approaches to re-direct the effector function of the T cell to virtually any cell surface target. However, it remains unclear whether toxicity resulting from over-activity of the T cell or lack of suitable target specificity is likely to be an issue. Models can provide some answer to this although the relevance of such models remains open to question.



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15:35 ErbB-Targeted CART cell Immunotherapy of Cancer

Daniela Achkova, Ph.D., Research Associate, Research Oncology, King's College London

We have developed a CAR-based T4 immunotherapy approach targeting 8 of 9 possible ErbB homo- and heterodimers. Efficacy has been demonstrated in established xenograft models of head and neck, ovarian, breast cancer and mesothelioma *in vivo*. Although this immunotherapy also recognises mouse ErbB receptors, toxicity does not occur following intra-tumoural administration. To exploit this, we have initiated a Phase I trial of T4 immunotherapy in patients with locally advanced/ recurrent squamous cell cancer of the head and neck.

16:05 Sponsored Presentation (Opportunity Available)

16:35 Refreshment Break in the Exhibit Hall with Poster Viewing

TCR TARGETS/ROLE OF B CELLS/CYTOKINES

17:15 Taking SPEART Cells to the Clinic – From TCR Target Selection to Clinical Manufacture

Jo Brewer, Ph.D., Director, Cell Research, Adaptimmune

SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell therapy, using engineered T-cell receptors (TCRs), is showing clear promise in sarcoma and multiple myeloma trials targeting NY-ESO. Trials are now open with other TCRs: MAGE A10 & AFP – and there will be more to come. I will discuss the lifecycle of a SPEAR T-cell product from target selection, TCR identification and optimization, preclinical safety testing and manufacturing to make a robust, clinical product suitable for commercial use.

17:45 B Cells and Antibody Responses in Solid Tumours

Sophia N. Karagiannis, Ph.D., Senior Lecturer, Translational Cancer Immunology, Head, Cancer Antibody Discovery and Immunotherapy, St. John's Institute of Dermatology, Division of Genetics and Molecular Medicine, King's College London

The nature and contribution of circulating and tumour-infiltrating B cells and the antibodies they produce remain largely unexplored. We report active B-cell immune surveillance and mature memory B cells with distinct immunoglobulin isotype-biased profiles in melanoma. We provide evidence in support of monitoring the humoral immune compartment in cancer to provide new prognostic tools and to inform therapeutic antibody design.

18:15 Bi- and Tri-Functional Antibody-Cytokine Fusion Proteins for Cancer Immunotherapy

Dafne Mueller, Ph.D., Group Leader, Cell Biology and Immunology, University of Stuttgart

IL-15 and costimulatory members of the B7 and TNF superfamily have shown great potential to support the generation and development of an anti-tumour immune response. In order to improve the efficacy of such molecules at the tumour site we designed bi- and tri-functional antibody-fusion proteins, focusing on targeted presentation and combined mode of action of diverse immunomodulatory molecules, demonstrating enhanced immune responsiveness *in vitro* and anti-tumour activity in a mouse model *in vivo*.

18:45 End of Novel Immunotherapy Strategies

“

Once more, PEGS Europe was an outstanding event with great science and a perfect setting for networking. Very nice combination of topics and speakers.

”

- PHILIPP M., PH.D., PROJECT LEADER, BIOMEDICINE, UNIVERSITY HOSPITAL OF BASEL



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2-3 November 2016

8th Annual

Advancing Bispecifics and Combination Therapy to the Clinic

Including New Focus on Immunotherapy Targets

Recommended Short Course*

SC1: Cancer Immunotherapy

*Separate registration required. Please see page 4 for details.

WEDNESDAY 2 NOVEMBER

07:45 Registration and Morning Coffee

BISPECIFICS FOR RETARGETING / REPROGRAMMING T CELLS

08:30 Chairperson's Remarks

Janine Schuurman, Ph.D., Vice President, Research, Genmab B.V.

08:35 KEYNOTE PRESENTATION: Bispecific T Cell Engagers (BiTEs) for the Treatment of Malignant Diseases

Matthias Friedrich, Ph.D., Director, Nonclinical Development, Amgen Research (Munich) GmbH

09:20 Novel T Cell-Redirecting Bispecific Antibody Targeting a Highly Tumour Specific Antigen

Hirotake Shiraiwa, Ph.D., Group Manager, Biologics Discovery, Chugai Pharmaceutical Co., Ltd.

We have generated a T cell-redirecting antibody against a highly tumour specific antigen. This fully bispecific antibody recognises both CD3 and tumour-specific antigens and exerts highly potent anti-tumour efficacy in various *in vivo* models, and its large scale production has been made possible by proprietary engineering technology. The findings observed in non-human primate toxicity studies were manageable and reversible. Optimisation, pharmacology, and toxicity of this antibody will be presented.

09:50 Development of REGN1979, a Fully Human CD20xCD3 Bispecific Antibody

Eric Smith, Ph.D., Associate Director, Bispecific Antibodies, Regeneron, Inc.

This presentation will describe the development of REGN1979, a fully human CD20xCD3 bispecific antibody generated with Regeneron's VelocImmune® technology. Characterization of the *in vitro* and *in vivo* properties of this bispecific will be discussed, along with findings from pre-clinical efficacy studies. In addition, an update on the clinical status of REGN1979 and future planned studies will be provided.

10:20 Sponsored Presentation (Opportunity Available)

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Development of a Highly Potent Anti-P-Cadherin / Anti-CD3 Bispecific DART Molecule with Extended Half-Life for the Treatment of Cancer

Adam Root, MSc, Senior Principal Scientist, Global BioTx Technologies, Pfizer, Inc.

We have made an extended-half-life dual-affinity re-targeting (DART) bispecific against P-cadherin and CD3 that demonstrates antibody-like properties. Identified through phage display and affinity-optimised to picomolar affinity, this bispecific molecule elicits P-cadherin-expression level-dependent CTL responses against different tumour lines and induces antigen-dependent T cell activation and cytokine release. PF-06671008 demonstrates potent *in vivo* anti-tumour activity with significant tumour growth inhibition observed across a range of tumour types expressing P-cadherin.

12:00 To the Clinic with T Cell-Engaging and Checkpoint-Inhibiting Bispecific Antibodies - A Modular Approach to Build and Develop Novel Cancer Immunotherapies

David E. Szymkowski, Ph.D., Senior Director, Research, Xencor, Inc.

Bispecific antibody-mediated co-engagement of T cells with tumour antigens is now a validated therapeutic strategy, but manufacturing and dosing concerns have slowed clinical development of such immunomodulatory drugs. We have engineered modular Fc-containing bispecifics by coupling a robust and portable single-chain CD3 domain with full-length antibodies against promising cancer targets, and have also extended this Fc platform to generate multiple-checkpoint inhibiting bispecifics. I will present case studies of several such bispecifics entering clinical development, supported by superior pharmacology and half-life in monkeys coupled with efficient commercial-scale manufacturing.

12:30 Sponsored Presentation (Opportunity Available)

13:00 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

13:30 Session Break

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THERAPEUTICS

2-3 November 2016

BISPECIFICS THAT TARGET CHECKPOINT REGULATION FOR IMMUNOTHERAPY

14:00 Chairperson's Remarks

Tariq Ghayur, Ph.D., Distinguished Research Fellow, Biologics, Abbvie Research

14:05 Design and Development of Next Generation Bispecific Antibodies for Cancer Immunotherapy

Jinming Gu, Ph.D., Executive Director, Biologics, Shanghai Hengrui Pharmaceuticals Co. Ltd.

Cancer immunotherapy has emerged as one of the major focuses in the pharmaceutical industry. The current limitation of anti-CTLA-4 or anti-PD-1 therapies is low response rate and high toxicity. This presentation will cover a few late stage preclinical bispecific programs in cancer immunotherapy, e.g. CD40/X, OX-40/X, and CD3/X.

14:35 Finding the Right Balance: Selective and Safe Targeting of the Ubiquitous CD47 Checkpoint Receptor on Cancer Cells

Nicolas Fischer, Ph.D., Head, Research, NovImmune SA

The immune checkpoint CD47 represents an attractive target in oncology. However, due to the ubiquitous expressions of CD47, the use of monoclonal antibodies faces safety and pharmacology liabilities. We have developed NI-1701, a bispecific $\kappa\lambda$ body, that selectively targets CD47 on B cells. CD47 inhibition drives effective phagocytosis of cancer cells *in vitro* and *in vivo* as well as the induction of durable anti-tumour responses in syngeneic animal models.

15:05 Vanucizumab, a Novel Bispecific Antibody Targeting VEGF-A and Angiopoietin-2: Preclinical and Clinical Development, and Preliminary Data on Combining with Cancer Immunotherapy

Oliver Krieter, M.D., Senior Translational Medicine Leader, Pharma Research and Early Development (pRED), Roche

15:35 Refreshment Break in the Exhibit Hall with Poster Viewing

T-CELL RETARGETING AND CHECKPOINT REGULATION (CONT.)

16:15 Duokines: A New Class of Bifunctional Immunostimulatory Molecule

Roland Kontermann, Ph.D., Professor, Biomedical Engineering, Cell Biology and Immunology, University of Stuttgart

Duokines are bifunctional fusion proteins of TNF ligand superfamily members expressed either as homotrimer molecules or as single-chain derivatives. They act either in cis or in trans and are capable of amplifying immune responses, e.g. as shown for the anti-tumour activity of T-cell retargeting bispecific antibodies.

16:45 Development of Bispecific DART Molecules to Mobilise Anti-Tumour Immunity

Paul Moore, Ph.D., Vice President, Cell Biology and Immunology, MacroGenics, Inc.

The DART® (Dual-Affinity ReTargeting) scaffold, a covalently-linked diabody-based bispecific module, can be tailored for single or multi-valency as well as fast or prolonged pharmacokinetics. Several DART molecules designed to recruit T cells through co-engagement with cancer antigens are currently in clinical development. Furthermore, the DART platform is ideally suited

for immunomodulation via co-checkpoint blockade, such as PD-1xLAG3. Preclinical studies supporting the development of these DART molecules will be presented.

17:15 Problem-Solving Breakout Discussions*

**See website for details.*

18:15 Networking Reception in the Exhibit Hall with Poster Viewing

19:15 End of Day

THURSDAY 3 NOVEMBER

08:00 Registration and Morning Coffee

SYNERGIES: MULTISPECIFIC ANTIBODIES AND COMBINATIONS OF MONO-SPECIFIC ANTIBODIES

08:30 Chairperson's Remarks

Nicolas Fischer, Ph.D., Head, Research, NovImmune SA

08:35 Functional Aspects of Antigen- and Fc-Dependent IgG Hexamer Formation

Janine Schuurman, Ph.D., Vice President, Research, Genmab B.V.

Monomeric antibodies of the IgG isotype can organise into ordered hexamers after binding their cognate antigen expressed on a cell surface. While unraveling the molecular mechanisms of IgG hexamerisation, we identified point mutations that either inhibited or stimulated the formation of IgG hexamers and complement-mediated cytotoxicity (CDC). Our studies demonstrate that IgG hexamer formation, in addition to potentiating CDC, can induce outside-in signaling and activate intracellular signaling pathways, which we will discuss using two Death Receptor 5 (DR5) specific antibodies.

09:05 Avidity Enhances the Efficacy of EGFR x cMet Bispecific Antibody

Mark Chiu, Ph.D., Associate Director, Structural Biology, Janssen Research and Development

Monovalent bispecific antibodies are typically thought to bind to their respective targets without avidity. However, we show how receptor densities of EGFR and cMet in different lung cancer cell lines can contribute to apparent synergy in targeting both receptors. This impacts the use of an appropriate selection strategy of bispecific antibodies.

09:35 Antibody Mixtures: From Bench to Bedside

Michael Kragh, Ph.D., Senior Director, Preclinical Development, Symphogen

This presentation will outline the receptor internalisation and degradation with two antibodies targeting non-overlapping epitopes, and demonstrate the ability of antibody mixtures to eliminate resistance due to increased ligand production, ectodomain escape mutations, or horizontal receptor cross-talk. It will also describe the MoA and translation into the clinic, and provide examples from development of two antibody mixtures, Sym004 (EGFR) and Pan-HER (EGFR, HER2, and HER3).

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THERAPEUTICS

2-3 November 2016

10:05 HERA - Hexavalent Receptor Agonists Targeting the TNFR-Superfamily for Cancer Immunotherapy

Oliver Hill, Ph.D., Vice President Molecular Biology, Apogenix AG

TNFRSF targeting compounds with a solely agonistic activity on immune cells are still rare. Apogenix's single-chain-based fusion proteins mimic the three-dimensional organization of the natural ligands (the TNFSF-proteins). In contrast to antibodies, their agonistic activity does not rely on secondary crosslinking events *in vitro* nor *in vivo*. We will present the molecular engineering concept and the current results obtained for the TRAIL-R-, CD40-, GITR-, HVEM- and CD27-agonists.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

BISPECIFICS IN THE CLINIC: FOCUS ON SAFETY AND EFFICACY

11:15 Clinical Developments with DVD Bispecifics

Tariq Ghayur, Ph.D., Distinguished Research Fellow, Biologics, AbbVie Research

This presentation will discuss: (i) Our efforts at building the DVD-Ig platform, including our preclinical and clinical experience to-date, (ii) our on-going efforts to identify novel target pairs, and (iii) our efforts in designing multi-specific biologics to modulate immune responses.

11:45 Multifunctional DARPIn™ Drugs – Next-Generation Oncology and Ophthalmology Treatment

H. Kaspar Binz, Ph.D., Vice President & Co-Founder, Molecular Partners

The DARPIn™ platform enables us to rapidly generate multi-functional drug candidates. Such drug candidates have the potential to improve therapy beyond current standard of care in ophthalmology and oncology. I will present interim data on the first-in-human systemic clinical phase I of MP0250, a multi-domain oncology drug candidate targeting VEGF and HGF.

12:15 Enjoy Lunch on Your Own

13:00 Dessert Break in the Exhibit Hall with Poster Viewing

13:30 End of Advancing Bispecifics and Combination Therapy to the Clinic



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Inaugural

Novel Therapies for Cancer and Emerging Targets

Improving Efficacy for Clinical Success

Recommended Short Course*

SC1: Cancer Immunotherapy

*Separate registration required, please see page 4 for details.

THURSDAY 3 NOVEMBER

12:30 Registration

13:00 Dessert Break in the Exhibit Hall with Poster Viewing

CHALLENGE OF DISCOVERING NEW TARGETS

13:30 Chairperson's Opening Remarks

Horacio G. Nastri, Ph.D., Senior Director, Antibody Biotherapeutics, Incyte Corporation

13:35 KEYNOTE PRESENTATION: Talk Title to be Announced

Christophe Blanchetot, Ph.D., Director, Discovery, Argen-X

14:20 Immune Checkpoint in Melanoma

Paolo Ascierto, M.D., Director, Melanoma, Cancer Immunotherapy & Innovative Therapies, Istituto Nazionale Tumori Napoli

Over the last few years, through numerous clinical trials and real-world experience, we have accumulated a large amount of evidence regarding the potential for long-term survival with immunotherapy agents in various types of malignancy. The results of these studies have also highlighted a number of recurring observations with immuno-oncology agents, including their potential for clinical application across a broad patient population and for both conventional and unconventional response patterns.

14:50 Sponsored Presentation (Opportunity Available)

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

CHALLENGE OF DISCOVERING NEW TARGETS (CONT.)

16:05 Addressing the Challenges in Effective Cancer Vaccine Development

Pedro Romero, M.D., Professor, Associate Director, Fundamental Oncology, Ludwig Cancer Research Center, Faculty of Biology and Medicine, University of Lausanne

The recent breakthrough with immune checkpoint inhibitors has shown that the adaptive immune system can eliminate a wide range of tumors in a subset of cancer patients. The absence of naturally acquired T-cell responses to cancer antigens may be one of the reasons for failure of immune checkpoint blockade therapy, thus providing a strong incentive to accelerate vaccine development. Rapid optimization of cancer vaccines is urgently needed to attain significant clinical impact.

16:35 Anti-Glycan Monoclonal Antibodies for Cancer Therapy

Lindy Durrant, Ph.D., Professor, Cancer Immunotherapy, Academic Clinical Oncology, University of Nottingham

Glycomic profiling of tumour tissues consistently shows alterations in N- and O-glycosylation profiles of glycoproteins and glycolipids compared to healthy tissues, with important functional implications for cancer cell biology. Despite the attractiveness of the targets, there are very few mAbs recognising glycans as they typically induce low affinity IgM responses. In this talk, we will show how we have overcome this limitation using complex immunisation regimes.

17:05 End of Day

17:00 Dinner Short Course Registration

Recommended Dinner Short Course*

SC5: Troubleshooting and Engineering of Antibody Constructs

*Separate registration required, please see page 4 for details.

FRIDAY 4 NOVEMBER

08:00 Registration and Morning Coffee

ENGINEERING BISPECIFIC ANTIBODIES FOR CLEVER USE OF THE IMMUNE SYSTEM

08:30 Chairperson's Remarks

Neil Brewis, Ph.D., CSO, F-star

08:35 Anti-Cytokine Bispecific Antibodies for Asthma: A Brief History of the Ups and Downs

Stephen Martin, Ph.D., Vice President and Head, Biopharm Discovery, GlaxoSmithKline

Developing bispecific antibodies that are both manufacturable and clinically developable is challenging. This talk will describe some of the issues we have encountered and what we have learned, focusing on strategies to select the best molecules from the outset, understanding molecule conformation under stress and how we can use this data to build confidence to progress to the clinic.

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THERAPEUTICS

3-4 November 2016

09:05 *In vivo* Efficacy of Bispecific Antibodies Targeting Two Immune-Modulatory Receptors

Jacqueline Doody, Ph.D., Vice President, Immunology, F-star Biotechnology Ltd.
Combining immunotherapeutic antibodies has shown benefits over single agent in treating cancer patients. Bispecific antibodies are an alternative that not only bring two biologies together but results in novel biological mechanisms. F-star has a unique bispecific format that allows two antigen binding sites to reside within a normal IgG framework. Using this format, several immunomodulatory bispecifics were produced for proof of concept studies in murine tumour models.

09:35 IMCgp100: A Novel TCR-Based Immunotherapy against Malignant Melanoma

Joseph Dukes, Ph.D., Head, Pre-Clinical Biology, Cell Biology, Immunocore
ImmTACs are bi-specific reagents that target tumors via a soluble monoclonal TCR with exceptionally high sensitivity and specificity and redirect host polyclonal T-cells via an anti-CD3 antibody fragment. Emerging data from the first ImmTAC, IMCgp100, to enter Phase I/IIa clinical trials demonstrate durable responses in patients with advanced melanoma and a favorable safety profile. Development of IMCgp100 continues in uveal and cutaneous melanoma and in combination with checkpoint inhibitors.

10:05 Coffee Break in the Foyer with Poster Viewing

HOW TO ENGINEER CART THERAPY TO BE MORE EFFECTIVE

10:30 Chairperson's Remarks

Mitchell Ho, Ph.D., Chief, Antibody Therapy Section, Laboratory of Molecular Biology, National Cancer Institute, NIH

10:35 CAR Modified Autologous Cells – CMC of an ATIMP

Christoph Priesner, Qualified Person, Quality Manager, Institute of Cellular Therapeutics, Hannover Medical School

Gene-therapy medicines are re-emerging as promising pharmaceutical candidates for especially haemato-oncological indications. The patient-specific manufacture of genetically modified and expanded cellular therapeutics as investigational medicinal products challenges multi-purpose academic cell processing units as regards biosafety requirements and analytical expertise to regulatory requirements. Highlighting these aspects, we present a case study on the academic-industrial co-development and academic manufacture of an advanced therapy investigational medicinal product.

11:05 CART cells: From the Mouse Cage to the Patient's Health

Zelig Eshhar, Ph.D., Professor, Chemical & Cellular Immunology; Chair, Laboratory of Cancer Immunotherapy, Immunology, Weizmann Institute of Science and Tel Aviv Sourasky Medical Center

Along with Eshhar's interest in the molecular recognition in the immune system, his lab. pioneered and developed the "T-Body" unique immune cell approach that involves genetic modifications of T-cells that is called today CAR T-cell, or as he nicknamed it "T body", which is being used to fight cancer. The genetically-engineered T cells have been shown to effectively kill human tumor cells both *in vitro*, and in experimental modes to treat local as well as metastatic disease. Lessons learnt from these pre-clinical trials have been applied end-stage patients with B cell lymphomas and leukemias resulting in a large proportion (>45%) of remission.

11:35 Glypican-3 as a Liver Cancer Target for Antibody-Based Therapies

Mitchell Ho, Ph.D., Senior Investigator and Chief, Antibody Therapy Section, Laboratory of Molecular Biology, National Cancer Institute, NIH

My lab has pioneered the production of inhibitory antibodies that recognize tumor-specific heparan sulfate proteoglycans. These antibodies have been shown to inactivate the Wnt/Yap signaling pathway known to be important for cancer pathogenesis. We have established glypican-3 as an immunotoxin target for the treatment of liver cancer. Its mechanism of action appears to involve both inhibition of cancer signaling (Wnt/Yap) and reduction in protein synthesis. Our ongoing development of chimeric antigen receptors for T-cell immunotherapy will also be discussed.

12:05 Sponsored Presentation (Opportunity Available)

12:35 Problem-Solving Breakout Discussions with a Light Snack in the Foyer*

*See website for more details.

13:35 Session Break

WHY DOES CART THERAPY NOT WORK IN SOLID TUMORS YET?

14:00 Chairperson's Remarks

Soldano Ferrone, M.D., Ph.D., Division of Surgical Oncology, Surgery, Massachusetts General Hospital, Harvard Medical School

14:05 Why Do CART cells Not Work in Solid Tumors Yet?

Attilio Bondanza, M.D., Ph.D., Head, Innovative Immunotherapies Unit, San Raffaele University Hospital and Scientific Institute

While CAR T-cells have demonstrated remarkable antitumor activity in hematological malignancies, they currently struggle to achieve significant results in solid tumors. Target-antigen choice, *in vivo* persistence and the penetration of CAR T-cells in the hostile microenvironment of solid tumors are among the factors potentially limiting their efficacy in other cancer indications. This talk will focus on each of these factors and propose innovative approaches for successfully circumventing them.

14:35 Engineering of ROR1-Chimeric Antigen Receptor (CAR)-Modified T-Cells for Adoptive Immunotherapy of Cancer – Emerging Opportunities and Challenges

Michael Hudecek, M.D., Ph.D., Physician and Research Group Leader, Medicine, Wurzburg University

A current challenge is to establish CAR T-cell therapy in the context of solid tumors. We developed a CAR specific for the antigen ROR1 that is expressed on epithelial cancers and demonstrated the ability of ROR1-specific CAR T-cells to confer anti-tumor reactivity in pre-clinical models. We are in the process of establishing GMP manufacturing in preparation for a clinical trial exploring the safety and efficacy of this therapeutic modality.



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THERAPEUTICS

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15:05 Hurdles and Attempts to Improve CART Therapy of Solid Tumors

Andrew Kaiser, Ph.D., R&D Manager and Senior Group Leader, Immunotherapy and Gene Engineering, Miltenyi Biotec GmbH

CAR T-cells are increasingly proving their worth against hematopoietic malignancies. However, the structural and suppressive microenvironment of solid cancers presents different challenges. Additionally, the difficulties in defining discrete tumor antigens as is the case in ALL and CLL as well as complexities of the manufacturing add to the difficulties in combating solid cancers and testing treatments. We will address the potential benefits of targeting cancer sustaining cells in the context of a planned Phase I/II clinical trial and improvements in the ease of CAR T manufacturing.

15:35 How Can We Make CART Cells Able to Activate Bystander Immunity and Resist Immune Suppression?

Magnus Essand, Ph.D., Professor, Immunology, Genetics and Pathology, Uppsala University

The success of CD19 CAR T-cells in treatment of B-cell malignancies has led to hopes that CAR T-cells may also be used to treat solid tumors. The main challenges though are lack of specific and uniformly expressed target antigens and an immunosuppressive microenvironment found in most solid tumors. This presentation will discuss approaches to generate CAR T-cells able to resist immunosuppression and activate bystander effector cells to kill antigen-negative tumor cells.

16:05 CART Cell Immunotherapy of Solid Tumors and Hypoxia Induced Escape Mechanisms

Soldano Ferrone, M.D., Ph.D., Division of Surgical Oncology, Surgery, Massachusetts General Hospital and Harvard Medical School

Hypoxia induces changes in T cells and target cells. These changes lead to the development of escape mechanisms utilized by tumor cells to avoid immune recognition and destruction. These escape mechanisms will be described. In addition, the strategies developed to counteract these escape mechanisms will be discussed.

16:35 End of Conference

"I have enjoyed this meeting very much and the quality of the talks has been very good. I also enjoyed our roundtable. It was a very engaged group and I thought the discussion went very well." - Luis B., Ph.D., Scientific Director, Amgen, Inc.



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7th Annual

Optimisation & Developability

Selecting and Enhancing the Best Molecule to Move Forward

Recommended Short Course*

SC2: Mutation and Selection Strategies beyond Affinity Optimisation

*Separate registration required, please see page 4 for details

MONDAY 31 OCTOBER

12:00 Registration

PLENARY KEYNOTE SESSION

13:40 Welcome from PEGS Europe Team

13:45 Chairperson's Opening Remarks

Ana Barbas, Ph.D., Coordinator, Bayer Satellite Laboratory at iBET, iBET and Bayer Portugal SA

13:50 Biotherapeutic Programs that Re-Direct Cytotoxic Lymphocytes to Cancer Cells



Paul Adam, Ph.D., Executive Director, Immune Modulation and Biotherapeutics Discovery, Boehringer Ingelheim

Cytotoxic lymphocytes such as NK and T cells have the capability to control cancer development and progression. Harnessing this cytotoxic potential with biotherapeutic agents is predicted

to become a future pillar of cancer therapy in light of recent clinical successes. This presentation will describe novel biotherapeutics whose mode of action involves the engagement and re-direction of NK and T cells to hematological tumors.

14:30 Antibody-Based Combination Cancer Immunotherapy at Roche pRED



Christian Klein, Ph.D., Distinguished Scientist, Head, Oncology Programs, Cancer Immunotherapy Discovery, Roche Pharmaceutical Research and Early Development, Roche Innovation Center Zurich

This presentation will introduce novel antibody cancer immunotherapies developed at Roche pRED including novel IL2 variant immunocytokines and T cell bispecifics as well as preclinical data for their optimal combination and scheduling.

15:10 Safety Concerns Associated with Immunotherapy and Novel Biotherapeutics and Challenges in Investigating Their Immunotoxicity



Sandra S. Diebold, Ph.D., Principal Scientist, Immunotoxicology, Biotherapeutics, National Institute for Biological Standards and Control (NIBSC)

The pre-clinical assessment of the risks associated with immunotherapy and novel biotherapeutics is challenging since

the bioassays have to be individually tailored to the investigated reagent. The immunotoxic activity and adverse responses that may be observed in patients are depending to a large degree on the mechanism of action of the biotherapeutic. The specific set-up of *in vitro* assays plus the identification of suitable animal models is critical for obtaining predictive pre-clinical data.

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

DEVELOPABILITY & MANUFACTURABILITY ASSESSMENT TO GUIDE CANDIDATE SELECTION

16:50 Chairperson's Remarks

Jonathan Bones, Ph.D., Principal Investigator, National Institute for Bioprocessing Research & Training

16:55 Analytical Strategies to Guide Candidate Selection through Optimization and Developability Assessment

Matthew Traylor, Ph.D., Senior Scientist, Analytical Development, Shire
Selecting and optimizing complex recombinant non-mAb molecules can be extremely challenging. Many of these molecules exhibit complex sets of post-translational modifications (PTM) that afford unique challenges for cell line and/or clone selection. With an increasing number of non-mAb molecules in the pipeline an increased reliance on innovative technologies and approaches are being adopted to increase speed, throughput, and quality of the overall analytical support for candidate selection/optimization.

17:25 Towards a Predictive Manufacturability Assessment Platform for Monoclonal Antibodies

Jonathan Bones, Ph.D., Principal Investigator, National Institute for Bioprocessing Research & Training

17:55 Precisely Controlled, Highly Diverse Gene Mutant Libraries for Synthetic Biology and Bio-Therapeutic Drug Discovery

Ross Kettleborough, Ph.D., European Field Applications Specialist, Twist Bioscience

Effective synthetic libraries are critical for successful discovery and development. Twist's innovative silicon-based DNA synthesis, reaction volumes are miniaturized by a factor of 1000. By implementing rational design and expertise in synthetic DNA, Twist synthesizes each variant individually. This results in libraries with exceptional representation and diversity and screening efficiency.

18:25 Welcome Reception in the Exhibit Hall with Poster Viewing

19:25 End of Day

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TUESDAY 1 NOVEMBER

07:45 Registration and Morning Coffee

IDENTIFYING VARIATIONS AND ASSESSING DEVELOPABILITY

08:30 Chairperson's Remarks

Mike Molloy, Ph.D., Head, Analytical and Product Characterisation, GlaxoSmithKline

08:40 Fingerprinting Antibody Epitopes: Identifying Even Minor Variations for QC and IP

Michael Szardenings, Dr.rer.nat., Group Leader, Immunology, Ligand Development, Fraunhofer Institute for Cell Therapy and Immunology

Precise and comparative description of antibody binding sites is important for many reasons. Next generation sequencing in combination with a novel peptide phage display setup allows almost automated *in silico* analysis of a plethora of binding peptide variants. This routine procedure reveals not only the epitope, it renders in depth details of mimotope variations. These variations are individual signatures not only of different antibodies but also of batch to batch differences.

09:10 New Capillary Electrophoretic Systems for the Affinity Assessment of Protein Mixture Components

Gerhardus de Jong, Ph.D., Professor, Pharmaceutical Sciences, Utrecht University

We have developed capillary electrophoresis (CE) systems for the study of the affinity of proteins and protein variants to receptors and enzymes. In the first approach, different concentrations of the target protein or ligand are added to the background electrolyte and the affinity of the proteins is assessed by the change of electrophoretic mobility. In the second approach, affinity-specific detection is obtained by the on-line combination of CE and surface plasmon resonance.

09:40 Problem-Solving Breakout Discussions*

*See website for details.

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

11:20 Novel Approaches for Rapid Degradation Hotspot Profiling of Biotherapeutic Candidates

Bjoern Hueber, Senior Analytical Expert, Novartis Pharma AG

Degradation reactions such as asparagine deamidation and aspartate isomerization can present major risks for the developability of innovative biotherapeutics. Although *in silico* sequence analysis can help to predict potential degradation sites, time- and labor- intense characterization is still required to identify critical degradation hotspots in biologics lead candidates. This talk presents case studies using novel screening assays combined with a new UPLC-IM-MS platform for rapid and higher throughput monitoring of deamidation or isomerization hotspots.

11:50 Developability Assessment of Complex Biologics

Laurent Lariviere, Ph.D., Principal Scientist, Large Molecule Research, Roche Pharma Research and Early Development, Roche Innovation Center Penzberg, Roche Diagnostics GmbH

Complex biologics such as multispecific antibodies or fusion proteins play an increasingly important role as emerging new pharmaceuticals. In contrast to classic monoclonal antibodies, complex biologics can pose additional developability challenges. The talk will focus on our strategies to design and optimize stable, well-behaved drug candidates.

12:20 New Applications for Array-Based SPR Imaging

Alex van der Kooi, Manager, Interaction Laboratory, IBIS Technologies

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12:50 Explore Prometheus: Biologics Stability Screening Has Never Been Faster, Easier & More Fun

Dennis Breitsprecher, Ph.D., Head, Research and Development – Biochemistry, NanoTemper Technologies, GmbH

Beate Kern, Ph.D., Application Specialist, NanoTemper Technologies, GmbH

Prometheus series instruments allow for rapid and precise high-throughput stability screenings, while providing best-in-class high resolution thermal unfolding data for biologics, independent of buffer or protein concentration. It allows for an exact detection of aggregation onset temperatures and aggregation behavior to find the conditions in which the protein is most stable. Explore the Prometheus at the live demo and see how instrument and straightforward software solutions bring a whole new experience to your lab!

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13:20 Session Break

14:00 Dessert Break in the Exhibit Hall with Poster Viewing

OPTIMISATION FOR IMPROVED PROPERTIES AND MANUFACTURABILITY

14:30 Chairperson's Remarks

Speaker to be Confirmed

14:35 Building a Pipeline in Immuno-Oncology: Bispecific Antibodies from Engineering to Optimized In House Phase One Manufacturing

Stanislas Blein, Ph.D., Head, Antibody Engineering, Glenmark Pharmaceuticals
Glenmark Pharmaceuticals' BEAT® platform is a robust and versatile bispecific antibody platform based on a unique heavy chain hetero-dimerization technology. We have produced several T-cell recruiting bispecific antibodies against different cancers, with GBR 1302 being our most advanced development candidate. This BEAT® antibody potently re-directs T-cells to HER2 positive cancer cells with an excellent safety-efficacy margin. GBR 1302 was successfully manufactured and will shortly enter clinical phase. Bioprocess and preclinical data will be presented.

15:05 New Strategy for an Old Target: How to Make Extremely Potent Anti-ErbB2 Agents

Rastislav Tamaskovic, Ph.D., Researcher, Department of Biochemistry, University of Zurich



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31 October – 1 November 2016

We have recently developed a novel approach employing biparatopic anti-ErbB2 Designed Ankyrin Repeat Proteins (DARPs). By creating an intermolecular trap with DARPin agents, which simultaneously target two distinct ectodomain epitopes of ErbB2, the receptors adopt an inactive conformation with kinase domains incapable of productive interactions. This strategy represents a rational approach to engineer anti-ErbB2 agents inducing cell-specific apoptosis based on a structurally and mechanistically understood principle, without using a toxic payload causing potential off-tumor side effects.

15:35 The Importance of Biophysical Screening in Predicting the Perils of UF/DF

Marisa Barnard, Ph.D., Senior Scientist, Biopharm Molecular Discovery, GlaxoSmithKline

16:05 Extending Drug Half-Life to Achieve Monthly Dosing? The Potential of Veltis® Engineered Albumins for Optimized Dosing

Joanna Hay, Ph.D., Science Manager, Customer Solution, Albumedix Ltd.

Short circulatory half-life represents a major obstacle for many protein and peptide-based therapeutics. This can be significantly improved by conjugation or fusion to albumin, due to increased size and recycling via the neonatal Fc receptor (FcRn). The increased FcRn affinity of the Veltis® engineered albumins translates to more than doubling of the already long half-life of native albumin. We will describe rationally engineered albumins and their application to improve the pharmacokinetic properties of therapeutic candidates.

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 Albumedix

16:35 Refreshment Break in the Exhibit Hall with Poster Viewing

17:15 New Solution for Label-Free Biomolecular Interaction Screening

Chiraz Frydman, Ph.D., Product Manager, Horiba Scientific

Label-free biomolecular interaction analysis is increasingly moving towards screening approaches. The XelPlex platform makes it easier and faster than the conventional techniques. Let's show you how your assay will benefit not only from the advantage of the multiplex but also of the binding affinity determination.

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 HORIBA Scientific

17:30 Improve Productivity of Cell Line Development Using the ClonePix™ 2 and CloneSelect™ Imagers

Sarah Rowe, European Application Scientist, Molecular Devices

Molecular Devices offers automated solutions for screening and selection of mammalian clones or microbial colonies. The CloneSelect™ Imager replaces time-consuming, subjective manual inspections of mammalian cells with consistency and objectivity. Re-designed to provide high resolution and fluorescence imaging, all of our CSI models have proven scalable automated use.

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 MOLECULAR DEVICES

17:45 Attribute Tailored Bioprocess Development to Allow 'Designed In' Appropriate Product Quality

Karolina Les, Ph.D., Scientist I, Purification Process Sciences, Biopharmaceutical Development, MedImmune

MedImmune's pipeline has diversified from predominantly antibodies to include many novel molecules of increased complexity. Development of novel biologics can be challenging and often carry higher risks. These can be addressed by early developability assessments and identification of potential critical quality attributes (pCQA). Case studies highlighting challenges encountered during

early development of novel molecules are presented, showcasing how quality can be built into the molecules and bioprocesses in a systematic, science-based manner.

18:15 Preclinical Tools in Formulation Optimization to Improve Biological Performance of Antibodies

Sabine Eichling, Ph.D. Student, NBE Formulation Sciences, Abbvie Deutschland GmbH & Co. KG, University of Heidelberg

Formulation development for biologics has primarily focused on the refinement of physical and chemical stability during shelf-life. Effects of formulation composition following subcutaneous injection and reduced bioavailability were usually not considered. The addition of biological read out parameters enables further improvement in the antibody transport to the target tissue. We develop translatable models to understand the transport of antibodies following subcutaneous injection and predict the effect of the formulation on the bioavailability.

18:45 End of Optimisation & Developability

“PEGS Europe and PEGS keep going from strength to strength. One week at a PEGS event can stimulate ideas for a whole year. The presentations were exceptional, covering an extraordinary array of antibody and antibody-alternative technologies. PEGS Europe is unparalleled in both scope and quality.”

KEVIN R., PH.D., SCIENTIST, WELLCOME TRUST SANGER INSTITUTE



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3rd Annual

Analytical Characterisation of Biotherapeutics

Harnessing Technologies and Proven Strategies to Improve Analytics

Recommended Short Course*

SC8: Protein Aggregation: Mechanism, Characterisation and Consequences

*Separate registration required, please see page 4 for details

WEDNESDAY 2 NOVEMBER

07:45 Registration and Morning Coffee

BIOSIMILARITY AND COMPARABILITY ASSESSMENT

08:30 Chairperson's Remarks

Chris R. Cornell, Ph.D., Research Associate, Analytical Chemistry, Genentech, Inc.

08:35 KEYNOTE PRESENTATION:

High Throughput Assays for the Quantification of the Potency and Comparability of Biosimilars and Innovator Products

Michael Tovey, Ph.D., INSERM Director, Research, Laboratory of Biotechnology & Applied Pharmacology, Ecole Normale Supérieure de Cachan

Successful development of biosimilars is dependent upon direct comparisons of the relative potency and comparability of innovator molecules and biosimilars. A validated standardized high throughput 384 assay platform will be described that is applicable to most biopharmaceuticals and that allows direct comparison of drug potency and comparability of innovator molecules and biosimilars in the same assay. Case studies will be presented for products ranging from Neupogen to Remicade and Enbrel.

09:20 Characterization of Filgrastim Using Intact and Top-Down MS

Urs Lewandrowski, Ph.D., Lab Head, Analytical Characterization, Sandoz

The detailed analytical comparison of Zarxio and the reference product Neupogen provided the foundation for FDA's approval of Sandoz's Zarxio as the first biosimilar in the United States. Intact and top-down MS are becoming highly attractive techniques for detailed protein characterization. Using a benchtop Exactive MS, modifications in filgrastim were detected with high sensitivity on the intact level followed by site assignment using all-ion fragmentation mode. Examples of successful top-down MS experiments will be demonstrated.

09:50 Presentation to be Announced

10:20 An Integrated Approach to Managing Immunogenicity Risk and Drug Immune Modulation

Jeremy Fry, D.Phil., Director, Sales, ProImmune

Immunogenicity is one of the most complex issues to address in drug design and development. I will provide an overview of the best tools to mitigate immunogenicity risk, including Mass Spectrometry antigen presentation assays; DC-T and T cell proliferation assays for biologic lead selection/ optimization; HLA-peptide binding assays to characterize individual epitopes as well as undiluted whole blood cytokine storm assays.

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

11:30 Overcoming Formulation and Analytical Challenges for Developing Biosimilar Products

Jun Liu, Ph.D., Senior Director, Analytical and Pharmaceutical Science, Coherus Bioscience

Due to the complex nature of biopharmaceuticals, analysis and control of the similarity of biosimilar products to innovators products remains key challenges. Furthermore, critical IP on formulation and process provided additional challenges to introduce biosimilar products into major US and EU markets. In this presentation, we will discuss these challenges on pharmaceutical and analytical development. A case study example will be provided to discuss the strategy to overcome these challenges.

12:00 FTIR Spectroscopy as a Multi-Parameter Analytical Tool for Stability Studies and Batch Consistency Testing of Therapeutic Proteins

Allison Derenne, Ph.D., Researcher, Science-Chemistry, Université libre de Bruxelles

Harnessing the strengths of infrared spectroscopy and recent improvements in chemometric methods, new analytical methods have been developed to study the stability and verify batch-to-batch consistency of therapeutic proteins. The presentation will demonstrate the feasibility, through one quick and direct measurement, to simultaneously obtain information concerning four key characteristics of therapeutic proteins: (i) structural integrity, (ii) quantification of post-translational modifications, (iii) overall protein concentration and (iv) quantification of key excipients.

12:30 Assessing an Interaction Parameter for Bioformulation Stability in One Measurement, using TDA Concentration Gradients

Markos Trikeriotis, Ph.D., Applications Development Scientist, Malvern Instruments Ltd.

The self-association characteristics of molecules in dilute solutions can provide an assessment of stability at an early stage. The diffusion interaction parameter (kD) is a measure of the propensity for self-association, but the determination of this parameter using existing methodologies requires

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several measurements over a concentration series. Here, we show how Taylor Dispersion Analysis can be used to generate a concentration gradient from which the kD can be extracted in a single, low volume measurement.

13:00 Luncheon Presentation: *In silico* Approaches for Early Assessment of Immunogenicity

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Speaker to be Announced

Unexpected adverse events are reasons of drug development failures that contribute to the attrition rate in the pharmaceutical industry. A possible cause specifically associated to Biotherapeutics (peptides/proteins) is immunogenicity: the ability of some biotherapeutics to trigger immune responses that conduct to the generation of antibodies specifically directed against the drug. This immune response can possibly reduce the treatment efficacy and provoke adverse effects. Predicting immunogenicity is proving difficult because of the complexity of the underlying biological processes. We present here an informatics application based on modeling and simulation approaches that can help pharmaceutical R&D to prioritize promising drugs with respect to the immunogenicity risk.

13:30 Session Break

TOOLS AND TECHNIQUES FOR PRODUCT CHARACTERISATION

14:00 Chairperson's Remarks

Peter M. Ihnat, Ph.D., Principal Research Scientist, Drug Product Development Pre-Formulation, AbbVie Bioresearch Center

14:05 Analytical Characterization of Conjugation-Related Events in the Manufacture of ADCs

Chris R. Cornell, Ph.D., Research Associate, Analytical Chemistry, Genentech, Inc.

The manufacture of cysteine-linked antibody-drug conjugates (ADCs) involves the partial reduction of inter-chain disulfide bonds, and subsequent conjugation of the reduced cysteine residues to a maleimide-containing drug-linker. This presentation will focus on the LC-MS characterization of the products of the conjugation reaction, with an emphasis on how various conjugation process parameters may impact reaction specificity.

14:35 Product Characterization and Control Strategy

Ping Feng, MSc., Director, Analytical Sciences and Operation, Teva Pharmaceuticals

Product characterization should be planned based on knowledge of protein sequence and manufacturing process impact. The level of characterization should be phase-appropriate for an adequate balance between risk and benefit. A well-designed characterization study can be very valuable to support commercial specification with reduced release testing or more robust range of a criterion allowed. Two case studies will be presented: antibody glycan analysis and product variant characterization of a HAS fusion protein.

15:05 Advances in Epitope Characterization Using Label-Free Biosensors

Yasmina Abdiche, Ph.D., Research Fellow, Oncology Research Unit, Pfizer-Rinat

This talk will describe methods used to explore the epitope diversity observed across panels of monoclonal antibodies generated by different I and *in vivo* platforms, including chicken immunizations. High throughput epitope binning experiments on label-free biosensors were used to merge large panels of antibodies and compare their epitope outputs. Data will be presented for both, wild-type and transgenic chickens, highlighting the therapeutic potential of chicken-derived antibodies.

15:35 Refreshment Break in the Exhibit Hall with Poster Viewing

16:15 Investigating the Interaction between FcRn and IgG Variants by Hydrogen/Deuterium Exchange Mass Spectrometry

Maximiliane Hilger, Ph.D., Senior Scientist, Mass Spectrometry, Large Molecule Research, Pharma Research and Early Development, Roche Innovation Center Munich

The recycling of IgGs by FcRn regulates antibody plasma levels and half-life. Here we study the IgG1-FcRn interaction by HDX-MS to gain deeper molecular understanding that will ultimately allow us to optimize antibody pharmacokinetics, efficacy and safety. Interestingly, our data demonstrate a conformational interplay between the Fab and Fc regions of the antibodies upon FcRn binding and suggest the presence of direct FcRn interaction sites in the Fab region.

16:45 Using Viscosity-Derived Parameters and Thermal Analysis to Evaluate the Solution Properties of Bispecific Dual Variable Domain Immunoglobulins

Peter M. Ihnat, Ph.D., Principal Research Scientist, Drug Product Development Pre-Formulation, AbbVie Bioresearch Center

The Fab regions of dual variable domain immunoglobulins (DVD-Ig) consist of outer and inner complementarity determining regions (CDR) that confer bivalent antigen specificity. The protein – protein interactions (PPI) and protein – solvent interactions (PSI) of DVD-Ig solutions were studied by light scattering and rheological techniques to identify the factors that contribute to achieving stable high concentrations.

17:15 Problem-Solving Breakout Discussions*

*See website for details.

18:15 Networking Reception in the Exhibit Hall with Poster Viewing

19:15 End of Day

THURSDAY 3 NOVEMBER

08:00 Registration and Morning Coffee

CHARACTERISING PRODUCT- AND PROCESS-RELATED IMPURITIES

08:30 Chairperson's Remarks

Jihong Yang, Ph.D., Senior Scientist, Bioanalytical Sciences, Genentech



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08:35 Enhanced Detection of Product-Related Variants and Impurities in Recombinant Glycoproteins

Francois Griaud, Ph.D., Functional Lead Analytics, Biologics Process Development/Late Phase Analytical Development, Novartis Pharma AG

Monitoring and controlling post-translational modifications (PTMs) in recombinant glycoproteins is a requirement to ensure manufacturing process consistency and product quality. Aside from the example of glycosylation, the analyst may face the challenging task of detecting less predictable post-translational modifications, product-related variants and impurities. This presentation will focus on different mass spectrometry and data analysis approaches to enable the semi-automated detection of such species during technical development.

09:05 Identification and Monitoring of HCPs by Mass Spectrometry in Bioprocess Development

Yan-Hui Liu, Ph.D., Senior Principal Scientist, Merck Research Lab

09:35 Pyrogen Detection by Monocyte Activation Test in Antibody Formulations

Anya Fritsch, Ph.D., CSO, Conforma France SAS

10:05 Simultaneous Detection of Protein Aggregation and Affinity Measurements in a Single SPR Experiment

Eric Reese, Ph.D., Vice President, Sales and Marketing, SensiQ Technologies, Inc.

SensiQ presents data from a Genentech collaboration highlighting the simultaneous detection of protein aggregation and affinity determination in a single experiment as enabled by Pioneer FE SPR instrumentation with diSPR® injection technology. This is the first presentation of an SPR biosensor capable of both key measurements in a single experiment.

10:20 Semi-Automated, Mass Spectrometric Determination and Evaluation of Glycosylation CQAs at the Bioreactor Level

Catherine Evans, Ph.D., Business Development Manager – Biopharma, Bruker Daltonics

Mass spectrometry is a powerful tool for monitoring CQAs related to bioproduction, providing insights into the design-space and its impact on the product specification. We present here a standalone analytical platform developed for the direct connection of bioreactors to an MS system for real time at-line monitoring of mAb CQAs.

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10:35 Coffee Break in the Exhibit Hall with Poster Viewing

CHARACTERISATION OF POTENCY ASSAYS AND ASSAY REAGENTS

11:15 Potency Assays for Biopharmaceuticals: A Regulatory Perspective

Baolin Zhang, Ph.D., Senior Investigator & Product Quality Reviewer, Office of Biotechnology Products, CDER, FDA (Invited)

Because of the complex nature of biopharmaceuticals, it can be scientifically challenging to develop appropriate potency assays for each product. A regulatory evaluation of adequacy of potency assays is made on a case-by-case basis, taking into account multiple factors including, but not limited to, product type, MoA, associated risk, and phases of development. This presentation provides an overview of regulatory expectations regarding potency assays and discusses several case studies that highlight some of the relevant issues commonly seen in the regulatory submissions.

11:45 Robust Characterization Methods to Ensure Quality Bioanalytical Assay Reagents

Jihong Yang, Ph.D., Senior Scientist, Bioanalytical Sciences, Genentech

Bioanalytical assays are critical for the assessment of the exposure-response relationship, safety, and efficacy of biotherapeutics. Robust biophysical and bioanalytical methods can be used to generate important characterization data for critical assay reagents. The talk will highlight some of the emerging analytical and bioanalytical technologies that can be used to characterize assay reagents and describe case studies to demonstrate the application of these methods to support biotherapeutic development.

12:15 Luncheon Presentation: How Similar is my Biosimilar? A LC and MS Prospective

John C. Gebler, Ph.D., Director, Biopharma Business Development, Waters Corporation

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13:00 Dessert Break in the Exhibit Hall with Poster Viewing

13:30 End of Analytical Characterisation of Biotherapeutics



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Protein Aggregates & Particles

Understanding Aggregation Kinetics to Effect Control and Minimise Immunogenicity Risks

Recommended Short Course*

SC8: Protein Aggregation: Mechanism, Characterisation and Consequences

*Separate registration required, please see page 4 for details

THURSDAY 3 NOVEMBER

12:30 Registration

13:00 Dessert Break in the Exhibit Hall with Poster Viewing

AGGREGATION AND IMMUNOGENICITY RISKS

13:30 Chairperson's Opening Remarks

Jeremy Derrick, Ph.D., Professor, Molecular Microbiology, University of Manchester

13:35 KEYNOTE PRESENTATION:

The Immunogenicity of Antibody Therapeutics: Aggregates and Immune Complexes

Roy Jefferis, Ph.D., MRCP, FRCPATH, D.Sc., Professor Emeritus, University of Birmingham

Many parameters contribute to the development of anti-drug antibodies (ADA) to protein therapeutics; aggregation being considered a particular risk. However, administration of IgG antibody therapeutics results in the formation immune complexes (aggregates!) that may similarly activate pathways leading to ADA production. Individual mAb therapeutics should be evaluated for the propensity of both aggregates and immune complexes to activate downstream effector cascades.

14:20 Understanding the Relationship between Aggregation and Immunogenicity of Biotherapeutic Proteins

Jeremy Derrick, Ph.D., Professor, Molecular Microbiology, University of Manchester

Aggregation is known to play an important part in the immunogenicity of therapeutic proteins. I will describe recent experiments which compared the immunological responses to immunization of selected example proteins, in monomeric and aggregated forms, in a mouse model. In addition, we also examined the effect of the heat shock protein DnaK, a common HCP, and show that it can play a role in modulating the immune response to aggregates.

14:50 Formulate and Characterize More Biologic Formulations than Ever before

Daniel Lund, Ph.D., Applications Scientist. Unchained Labs

Biologic formulations are hard to make and difficult to characterize. The process to buffer exchange and concentrate proteins can take days. Screening them for stability take days to weeks and figuring out if they will aggregate can

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take months. In this talk, we'll present a rapid, total solution for formulating proteins, characterizing them for stability, predicting whether they will aggregate and determining the pathway of aggregation.

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

16:05 Using Denaturant Solutions to Probe the Colloidal Stability of Partially Folded Proteins and the Link to Aggregation

Robin Curtis, Ph.D., Senior Lecturer, School of Chemical Engineering and Analytical Sciences, University of Manchester

16:35 Immunogenicity Risk of Protein Aggregates – Could Bedside Filtration Be of Help?

Gerhard Winter, Ph.D., Professor, Pharmaceutical Technology and Biopharmaceutics, University of Munich

Characterization of protein particles has become a regular request by the authorities and measures to reduce such contaminations are taken. But, it will remain impossible to guarantee for each single container the absence of particles. Why has bedside filtration not been applied more often to reduce the potential risk dramatically? We will present the status quo of bedside filtration of biopharmaceuticals and describe technical aspects like injection forces, particle shedding, particle removal, dead volumes.

17:05 End of Day

17:00 Dinner Short Course Registration

Recommended Dinner Short Course*

SC8: Protein Aggregation: Mechanism, Characterisation and Consequences

*Separate registration required, please see page 4 for details

FRIDAY 4 NOVEMBER

08:00 Registration and Morning Coffee

MECHANISMS AND KINETICS OF AGGREGATION

08:30 Chairperson's Remarks

Hans Kiefer, Ph.D., Professor, Applied Biotechnology, Biberach University of Applied Sciences

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08:35 KEYNOTE PRESENTATION: Impact of Non-Proteinaceous Particles on the Characterization and Formation of Protein Particles

Wim Jiskoot, Ph.D., Professor, Gorlaeus Laboratories, Division of Drug Delivery Technology, Leiden Academic Centre for Drug Research (LACDR)

Particulate impurities in protein formulations pose an analytical challenge and may compromise protein stability. In this presentation I will present a case study about the root cause of nanoparticulate (100–200 nm) impurities in protein formulations containing commonly used sugar excipients. These impurities interfere with the characterization of proteinaceous particles by dynamic light scattering and nanoparticle tracking analysis. Moreover, they compromise protein stability and potentially increase their immunogenicity.

09:05 Mechanisms of Protein Aggregation

Thomas Laue, Ph.D., Professor, Molecular, Cellular & Biomedical Sciences, University of New Hampshire

The proximity energy framework will be described as a useful way to think about high concentration solutions. Protein solvation, hydrophobic interactions and molecular crowding are incorporated into this framework. Protein charge contributes significantly to preventing aggregation and reducing viscosity. Charge cannot be calculated, so the importance and simplicity of measuring charge will be emphasized. Data presented showing how proximity energies impact protein-protein interactions in high concentration formulations as well as in serum.

09:35 Elucidation of Aggregation Mechanisms in Therapeutic Protein, and Prediction of Formulation Strategies

Paul Dalby, Ph.D., Professor, Biochemical Engineering, University College London

Various biophysical methods have investigated the aggregation kinetics, solution conformations, and conformational stabilities of several IgGs and Fab molecules. Structural changes in these molecules have been observed that correlate with their aggregation propensities. These studies have been complemented by molecular dynamics and docking simulations that then together reveal the potential features of protein structure that promote aggregation propensity, and also the potential mechanisms by which particular excipients increase protein stability.

10:05 Coffee Break in the Foyer with Poster Viewing

EVALUATING AGGREGATION PROPENSITY

10:35 Relationship between Aggregate Propensity and Biophysical Parameters of Proteins in Solution

Susumu Uchiyama, Ph.D., Associate Professor, Graduate School of Engineering, Osaka University

Aggregates formation of therapeutic proteins is one of the issues that should be solved. Here I will show how experimentally obtained biophysical parameters of proteins in solution, such as secondary virial coefficient and thermal unfolding temperature, are useful to predict aggregates formation during transport and storage. In addition, how chemical modification of protein changes its stability will be introduced. Finally total formulation developments of therapeutic proteins in solution are proposed.

11:05 Large Scale All-Atom Molecular Dynamics Analysis of Multi-Peptide Systems Reproduces Peptide Aggregation Propensity In Line with Experimental Observations

Yutaka Kuroda, Ph.D., Associate Professor, Life Science and Biotechnology, Tokyo University of Agriculture and Technology

We carried out all-atom molecular dynamics simulation for 18 systems containing ~3x10⁴ water molecules and 27 tetra-peptides made from a single amino acid type and using a standard force-field without "artificial" hydrophobic forces. Surprisingly, hydrophobic peptides rapidly formed clusters whereas hydrophilic ones remained monomeric in line with experimental expectations. We believe that this study represents a step toward a molecular understanding of peptide/protein solubility, based on physico-chemical first principles.

DEVELOPING PARTICLE STANDARDS

11:35 Development and Applications of Protein-Like Reference Materials for Monitoring Protein Particles

Srivalli Telikepalli, Ph.D., Research Chemist, National Institute of Standards and Technology

NIST is developing subvisible and visible particle standards using ethylene tetrafluoroethylene polymer and SU-8 photoresist since these materials better mimic the morphology and optical properties of protein particles compared to the currently available particle standards. The development, stability, and challenges associated with working with these materials will be briefly described. Applications of the ETE particles to standardize subvisible particle measurements and to standardize visual inspection processes will be discussed.

12:05 When Standard Formulation Strategies Fails - Recombinant Albumin for Stabilization of Hard-to-Formulate Biotherapeutics

Phil Morton, Ph.D., Science Director, Bioprocess & Characterisation, Alumedix Ltd.

The expanding field of biotherapeutics gives promise for improvement of several treatment options. Many of the biopharmaceuticals found to be efficacious, however continue to face ex vivo instability challenges that are not readily solved by standard excipients. Recombinant human albumin, however, can potentially alleviate these shortcomings. The mechanisms by which albumin help stabilize biopharmaceuticals are multiple and dependent on the specific drug. Data is presented here that exemplifies these different mechanisms.

12:35 Problem-Solving Breakout Discussions with a Light Snack in the Foyer*

*See website for more details

13:35 Session Break

PARTICLE ANALYSIS AND CHARACTERISATION – DETECTION, IDENTIFICATION, CHARACTERISATION AND CONTROL

14:00 Chairperson's Remarks

Thomas Laue, Ph.D., Professor, Molecular, Cellular & Biomedical Sciences, University of New Hampshire



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14:05 Comparisons between Particle Identification Techniques

Jonas Hoeg Thygesen, Ph.D., Research Scientist, R&D, Microanalysis Centre, Novo Nordisk Pharmatech A/S

MicroFlow Imaging (MFI), Raman and Fourier-Transform Infrared (FTIR) Spectroscopy, Electron- and Optical microscopy are strong and versatile tools for particle identification and characterization. This talk will provide specific cases to highlight advantages and challenges using the different techniques, and furthermore, illustrate how they may complement each other.

14:35 Microscopy-Based Particle Counting and Characterization in a High-Throughput Formulation Screening Platform

Christian Ried, Ph.D., Senior Scientist, Drug Product Development, AbbVie Deutschland GmbH & Co. KG

Protein particles formed from biologics during manufacture and storage might trigger unwanted effects like anti-drug antibody response in patients. Recently, we have set up an automated platform for high-throughput formulation screening of biologics. Here we present a method that allows for particle counting and characterization from microliter-sized samples as a final step in the screening process.

15:05 Mitigation of Aggregation during Elution from Protein A

John K. Kawooya, Ph.D., Director, Biologics Optimization, Amgen, Inc.

Bispecific protein engineering has produced many new "antibody-like" molecules that are not as stable as antibodies. Some of these molecules aggregate upon exposure to the strong acidic pH (2.5-3.7) encountered during elution from Protein Affinity columns. Presented here are strategies for mitigating aggregation by either protecting the molecules at low pH or by eluting the molecules at neutral pH (7.2) or mildly acidic pH (4.5-5.2).

15:35 Identification and Discriminant Analysis of Subvisible (Proteinaceous and Non-Proteinaceous) Particles

Zahir Akhunzada, Ph.D., Research Scientist, PPD, Bristol-Myers Squibb

This presentation discusses a method that successfully characterizes and distinguishes, both potentially proteinaceous and non-proteinaceous subvisible particles (SVPs) in protein formulations by using Microflow Imaging in conjunction with the MVAS software. Discriminant analysis approach will be discussed that will include measurements on seven morphological and light intensity parameters: Image Shape ratio, (C-circularity); Size; Pixel Intensity. The goal is to identify a mechanism that will discriminate a particle based on its parametric measurements.

16:05 QSAR Analysis of Additive Effects on the Aggregation of Monoclonal Antibodies in Downstream Processing

Hans Kiefer, Ph.D., Professor, Applied Biotechnology, Biberach University of Applied Sciences

We have established model experiments to induce aggregation of monoclonal antibodies through various stresses common in downstream processing. Aggregation rate constants of nucleation and growth were extracted from kinetic traces. In an additive screen using 150 compounds, molecular descriptors were correlated with rate constants and thermal stability changes using a quantitative structure activity relationship (QSAR) approach. Molecular properties of additives correlating with protective effects were extracted.

16:35 From *in silico* Simulations to Market: Improving Antibody CMC Protein Aggregation Properties by Rational Design

Patrick Garidel, Ph.D., Head, Protein Science, Boehringer Ingelheim Pharma GmbH & Co. KG

Early detection and mitigation of CMC risk factors such as protein aggregation propensity is vital for predictable and short timelines in the development of biologicals. We assembled a set of bioinformatics methods to assess candidate amino acid sequences for thermodynamic and colloidal stability and complementary biophysical methods to link a subset of residues to these properties. This knowledge serves as a basis for protein engineering to enhance developability.

17:05 End of Conference



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Day 1: 31 October 13:40 – 18:25

Day 2: 1 November 08:30 – 18:45

Introduction to Expression Systems:

This seminar includes an introduction to heterologous protein expression and simple cloning technologies and covers the main systems: bacterial, insect and mammalian cells. In parallel, Mario discusses the basic considerations for protein purification and purification considerations for the different systems and downstream applications.

Instructors:

Tsafi Danieli, Ph.D., Director, BioGiv Excubator & Head, Protein Expression Facility, Wolfson Centre for Applied Structural Biology, Alexander Silberman Institute of Life Sciences, The Hebrew University of Jerusalem

Mario Lebendiker, Ph.D., Head, Protein Purification Facility, Wolfson Centre for Applied Structural Biology, Alexander Silberman Institute of Life Sciences, The Hebrew University of Jerusalem

Brief Description:

This seminar is designed to introduce basic technologies, strategies and considerations in recombinant protein production designed for core facility personnel. It will supply a basic toolbox for management of multiple and diverse projects.

Syllabus:

- Overview of recombinant proteins production: initiating a project, design and options for various downstream applications, requirements for customer/collaborator, and matching expectations
- Introduction to expression systems, covering the differences between the standard ones (*E. coli*, insect cells and mammalian cells) in protein quality, quantity and downstream applications, cost considerations, implementation time, required expertise and more
- Basic principles in affinity chromatography, ion exchange, hydrophobic exchange, size exclusion and mixed mode chromatography
- Protein purification strategies: input for purification protocol development, guidelines for protein purification, selection and combination of purification techniques
- Troubleshooting and case studies
- Balancing multiple projects: the challenge of “the few serving the many”

CLOSING PANEL DISCUSSION: Protein Production Core Facility Challenges: Methodologies, Strategies, and the Art of Managing Multiple Projects

There are many challenges in operating protein production core facilities. This seminar's panel of experts focuses on the following topics: Initiating projects, basic expression and purification systems, pros and cons for each system, screening platforms, troubleshooting and how much time should be spent on each system before moving to the next option. On top of “hands on” tips, we touch upon strategies on how to manage multiple “top priority” projects.

Moderator:

Tsafi Danieli, Ph.D., Director, BioGiv Excubator & Head, Protein Expression Facility, Wolfson Centre for Applied Structural Biology, Alexander Silberman Institute of Life Sciences, The Hebrew University of Jerusalem

Panelists:

Richard Altman, MS, Scientist, Protein Technologies, Amgen, Inc.

Nicola Burgess-Brown, Ph.D., Principal Investigator, Biotechnology, Structural Genomics Consortium (SGC), University of Oxford

Dominic Esposito, Ph.D., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc. Mario Lebendiker, Ph.D., Head, Protein Purification Facility, Wolfson Centre for Applied Structural Biology, Alexander Silberman Institute of Life Sciences, The Hebrew University of Jerusalem

Bjørn Voldborg, MSc, Director, CHO Cell Line Development, Novo Nordisk Foundation Center for Biosustainability (CFB), DTU Biosustain, Technical University of Denmark

Who should attend the training seminar?

The seminar is designed for researchers establishing a new core facility or entering an already established facility, students, postdocs, technicians and engineers wishing to expand their knowledge and basic technologies in recombinant protein production.

Each CHI Training Seminar offers 1.5 Days of instruction with start and stop times for each day shown above and on the Event-at-a-Glance published in the onsite Program & Event Guide. Training Seminars will include morning and afternoon refreshment breaks, as applicable, and lunch will be provided to all registered attendees on the full day of the class.

Each person registered specifically for the training seminar will be provided with a hard copy handbook for the seminar in which they are registered. A limited number of additional handbooks will be available for other delegates who wish to attend the seminar, but after these have been distributed no additional books will be available.

Though CHI encourages track hopping between conference programs, we ask that Training Seminars not be disturbed once they have begun. In the interest of maintaining the highest quality learning environment for Training Seminar attendees, and because Seminars are conducted differently than conference programming, we ask that attendees commit to attending the entire program, and NOT engaging in track hopping, as to not disturb the hands-on style instruction being offered to the other participants.

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- Display of Antibodies
- Engineering Antibodies
- Engineering Bispecifics
- Engineering Next-Generation ADCs

THERAPEUTICS

- Novel Immunotherapy Strategies
- Advancing Bispecifics
- Novel Therapies for Cancer

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- Optimisation & Developability
- Analytical Characterisation
- Aggregates & Particles

EXPRESSION

- Protein Expression Technologies
- Optimising Expression Platforms
- Protein Purification Technologies

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9th Annual

Optimising Expression Platforms

Meeting the Demand for Recombinant Antibodies

Recommended Short Courses*

SC4: Transient Protein Expression: A Key Tool to Enable Rapid Protein Engineering

SC7: Protein Purification Strategies: Dealing with Proteins that are Prone to Aggregate

*Separate registration required, please see page 4 for details

WEDNESDAY 2 NOVEMBER

07:45 Registration and Morning Coffee

ENGINEERING EXPRESSION PLATFORMS TO MEET THE DEMAND

08:30 Chairperson's Remarks

Bjørn Voldborg, MSc, Director, CHO Cell Line Development, Novo Nordisk Foundation Center for Biosustainability (CFB), DTU Biosustain, Technical University of Denmark

08:35 KEYNOTE PRESENTATION:

Animal Cells in Bioreactors for Production of High-Value Biologics – From Vaccines to Therapeutic Proteins, Lessons of the Past Applied Today and Tomorrow

Florian M. Wurm, Dr. rer. nat., Honorary Professor, Swiss Federal Institute of Technology Lausanne (EPFL); CEO, ExcellGene SA

The talk reviews the dramatic history of our industry – 100 years – towards high-value biologicals whose manufacturing requires a huge range of knowledge of fundamental and applied sciences in fields as diverse as molecular biology to fluid dynamics of water and gas. Reflecting and analysing the involved technologies in production provide excellent leads and opportunities for the future. CHO cells in bioreactors will be a central part of this discussion.

09:20 The Effect of Vector Design on the Expression of Bispecific Antibodies

Jason Saunders, MSc, Senior Scientist, Biologics Expression and Technology, Merck & Co., Inc.

09:50 Complementary Approaches for Protein Production in Insect and Mammalian Cell Lines

Konrad Buessow, Ph.D., Scientist, Helmholtz Centre for Infection Research

10:20 Strep-Tactin XT - A Superior Next-Generation System for Purification of Proteins, Isolation of Cells & Assay Development

Dennis Niermeier, M.Sc., Scientist, IBA GmbH

The new third-generation Strep-tag® system is based on recently engineered Strep-Tactin®XT and Twin-Strep-tag®. Due to the affinity improved but still

reversible binding of Strep-Tactin®XT to Twin-Strep-tag® in the low pM range, the system is superior to other affinity purification systems and now also suitable for assay development.

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10:35 Presentation to be Announced

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

ENGINEERING GENES

11:30 Engineering the Baculovirus Genome to Improve Protein Production

Dominic Esposito, Ph.D., Director, Protein Expression Laboratory, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc.

The use of insect cell expression systems for the production of pharmaceutically relevant protein targets has dramatically increased over the last few years, with several products already approved by major regulatory agencies. In our laboratory, this system has been vital for production of post-translationally modified RAS proteins essential for cancer drug discovery. In using this system, we have developed a number of process and technology improvements which permit increased protein yield, protein quality, and virus stability. We discuss in detail the enhancements to the system and how they have been applied to high-level production of clinically relevant proteins, and examine ways in which synthetic biology and genome engineering can further enhance the utility of this system.

12:00 SINEUPs: A New Class of Antisense Long Non-Coding RNAs that Specifically Activate Translation of Targeted Proteins

Silvia Zucchelli, Ph.D., Assistant Professor, Health Sciences, University of Eastern Piedmont; CSO, TransSINE Technologies Inc.

SINEUPs represent a new functional class of natural and synthetic antisense long non-coding RNAs that upregulate translation of partially overlapping sense mRNAs through the activity of an inverted SINEB2 element. Given their modular structure, SINEUPs can be designed to increase protein synthesis of potentially any gene of interest. We propose SINEUPs as reagents for molecular biology experiments, in protein manufacturing as well as in therapy of haploinsufficiencies.

12:30 Engineering of CHO Cell Lines for Enhanced Process Robustness

Pierre-Alain Girod, Ph.D., CSO, Selexis

High-quality production cell lines secreting maximal levels of recombinant proteins require stable integration of the recombinant DNA, elevated gene transcription, optimized secretion machinery to handle increased protein secretion and folding loads and, ideally, being easily tracked during manufacturing. Using the data from our CHO-K1 genome and transcriptome, we have engineered our CHO-K1 to address these issues, particularly for difficult-to-express proteins, as well as to provide detailed genomic analysis packages for manufacturing cell lines.

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13:00 A Stable Episomal Expression System to Streamline

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Mammalian Protein Production

Meelis Kadaja, Ph.D., MBA, Director, Business Development, Icosagen Cell Factory OU

We have found the way to stably maintain expression vectors in dividing mammalian cells as extrachromosomal units. This stable episomal expression system is scalable, and requires only 1 µg of DNA to produce up to gram quantities of recombinant proteins with low endotoxin levels in few weeks. Our system enables to generate production cell banks in 10 days, and is also used in antibody discovery to express and screen antibodies.

13:30 Session Break

ENGINEERING HOSTS: CHO CELLS

14:00 Chairperson's Remarks

Nicola Burgess-Brown, Ph.D., Principal Investigator, Biotechnology, Structural Genomics Consortium (SGC), University of Oxford

14:05 CHO Cell Energetics: Understanding the Powerhouse of the Cell through Mitochondrial Deep Sequencing

Paul S. Kelly, Ph.D., Senior Postdoctoral Researcher, School of Biotechnology, National Institute for Cellular Biotechnology, Dublin City University

The predominant metabolic pathways, glycolysis and oxidative phosphorylation, have been linked to critical bioprocess relevant CHO cell phenotypes, growth and productivity. We have shown SEAP producing CHO cells engineered to be depleted of microRNA-23b exhibited a 3-fold increase in product yield associated with elevated mitochondrial activity. Given CHO cells' genetic instability, we sought to compare the mitochondrial genomic sequence of 22 CHO cell lines and provide a mitochondrial genome reference sequence from the hamster.

14:35 Precision Control of Recombinant Gene Expression for CHO Cell Synthetic Biology

Adam Brown, Ph.D., Research Fellow, Department of Chemical and Biological Engineering, University of Sheffield

To successfully apply the core concepts underpinning synthetic biology to CHO cell engineering, we must develop practical and robust enabling technologies. Fundamentally, we will require the ability to precisely control the relative stoichiometry of numerous functional components that are simultaneously introduced into the host cell factory. In order to enable this, we have developed a suite of complementary technologies that enable precise control of recombinant gene expression in CHO cells. Using synthetic promoters as an exemplar, the function of these tools in the context of CHO cell engineering will be described.

15:05 Inactivation of GDP-Fucose Transporter in CHO Cells: A New Strategy for Producing Fucose-Free Biobetter Antibody Therapeutics

*Zhiwei Song, Ph.D., Principal Scientist, Expression Engineering Group, Lead PI for GlycoSing Programme, Bioprocessing Technology Institute, A*STAR*

Removal of core fucose from IgG1 has been shown to significantly enhance its affinity to FcγRIII and thereby dramatically improves its antibody-dependent cellular cytotoxicity (ADCC). To address these industry-specific needs, we have inactivated the GDP-fucose transporter in CHO cells. The DHFR and GS genes have also been inactivated in these cells as selection markers. Using these

cells, stable lines have been developed to produce fucose-free rituximab and fucose-free obinutuzumab (Gazyva).

15:35 Refreshment Break in the Exhibit Hall with Poster Viewing

ENGINEERING HOSTS: CHO CELLS (CONT.)

16:15 A Big Step Forward for Next-Generation CHO Clone Characterization and Selection

Oliver Popp, Dr. rer. nat., Senior Scientist, Pharma Research and Early Development, Large Molecule Research, Roche Innovation Center Munich, Roche Diagnostics GmbH

In-depth characterization of high-producer cell lines and bioprocesses is vital to ensure robust and consistent production of recombinant therapeutic proteins in high quantity and quality for clinical applications. For that, we established a novel hybrid approach for supporting comprehensive characterization of metabolic CHO clone performance. The proposed approach also provides a mechanistic link between observed clone phenotype, process setup, and feeding regimes, and thereby offers concrete starting points for subsequent process optimization.

16:45 FEATURED PRESENTATION: Engineering the CHO Cell

Bjørn Voldborg, MSc, Director, CHO Cell Line Development, Novo Nordisk Foundation Center for Biosustainability (CFB), DTU Biosustain, Technical University of Denmark

Using high-throughput (HT) technologies, the CHO Cell Line Engineering project at the Center for Biosustainability is genetically modifying CHO cells based on experimental and *in silico* generated data, to engineer CHO cell lines optimised for the production of therapeutic proteins. The HT cell line engineering pipeline as well as examples of the engineered improved cell lines will be described.

17:15 Cmax: A Heterotrophic Cell Platform for Improved Biologics Production

Nicky C. Caiazza, Ph.D., Principal Scientist, Metabolic Engineering and Synthetic Biology, Heterotrophic Cell Systems, Synthetic Genomics Inc.

We have developed a robustly fermentative heterotrophic system for efficient end-to-end biologics discovery, development and manufacturing. This platform has intrinsic advantages for biologics production and a suite of synthetic biology tools that has enabled high productivity (>1 g/l/d) mAb production with beneficial attributes for downstream processing. Here we show that these organisms can be engineered to secrete genuine, functional monoclonal antibody with favorable characteristics related to protein production and quality.

17:45 Problem-Solving Breakout Discussions*

*See website for details.

18:15 Networking Reception in the Exhibit Hall with Poster Viewing

19:15 End of Day

THURSDAY 3 NOVEMBER

08:00 Registration and Morning Coffee

CASE STUDIES: PROTEIN TO PRODUCT

08:30 Chairperson's Remarks

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Henry C. Chiou, Ph.D., Associate Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific

08:35 Expression of IgG in Genetically Engineered *E. coli*

Na Ke, Ph.D., Research Scientist, Protein Expression and Modification Division, New England Biolabs

We have expressed for the first time in the cytoplasm of *E. coli* full-length human, rabbit and mouse antibodies, along with chimeric versions, including the commercial blockbuster Humira. The expression is further improved by the co-expression of a series of protein-folding helpers. Microbial expression of IgG offers an expanded potential for rapid screening, engineering and expression antibodies.

09:05 Meeting Demand: Optimisation of Our Transient Expression Platforms to Increase Throughput and Titre

Christina Gordon, Scientist, New Meds, UCB Pharma

Development of antibody therapeutics, from early stage research to preclinical and clinical development, requires ever-increasing amounts of reagents. To meet the challenge of furnishing a diverse and full pipeline, we utilise several different transient platforms. Through continuous optimisation, streamlining and automation of component parts of our panel of platforms (utilising both HEK293 and CHO host cells with a variety of transfection methods), we now have the capability to produce microgram-to-gram quantities of panels of purified antibodies and antibody fragments in as few as four weeks from receipt of plasmid DNA.

09:35 Server of Many Masters: The Challenges of a Slim Protein Expression Core Facility

Tsafi Danieli, Ph.D., Director, BioGiv Excubator & Head, Protein Expression Facility, Wolfson Centre for Applied Structural Biology, Alexander Silberman Institute of Life Sciences, The Hebrew University of Jerusalem

Running a small core facility that serves multiple academic groups with a wide range of disciplines is extremely challenging. Trying to do it with one technician, two postdocs and no automated platforms sounds like mission impossible. However, it is all about the surrounding! An academic environment and supporting ecosystem allowed our facility to turn the challenge into a new model that successfully accommodates not only academic groups but also early stage biotech startups.

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10:05 Presentation to be Announced

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

CASE STUDIES: PROTEIN TO PRODUCT (CONT.)

11:15 Efficient Production of Recombinant Human Monoclonal Antibodies from Single B Cells

Hugo Mouquet, Ph.D., Head, Laboratory of Humoral Response to Pathogens, Immunology, Institut Pasteur

The molecular dissection of anti-pathogen B-cell responses using modern technologies to efficiently generate and characterize antigen-specific human monoclonal antibodies has allowed breakthrough discoveries in antiviral responses to viruses such as Influenza virus and HIV-1. These recombinant antibodies represent unique "fingerprints" for each B-cell clone and when characterized at a molecular and functional level, provide crucial information to help developing therapeutic and vaccine strategies against a given pathogen.

11:45 FEATURED PRESENTATION: Expressing Challenging Proteins at the SGC

Nicola Burgess-Brown, Ph.D., Principal Investigator, Biotechnology, Structural Genomics Consortium (SGC), University of Oxford

The SGC has solved >1700 human protein structures and 6 novel integral membrane proteins. Although we have significantly contributed to structural biology and protein production for functional studies, there are many highly desired targets including protein-protein complexes and known drug targets that remain a challenge to obtain. We present our established expression systems using *E. coli* and BEVS, and new processes (BacMam and mutagenesis) to generate the most difficult-to-produce proteins.

12:15 Enjoy Lunch on Your Own

13:00 Dessert Break in the Exhibit Hall with Poster Viewing

13:30 End of Optimising Expression Platforms

“ PEGS Europe is a gem for protein engineers with depth and breadth in a stimulating and engaging environment! I am glad that I came all the way from California to be a part of it.

- Seung C., Ph.D., Associate Director, Cell Biology, Xencor, Inc.



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2nd Annual

Protein Purification Technologies

Streamlining Processes to Achieve Quality

THURSDAY 3 NOVEMBER

12:30 Registration

13:00 Dessert Break in the Exhibit Hall with Poster Viewing

PRODUCTIVITY STRATEGIES

13:30 Chairperson's Opening Remarks

Ana Cecília Afonso Roque, Ph.D., Assistant Professor, Chemistry, UCIBIO, Faculdade de Ciências e Tecnologia, Universidade Nova de Lisboa

13:35 KEYNOTE PRESENTATION:

Biopharmaceuticals: Past, Present & Future

Frank Riske, Ph.D., Senior Consultant, BioProcess Technology Consultants (BPTC)

14:20 Molecular Properties of Antibodies and Their Derivatives Impacting Manufacturing

Stefan Schmidt, Ph.D., MBA, Vice President, Process Science & Production, Rentschler Biotechnology

Certain molecular properties and process conditions can lead to aggregation, truncation and chemical modifications complicating downstream processing. Particularly highly engineered molecules differing from the original antibody format require a careful evaluation of parameters like contact time, ligand density, elution pH, capacity, etc. to identify optimal settings for the initial capture step. Several examples and case studies illustrate the general approaches undertaken to deliver high-quality antibodies and derivatives taking into account their molecular properties.

14:50 Sponsored Presentation (Opportunity Available)

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

ENHANCING PURIFICATION PROCESSES USING HIGH-THROUGHPUT TECHNIQUES

16:05 Development of an Automated Parallel System for Production of High-Quality Lead Candidate Antibodies – Keeping Pace with Researchers' Appetites

Lars Linden, Ph.D., Head, Protein Biochemistry, Bayer HealthCare

In early research, project teams profile multiple antibody candidates in functional and often cell-based assays. Within a growing portfolio, this leads to an increasing resource need for the production of mg amounts of high-quality antibodies. To meet this demand, transient transfection and expression were automated, a novel high-throughput 2-step chromatography system was set up, and an integrated automation concept for sample handling was developed.

16:35 Enhancing Operational Efficiency during Protein Purification

Martin Bader, Ph.D., Head, Biochemistry, Roche Pharmaceuticals

Purification of bispecific antibodies is often more labor-intensive due to complex impurity profiles. We have systematically analyzed and optimized individual process steps during preclinical protein supply. We have developed work flows that reduce operator time and combine critical pooling decisions with high-throughput analytics. In addition, generic steps are either automated or outsourced. In summary, we present a highly efficient purification platform for next-generation proteins.

17:05 End of Day

17:00 Dinner Short Course Registration

Recommended Dinner Short Course*

SC7: Protein Purification Strategies: Dealing with Proteins that are Prone to Aggregate

**Separate registration required, please see page 4 for details.*

FRIDAY 4 NOVEMBER

08:00 Registration and Morning Coffee

INCREASING SOLUBILITY AND PURIFYING MEMBRANE PROTEINS

08:30 Chairperson's Remarks

Stefan Schmidt, Ph.D., MBA, Vice President, Process Science & Production, Rentschler Biotechnology

08:35 Continuous Aqueous Two-Phase Extraction of Proteins – Novel Process Windows by Increasing Protein Solubility

Christoph Brandenbusch, Ph.D., Group Leader, Department of Biochemical and Chemical Engineering, Laboratory of Thermodynamics, TU Dortmund University

Increasing product titers in pharmaceutical protein production led to a demand for novel workup strategies (e.g. protein extraction by Aqueous Two-Phase Systems). However, the effort and costs required in selecting appropriate ATPS and process windows hinder the industrial applicability. Hybrid modeling approaches enable the estimation of efficient phase formers and novel displacement agents. This allows for both a selective purification and stabilization of the protein in solution by increasing solubility.

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09:05 Resolving Perplexing Purification Paradigms with CD-FAST: Calcium Dependent Fragment Assembly Separation Technology

David O'Connell, Ph.D., Lecturer & Director, Biomolecular & Biomedical Science, University College Dublin, and Founder, YourProteome

Membrane proteins and chaperone-assisted cytosolic proteins prove to be particularly perplexing when it comes to isolating them in sufficient quantity and purity for downstream assays. Most rationales involve multi-step strategies that consume valuable amounts of protein. The application of CD-FAST technology is a powerful innovation in the single step isolation of pure, functional proteins with recent advances in GPCR and aggregation-prone kinase purification and downstream assay reported here.

09:35 A Saposin-Based Nanoparticle System for Stabilization of Membrane Proteins

Jens Frauenfeld, Ph.D., CEO, Salipro Biotech AB

We present a saposin-lipoprotein nanoparticle system, which allows for the reconstitution of membrane proteins in a lipid environment. We demonstrate the applicability of the method on purified membrane proteins as well as by the direct solubilization and nanoparticle incorporation of membrane protein complexes from the virus membrane. The Salipro system allows for high-resolution cryo-EM of membrane proteins and is applicable for the development of novel drugs, vaccines and therapeutic antibodies.

10:05 Coffee Break in the Foyer with Poster Viewing

AFFINITY PURIFICATION

10:35 Versatile Affinity Ligands for Bioseparation Processes

Ana Cecília Afonso Roque, Ph.D., Assistant Professor, Chemistry, UCIBIO, Faculdade de Ciências e Tecnologia, Universidade Nova de Lisboa

We employed biological and chemical combinatorial libraries supported by computational design tools to develop robust peptidomimetics based on different scaffold molecules. The scaffold molecules ranged from small synthetic ligands, to artificial β -hairpin peptides and small protein domains produced chemically. We studied the potential of these scaffold affinity reagents to find binding partners against several targets (e.g. recombinant proteins, phosphorylated peptides, and virus-like particles), and to develop affinity-based purification processes.

11:05 Affitins as a Novel Tailored Class of Robust Reagents for Affinity Chromatography Purification of Antibodies and Non-Immunoglobulin Proteins

Frédéric Pecorari, Ph.D., Researcher, IRS-UN, Cancer Research Center Nantes-Angers, University of Nantes

This presentation reveals how Affitins can be used as ligands to design affinity columns for one-step purification of human immunoglobulin G (hIgG), with 95% purity and recovery of 100%. Affitin production in *E. coli* makes it possible to produce these affinity columns at low cost. Our results validate Affitins as a new class of tailored ligands for the affinity purification of potentially any proteins of interest including biopharmaceuticals.

11:35 A Novel IgG-Binding Purification Matrix for Mild Elution

Sophia Hober, Ph.D., Professor, Biotechnology, KTH-Royal Institute of Technology

Antibodies are widely used affinity molecules in many fields of biological science and the therapeutic field for monoclonal antibodies is constantly growing. The most common method for purification of antibodies is protein A affinity chromatography. It offers high-selectivity, and yields pure and concentrated antibodies. One of the major issues with protein A purification is the low pH that is essential to elute the bound antibody from the column. Here, we have addressed this by protein engineering of the IgG-binding domain from protein A.

12:05 Sponsored Presentation (Opportunity Available)

12:35 Problem-Solving Breakout Discussions with a Light Snack in the Foyer*

*See website for more details.

13:35 Session Break

IMPROVING AND INNOVATING PURIFICATION PROCESSES

14:00 Chairperson's Remarks

Christoph Brandenbusch, Ph.D., Group Leader, Department of Biochemical and Chemical Engineering, Laboratory of Thermodynamics, TU Dortmund University

14:05 Peptides in Headlock: A Novel Nanobody-Derived Capture/Detection System

Ulrich Rothbauer, Ph.D., Professor, Pharmaceutical Biotechnology, University of Tübingen

Single-domain antibodies (nanobodies) have emerged as an attractive alternative to traditional antibodies and have become highly valuable tools for numerous bioanalytical and biotechnical applications. Here we present a novel nanobody-derived capture/detection system that enables a fast and efficient isolation of epitope-tagged proteins from prokaryotic and eukaryotic expression systems. The high-affinity-binding and modifiable peptide tag of this system renders it a versatile and robust tool to combine biochemical analysis with microscopic studies.

14:35 Case Study: Human Kinase Crystallization, Phosphatase Co-Expression

Mario Lebendiker, Ph.D., Head, Protein Purification Facilities, Wolfson Centre for Applied Structural Biology, The Hebrew University of Jerusalem

We present a case study of production of a human Kinase co-expressed in *E. coli* cells together with phosphatase in order to get a homogeneous, non-phosphorylated, and crystallizable protein. The reproducible production of different batches in *E. coli* allow us to successfully crystallize our target with a great variety of ligands with possible therapeutic implications. We describe our expression and purification approach, bottlenecks, etc. Since this protein was crystallized in the past, this case study emphasizes the need to establish "minimal protein quality information" in publications in order to assure reproducibility of results.



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15:05 Use of Succinylated Trypsin as a Manufacturing Aid

Nina Madsen, M.S., Scientist, Downstream Process Development, Bristol-Myers Squibb

We present a robust method for the charge modification of lysine residues on trypsin, by way of an acylation reaction between succinic anhydride and the lysine functional group. We then demonstrate the use of this modified enzyme as a tool in the downstream manufacture of a recombinant microbial product. Our protein is expressed in *E. coli* as a prohormone precursor and is enzymatically converted to the desired product using trypsin.

15:35 Development of a Robust Ultrafiltration/Diafiltration Step for Highly Concentrated Drug Substance Using High-Throughput Methods and Aggregation Modelling

Dejan Arzenšek, Ph.D., Research Scientist, Downstream Process Development, Sandoz Biopharmaceuticals

The present study focused on evaluating critical parameters within the Ultrafiltration/Diafiltration (UF/DF) operation that lead to aggregation due mainly to the physical instability of therapeutic mAbs. Insight into the physical instability of the protein in solution was achieved by using a directed approach based on a more detailed biophysical characterization required to ensure successful process development. Aggregation and particle formation were monitored using multiple analytical techniques for UF/DF conditions tested.

16:05 A New Shaped Rocking Bioreactor for Insect and Mammalian Cells

Sabine Suppmann, Ph.D., Head, Recombinant Protein Production, Biochemistry Core Facility, Max Planck Institute of Biochemistry

Wave-rocking bioreactors have increasingly replaced traditional stainless steel stirred tank reactors for large-scale cultivation of insect or mammalian cells during the last decade. Disposable wave bags are available in many shapes and sizes from several commercial providers. In research laboratories, however, production in wave bags is much less established for cost reasons and still mainly performed in shaking flasks. We will discuss how we have developed a re-usable, fixed-shaped bioreactor, which can be used on the diverse rocking unit platforms that control temperature, aeration rate, rocking speed, and rocking angle.

16:35 End of Conference

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Jason Gerardi
Business Development Manager
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Cover

Conference-at-a-Glance

Sponsors

Short Courses

TRAINING SEMINARS

- Protein Expression Technologies
- Introduction to Protein Engineering

ENGINEERING

- Display of Antibodies
- Engineering Antibodies
- Engineering Bispecifics
- Engineering Next-Generation ADCs

THERAPEUTICS

- Novel Immunotherapy Strategies
- Advancing Bispecifics
- Novel Therapies for Cancer

ANALYTICAL

- Optimisation & Developability
- Analytical Characterisation
- Aggregates & Particles

EXPRESSION

- Protein Expression Technologies
- Optimising Expression Platforms
- Protein Purification Technologies

Sponsor & Exhibit Opportunities

Hotel & Travel Information

Registration Information

Record Attendance Confirmed!

**SAVE up to €300,
Register by 30 September**

PEGSummitEurope.com



Cambridge Healthtech Institute,
250 First Avenue, Suite 300,
Needham, MA 02494 USA
www.healthtech.com

HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:

EPIC SANA Lisboa Hotel
Avenida Engenheiro Duarte Pacheco 15,
1070-100 Lisbon, Portugal
Phone: +351-211-597-300

Reservations:

Go to the travel page of
PEGSummitEurope.com

Discounted Room Rate:

€150 single/ €170 double *
* includes complimentary breakfast & internet

Discounted Cut-off Date:

27 September 2016

Top Reasons to stay at the EPIC SANA Lisboa Hotel

- Breakfast and complimentary internet is included in the room rate.
- Located just minutes from the city's downtown Bacia, where you can admire Augusta Street, Russio and Comercio Square (shopping, galleries & theaters).
- 15 minutes from Lisbon's Portela International Airport.
- Minutes from local attractions like Avenida da Liberdade, Praça do Comercio (magnificent Square by the River), Estrelas Basilica, and Belem Tower to name a few.
- Close to Bairro Alto - one of Lisbon's Old Quarters with great dining options and site seeing.
- The hotel offers Sayanna Wellness, a world-class Spa and 24 hour Fitness Center.



**For additional information go to the travel page of
PEGSummitEurope.com**

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CONFERENCE PRICING

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated	Student*
One short course	€625	€375	€125
Two short courses	€895	€625	€195

Monday, 31 October (Morning Short Courses)	Thursday, 3 November (Dinner Short Courses)
SC1: Cancer Immunotherapy	SC5: Troubleshooting and Engineering of Antibody Constructs
SC2: Mutation and Selection Strategies beyond Affinity Optimisation	SC6: Engineering of Bispecific Antibodies
SC3: Designing Antibodies for Function and Low Risk of Immunity	SC7: Protein Purification Strategies: Dealing with Proteins that are Prone to Aggregate
SC4: Transient Protein Expression: A Key Tool to Enable Rapid Protein Engineering	SC8: Protein Aggregation: Mechanism, Characterisation and Consequences

CONFERENCE PRICING

PREMIUM PACKAGE - Best Value (Includes access to all 14 conferences/Training Seminars Monday-Friday, excludes short courses)

Early Registration Rate until 2 September	€2699	€1549	€695
Advance Registration Rate until 30 September	€2899	€1599	€695
Registration Rate after 30 September and on-site	€3099	€1699	€695

STANDARD PACKAGE (Includes access to two conferences/Training Seminars, excludes short courses)

Early Registration Rate until 2 September	€2349	€1199	€525
Advance Registration Rate until 30 September	€2549	€1249	€525
Registration Rate after 30 September and on-site	€2749	€1299	€525

BASIC PACKAGE (Includes access to one conference/Training Seminar, excludes short courses)

Early Registration Rate until 2 September	€1599	€849	€375
Advance Registration Rate until 30 September	€1799	€899	€375
Registration Rate after 30 September and on-site	€2099	€949	€375

	Monday - Tuesday 31 October - 1 November	Wednesday - Thursday (am) 2 - 3 November	Thursday (pm) - Friday 3 - 4 November
ENGINEERING STREAM	1A: Display of Antibodies 4A: Engineering Next-Generation Antibody-Drug Conjugates	1B: Engineering Antibodies	1C: Engineering Bispecifics
THERAPEUTICS STREAM	2A: Novel Immunotherapy Strategies	2B: Advancing Bispecifics and Combination Therapy to the Clinic	2C: Novel Therapies for Cancer and Emerging Targets
ANALYTICAL STREAM	3A: Optimisation & Developability	3B: Analytical Characterisation of Biotherapeutics	3C: Protein Aggregates & Particles
EXPRESSION STREAM	TS1: Basic Technologies in a Core Protein Expression Lab	4B: Optimising Expression Platforms	4C: Protein Purification Technologies
Training SEMINARS	TS2: Introduction to Protein Engineering		

Alumni Discount 20% Off

Poster Discount €45 Off

If you are unable to attend but would like to purchase the **PEGs Europe CD** for €600 (plus shipping), please visit PEGSummitEurope.com. Massachusetts delivery will include sales tax.

CONFERENCE DISCOUNTS

Poster Submission - Discount (€45 Off): Poster abstracts are due by 23 September 2016. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

REGISTER 3 - 4th IS FREE:

Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

ALUMNI DISCOUNT:

CHI appreciates your past participation at PEGs. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

GROUP DISCOUNTS:

Special rates are available for multiple attendees from the same organization. For more information on group discounts contact Joseph Verange at 781-247-6263 * Alumni, Group, Protein Society or Antibody Society Membership, Twitter, LinkedIn, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link. Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/ Cancellations Policy, go to www.healthtech.com/regdetails

VIDEO AND/OR AUDIO RECORDING OF ANY KIND IS PROHIBITED ONSITE AT ALL CHI EVENTS.



How to Register:

PEGSummitEurope.com

reg@healthtech.com

P: 781.972.5400

or Toll-free in the U.S.

888.999.6288

Please use keycode PGEF when registering