Organized by Cambridge Healthtech Institute

FINAL AGENDA

Inaugural

PEGS CHINA

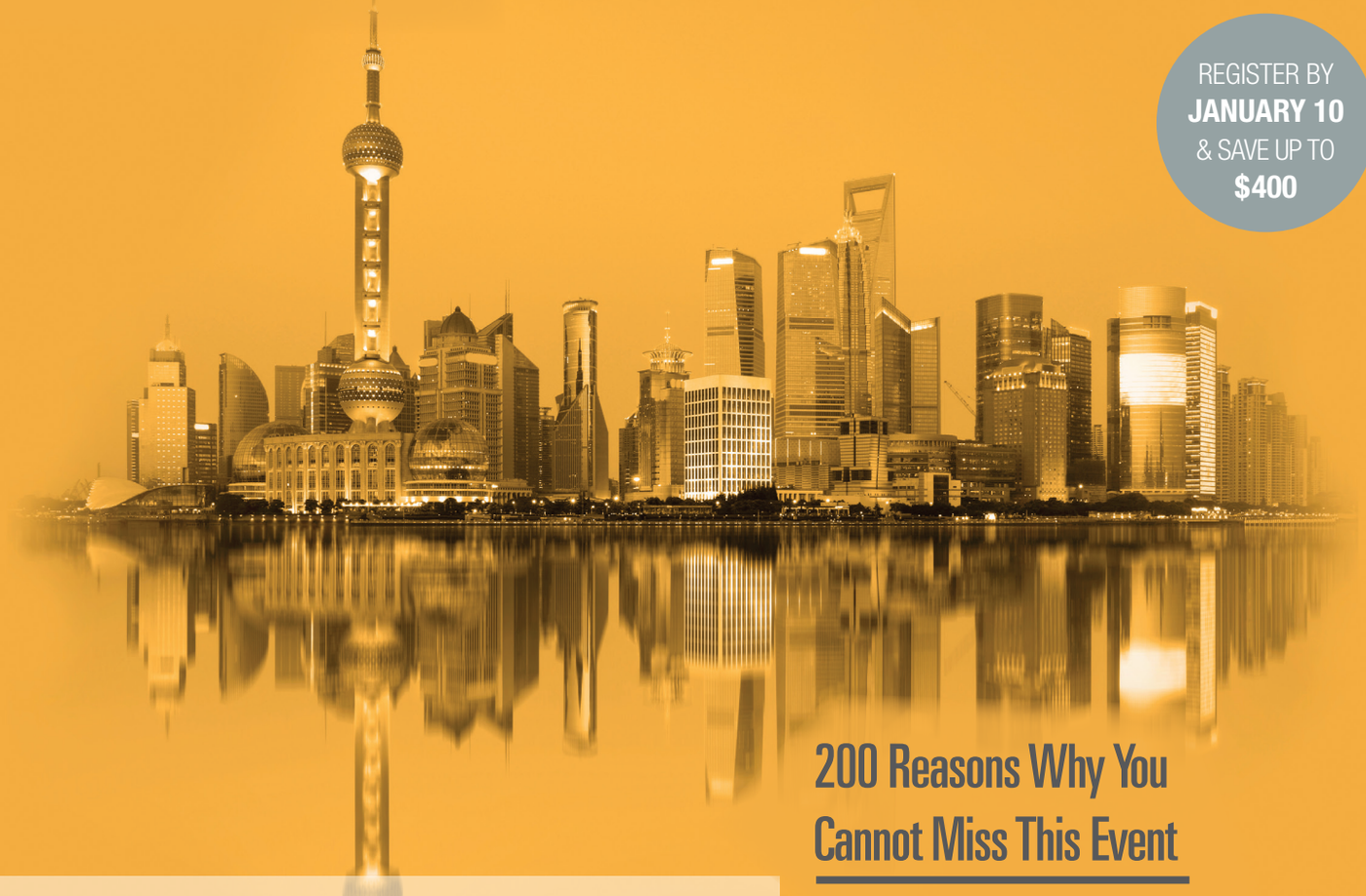
首届中国

蛋白与抗体工程及研发峰会

Protein & Antibody Engineering and Development Summit

April 1-3, 2014 // Shanghai Marriott Hotel Pudong East // Shanghai, China

REGISTER BY **JANUARY 10** & SAVE UP TO **$400**



Attend 1 or All 4 of the Conferences!

- Protein & Antibody Engineering
- Analytical Characterization & Stability
- Optimizing Protein Expression
- Quality, Scalability and CMC Strategies

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200 Reasons Why You Cannot Miss This Event

60 Speakers from More Than 10 Countries Represented on the Speaker Faculty

55 Presentations with Case Studies Sharing Tactical Solutions and Proven Strategies

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20 New, Unpublished Data Presentations

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Cambridge Healthtech Institute presents

The Inaugural

PEGS CHINA

Protein & Antibody Engineering and Development Summit

首届中国

蛋白与抗体工程及研发峰会

Spurred by the growth in the biopharmaceutical sectors in Asia and the demand by our participants and exhibitors for an internationally established event with high caliber speakers in this region, Cambridge Healthtech Institute (CHI) is proud to bring a new, dynamic and interactive 3-day event comprising 4 high-impact conferences:

- Protein & Antibody Engineering
- Optimizing Protein Expression
- Analytical Characterization & Stability
- Quality, Scalability and CMC Strategies

Featuring over 55 presentations covering case studies, proven strategies, novel technologies and new collaborations, this event will arm you with the tools and techniques to help you engineer your protein and antibody for better efficacy and safety; optimize your proteins for higher productivity; better characterize your products for stability and comparability; as well as develop processes to ensure product quality, consistency and scalability.

Meet and hear from our distinguished international Speaker Faculty including these **Keynotes & Featured Speakers:**

Florian M. Wurm, *Ph.D., Professor, Biotechnology, Swiss Federal Institute of Technology Lausanne (EPFL) & Founder, CSO, ExcellGene SA, Switzerland*

Ho Sung Cho, *Ph.D., CTO, Ambrx USA*

Feng Tian, *Ph.D., Director EuCODE Technology and Head, Ambrx China*

Chris Chen, *Ph.D., Senior Vice President and CTO, Biologics Services, Wuxi Apptec, PR China*

Vaughn B . Himes, *Ph.D., Executive Vice President, Process Sciences and Technical Operations, Seattle Genetics, USA*

Ian Hunt, *Ph.D., Head, Protein Sciences, Center for Proteomic Chemistry, Novartis Institutes for Biomedical Sciences, USA*

Johannes Salzbrunn, *Head, GMP Downstream/Fill & Finish, Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd., PR China*

Ingo Gorr, *Ph.D., Principal Scientist, Cell Culture Research, Large Molecule Research, Roche Diagnostics GmbH, Germany*

Thank you to our **Scientific Advisors** for their input and recommendations on the program:

Gerald Carson, *Ph.D., Senior Principal Research Scientist, Abbvie Biologics*

Wei Chen, *Ph.D., CSO, Phage Pharmaceuticals*

Ho Sung Cho, *Ph.D., CTO, Ambrx*

Danny K. Chou, *Pharm.D., Ph.D., Senior Research Scientist I, Gilead Sciences*

Weiguo Dai, *Ph.D., Scientific Director/Janssen Fellow, Johnson &Johnson*

Dimiter Dimitrov, *Ph.D., Senior Investigator, Center for Cancer Research, NCI, National Institutes of Health*

Daotian Fu, *Ph.D., Executive Vice President, Livzon Mabpharm, Inc.*

Ning Gao, *Senior Scientist, AstraZeneca R&D*

Nimish Gera, *Ph.D., Senior Scientist, Oncobiologics, Inc.*

Rui Gong, *Ph.D., Professor and Head, Antibody Engineering Group, Center for Emerging Infectious Diseases, Wuhan Institute of Virology*

Ping Guo, *Ph.D., Vice President, Bijing Yuantang Institute of Gene Science*

Andrea Ji, *Ph.D., Senior Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.*

Shan Jiang, *Ph.D., Director, Formulation and Fill/Finish, Seattle Genetics, Inc.*

Morten Munk, *Vice President, CMC Biologics A/S*

GS Reddy, *Ph.D., Chief General Manager, Manufacturing, Indian Immunologicals*

Sai Reddy, *Ph.D., Assistant Professor, Department of Biosystems Science and Engineering, ETH Zurich*

Li Shi, *Ph.D., CEO, Shanghai Zerun Biotechnology*

Sai Reddy, *Ph.D., Assistant Professor, Department of Biosystems Science and Engineering, ETH Zurich*

Daniel J. Sikkema, *Ph.D., Executive Director, Biopharm R&D, Head, Clinical Immunology, GlaxoSmithKline*

Scott M. Wheelwright, *Ph.D., Principal Consultant, Complya Asia Co., Ltd.*

Lei Zheng, *M.D., Ph.D., Assistant Professor, Oncology, John Hopkins University School of Medicine*

Marie M. Zhu, *Ph.D., Director, Process Sciences, Agensys Inc., an affiliate of Astellas Pharma, Inc.*

CONFERENCE AT A GLANCE

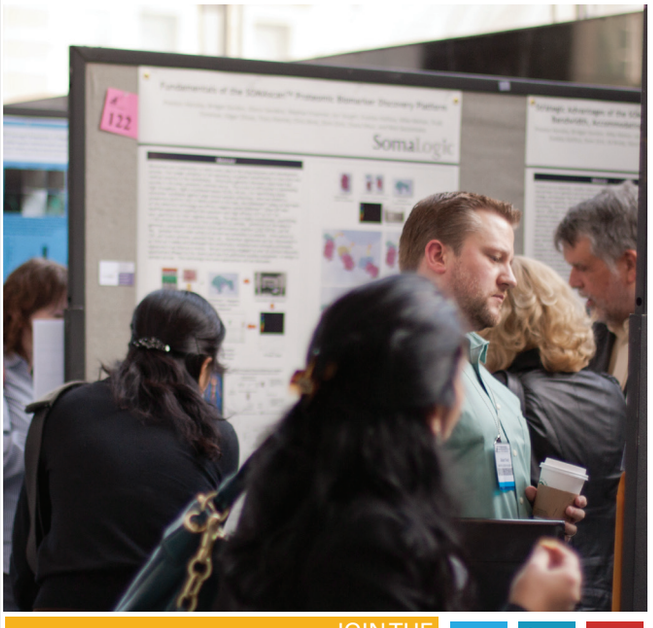
TUESDAY, APRIL 1	TRACK 1: PROTEIN & ANTIBODY ENGINEERING	TRACK 2: ANALYTICAL CHARACTERIZATION & STABILITY		
WEDNESDAY, APRIL 2 *morning session*	TRACK 1: PROTEIN & ANTIBODY ENGINEERING	TRACK 2: ANALYTICAL CHARACTERIZATION & STABILITY		
WEDNESDAY, APRIL 2 *afternoon session*	TRACK 1: PROTEIN & ANTIBODY ENGINEERING	TRACK 2: ANALYTICAL CHARACTERIZA-TION & STABILITY	TRACK 3: OPTIMIZING PROTEIN EXPRESSION	TRACK: 4 QUALITY, SCALABILITY AND CMC STRATEGIES
	PLENARY KEYNOTE SESSION & BREAKOUT DISCUSSIONS			
THURSDAY, APRIL 3	TRACK 3: OPTIMIZING PROTEIN EXPRESSION	TRACK: 4 QUALITY, SCALABILITY AND CMC STRATEGIES		

RESEARCH POSTER SUBMISSION

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by February 28, 2014.

Reasons you should present your research poster at this conference:

- Your poster will be exposed to our international delegation
- Receive $50 off your registration
- Your poster abstract will be published in our conference materials
- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes



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PROTEIN & ANTIBODY ENGINEERING

7:30 am Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Lei Zheng, M.D., Ph.D., Assistant Professor, Oncology, John Hopkins University School of Medicine, USA

GENERATING ANTIBODIES AGAINST GPCR

9:00 Novel GPCR-Targeting Therapeutic Antibodies
Anke Kretz-Rommel, Ph.D., Vice President, R&D, NA, RuiYi, Inc., USA
While many companies have successfully generated mAbs against chemokine receptors, the vast majority of GPCRs has not been addressed with mAbs due to the difficulty of obtaining pure GPCR protein in the proper conformation. RuiYi's core technology has now successfully been used to select a panel of mAbs against two class A GPCR receptors for the treatment of fibrotic diseases. mAbs obtained include many binders to extracellular loops of fairly short length, bind to conformational epitopes and do show functional activity, resulting in mAbs with desired therapeutic properties.

9:30 Challenging Targets: Generating High-Quality Antibodies against G-Protein Coupled Receptors
Case Study
Unpublished Data
Stefanie Urlinger, Ph.D., Director, R&D, Discovery Alliances Technologies, MorphoSys AG, Germany
The generation of antibodies of therapeutic potential against GPCRs is a technically challenging task. We have built up a broad platform of techniques that allow us to reliably generate specific and functionally active antibodies against GPCRs. We will show case studies for anti-GPCR antibody generation and detailed characterization of the antibodies.

10:00 Generation of Therapeutic Antibodies against GPCR Targets by Functional Live Cell Selection with dsDNA Display
Unpublished Data
Yan Chen, M.D., Ph.D., Senior Vice President, Research, X-BODY Biosciences, USA
We have established a functional live cell selection platform utilizing diverse dsDNA-displayed human VH libraries and *in vitro* selections executed against functionally active GPCRs. We have generated single domain VHs to GPCR targets displaying broad epitope coverage and exerting functional activities through distinct mechanisms of action. VHs are converted into full IgGs with a proprietary, non-covalent VL pairing technology to enhance target binding. X-BODY uses the platform to make therapeutic antibodies against GPCRs and ion channels.

10:30 Coffee Break

ANTIBODY DISCOVERY AND CLINICAL DEVELOPMENT

11:00 Implementing Systems Immunology Methods for Monoclonal Antibody Discovery
Sai Reddy, Ph.D., Assistant Professor, Department of Biosystems Science and Engineering, ETH Zurich, Switzerland
We have developed novel methods for monoclonal antibody discovery based on systems biology methods. Specifically, we now use the Illumina mi-Seq platform to obtain large datasets of antibody variable genes from immunized mice. We have developed bioinformatic software that is capable of processing sequence data and provide predictions for antigen-specific clones. Finally we use gene synthesis technology for recombinant expression and validation of monoclonal antibody specificity.

11:30 Clinical Development of Tanibirumab and Its Next Generation Therapeutics
Case Study
Jin-San Yoo, Ph.D., CEO, President & Founder, PharmAbcine, Korea
Tanibirumab is anti-KDR neutralizing fully human IgG with cross species cross reactivity which is unique. Its Phase I study is completed and we are evaluating all kinds of data we already got and we will get. From the preliminary data, Tanibirumab has no MTD and DLT up to 24mg/kg. We observed several stable disease patients among progression disease patients. In contrast to Ramucirumab, VEGF-Trap, Avastin, and other VEGF/KDR antagonist, Tanibirumab hasn't cause any hemorrhage, bleeding and hypertension. We are preparing for phase II study with recurrent GBM patients and exploring other indication.

12:00 pm Sponsored Presentations *(Opportunities Available)*

12:30 Networking Luncheon

ANALYTICAL CHARACTERIZATION & STABILITY

7:30 am Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Daotian Fu, Ph.D., Executive Vice President, Livzon Mabpharm, Inc., PR China

CHARACTERIZATION AND COMPARABILITY

9:00 Analytical and Quality Considerations to Support Product Characterization Comparability
Daotian Fu, Ph.D., Executive Vice President, Livzon Mabpharm, Inc., PR China
With wide implementation of QbD in the biotech industry and recent advances in analytical technologies, strategies of analytical characterization and product comparability continues to evolve. In this presentation, we will discuss implications of QbD applications in process development, and how it may be best used to support process characterization and product comparability.

9:30 Analysis of Complex Protein Therapeutics in Support of Product Development
Case Study
Unpublished Data
Xiaoyang Zheng, Ph.D., Staff Scientist II, Analytical Development, Genzyme Corporation, a sanofi Company, USA
Effective analytical support is critical to the evaluation of safety, efficacy, purity, and product consistency of a new therapeutic and its process development. This talk will focus on the strategies used to assess critical quality attributes and set specifications, as well as the use of characterization knowledge to optimize the production process.

10:00 Development of Antibody Arrays for mAb Higher Order Structure Analysis
Xing Wang, Ph.D., President, Array Bridge, USA
A novel technology is developed using antibody arrays to analyze monoclonal antibody therapeutics Higher Order Structure. This technology provides a sensitive, systematic and high-throughput approach for mAb Higher Order Structure comparability analysis, generating valuable information for cell line selection, process development and formulation development. Examples will be presented to demonstrate the application of the antibody array in biosimilar as well as novel mAb development and its complementary value to the bioassays and other analytical technologies.

10:30 Coffee Break

11:00 Assessing Antibody Fc Effector Functions via Multiple Assay Platforms
Jingyi Xiang, Ph.D., Head Bioanalytics, Eureka Therapeutics, Inc., USA
When developing and manufacturing biosimilar antibodies, it is critical to assess Fc effector function to ensure similarity to the originator compound. However, the historic lack of platforms designed to meet this specific need has made these comparisons murky at best. To address this issue, an integrated multiple assay approach is needed to explore the correlation between binding assays (such as FcR and complement binding), activity assays (including ADCC, CDC and ADCP), and glycosylation analyses.

11:30 New Approaches to Determine and Characterize CHO Host Cell Proteins
Unpublished Data
Harald Wegele, Ph.D., Director, Development Analytics, Pharma Biotech Development, Roche Diagnostics GmbH, Germany
Host cell proteins (HCPs) are process-related impurities in the development of biopharmaceuticals. As HCPs may act immunogenic, their characterization is of major interest. We apply electrochemiluminescent assays combined with prior 2D- chromatographic fractionation to monitor HCP removal. Since abundance and variety of HCPs change with the biologic molecule and/or the bioprocess, their profiles and coverage by anti-HCP antibodies is analyzed using 2-D Fluorescence Difference Gel Electrophoresis (2-D DIGE) and Western blot techniques.

12:00 pm Emerging Techniques Therapeutic Protein Characterization – Viscosity, Stability and Sub-Visible Particles
Sponsored by Malvern
Wei Qi, Ph.D., Senior Scientist, Bioscience Development Initiative, Malvern Instruments
Three exciting novel techniques are introduced for protein therapeutics characterization. With less than 10 mL sample, we could provide simultaneous measurement of viscosity up to 160 cP and concentration up to 200 mg/mL. Raman Spectroscopy and Dynamic Light Scattering were combined to determine protein structure and hydrodynamic size directly at high concentration, and then assess the colloidal and conformation stability under applied stresses. The sub-visible particles could be counted, imaged and chemical identified automatically with the combination of microscopy and in situ Raman spectrometry.

12:30 Networking Luncheon

PROTEIN & ANTIBODY ENGINEERING

1:40 Chairperson's Remarks
Dimiter Dimitrov, Ph.D., Senior Investigator, Center for Cancer Research, NCI, National Institutes of Health, USA

ANTIBODIES FOR CANCER IMMUNOTHERAPY

1:45 New Focus of Antibody-Based Therapeutics: Targeting Tumor Microenvironment
Lei Zheng, M.D., Ph.D., Assistant Professor, Oncology, John Hopkins University School of Medicine, USA
Unpublished Data
Rapid developments in antibody target discovery and antibody-based therapeutics have revolutionized cancer therapy. The tumor microenvironment is recognized as an important target for cancer therapy. Newly developed monoclonal antibodies targeting immune checkpoint signals in the tumor microenvironment are promising in overcoming the barriers to effective immunotherapy for gastrointestinal cancers. Appropriate combination of different therapeutic strategies is still a key to the success of cancer immunotherapy.

2:15 Immunotherapeutic Approaches to Kill Cancer Cells Employing NK and T Cells Bispecific Tetravalent TandAbs
Eugene Zhukovsky, Ph.D., CSO, Affimed Therapeutics AG, Germany
Case Study
Unpublished Data
The TandAb technology comprises CD3 RECRUIT and CD16 RECRUIT effector modules for the respective recruitment of T and NK cells, and an anti-tumor antigen module to target and lyse cancer cells. In hematological malignancies and solid tumor assays T cell recruiting TandAbs demonstrate better efficacy and potency *in vivo* and *in vitro* relative to other T cell engaging molecules, while the NK cell recruiting TandAb shows activity in the clinic. Both molecule classes possess excellent safety profile and superior drug-like properties.

2:45 Targeted Tumor Immunotherapy through Engineered Antibodies
Ting Xu, Ph.D., CEO, AlphaMab Co., Ltd., PR China
Unpublished Data
With novel mechanism discovered for monoclonal antibodies in hand, we have designed a series bispecific antibodies and antibody-protein hybrid. Those molecules have been constructed using the proprietary Fc heterodimeric technology developed in Alphamab. *In vitro* and *in vivo* efficacy data indicate that those novel molecules have broad application in tumor treatment.

3:15 Sponsored Presentations *(Opportunities Available)*

3:45 Refreshment Break

NOVEL SCAFFOLDS, ANTIBODY DOMAINS & FRAGMENTS

4:15 Engineered Human Antibody Domains, Fragments and Full-Size IgG1 against Cancer and Viruses
Dimiter Dimitrov, Ph.D., Senior Investigator, Center for Cancer Research, NCI, National Institutes of Health, USA
The work in our group in three major directions will be discussed: 1) engineered antibody domains and fragments as related to the development of exceptionally potent inhibitors of HIV-1 and tools for its eradication, 2) IgG1-based candidate therapeutics against cancer with an emphasis on novel concepts and evaluation in animal models, and 3) full-size IgG1s against emerging and biodefense-related viruses including henipaviruses and coronaviruses, especially for prophylaxis and therapy of humans.

4:45 Human VH Antibody Fragments from a Transgenic Mouse Platform
Mike Romanos, Ph.D., CEO, Crescendo Biologics, United Kingdom
Unpublished Data
Single domains are the smallest, most robust antibody fragments and as such have advantages for tissue and tumour penetration, engineering of multivalent products, topical delivery and simple manufacture. The Crescendo Mouse harnesses the benefits of *in vivo* maturation while generating heavy chain antibodies as a source of fully human VH. Data from multiple immunisations and discovery programmes will be used to illustrate the ability of the platform to rapidly generate a high diversity of potent leads with excellent biophysical properties.

5:15 Optimization on Antibody CH2 Domain for Reduction of Aggregation: Implication for New Scaffold Design
Rui Gong, Ph.D., Professor, Center for Emerging Infectious Diseases, Wuhan Institute of Virology, PR China
Unpublished Data
Antibody CH2 domain was proposed as novel scaffold for development of novel nanoantibodies as therapeutic candidates. However, isolated CH2 tends to aggregate. We found removal of seven residues at N-terminal in CH2 could decrease the aggregation tendency. Based on computer analysis, several aggregation prone regions in CH2 were also identified, which could be mutated to increase the aggregation resistance. Reduction of aggregation in CH2 can bring advantages in library construction and binder selection.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:45 Close of Conference Day One

ANALYTICAL CHARACTERIZATION & STABILITY

1:40 Chairperson's Remarks
Boyan Zhang, Ph.D., Vice President &CSO, Beijing Mab-Works, Inc., PR China

CHARACTERIZATION OF BIOSIMILARS

1:45 Tools for Protein Characterization - How Can the Quality of Biosimilars Be Improved?
Anand Khedkar, M.Tech, Chief Scientific Manager, R&D, Biocon Research Limited, India
The major challenge for a biosimilar is to show the similarity to that of an innovator. This brings us to the famous question, how similar is similar enough? Can we get a reasonable idea, during the development stages regarding the critical quality attributes, which could potentially be correlated with the biological properties? This could form the basis of process development and process controls.

2:15 How to Achieve and Demonstrate Comparability of Glycosylation for a Biosimilar Compared to the Innovator Drug
Daryl L. Fernandes, Ph.D., Chief Executive, Ludger Ltd., United Kingdom
Glycosylation can greatly alter the safety and efficacy of biologic drugs. For this reason, biosimilar companies must demonstrate to regulators that the glycosylation patterns of their copy drugs are comparable to those of the innovator's therapeutic. However, the complexity, heterogeneity and variability of glycosylation makes this one of the most challenging tasks for biosimilar developers. In this talk I will overview a practical system that biosimilar companies can follow to (a) achieve effective comparability of the glycosylation patterns of their copy drug to those of the innovator molecule and (b) demonstrate that properly to the regulatory authorities.

2:45 Developing Antibody Biosimilar Therapeutics in China: How Similar is Similar Enough?
Boyan Zhang, Ph.D., Vice President & CSO, Beijing Mab-Works, Inc., PR China
Unpublished Data
This presentation will share with you IND filing experience with CFDA for two antibody biosimilars and understanding of the regulatory environment in China. The CMC comparability study and critical quality attribute (CQA) analysis strategies will be discussed. Beijing Mab-Works' in-house platform technology and development strategy for antibody-based therapeutics for China market will also be described.

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3:15 Sponsored Presentation
Speaker to Be Announced

3:45 Refreshment Break

4:15 Characterization of a Biosimilar for Development in China
Joanne Sun, Ph.D., Executive Director, Quality and Analytical Development, Innovent Biologics, Inc.

IMMUNOGENICITY

4:45 Integrating Immunogenicity of Biotherapeutics with PK, Efficacy and Safety
Daniel J. Sikkema, Ph.D., Executive Director, Clinical Immunology, Biopharm R&D, GlaxoSmithKline, USA
Case Study
A major limitation to the use of biotherapeutics is the development of anti-drug antibodies (ADA) in a subset of patients. These may decrease efficacy by neutralizing them or modifying drug clearance, and they may be associated with drug-specific hypersensitivity reactions. ADA may also cross-react with closely related endogenous counterparts, compromising important physiologic functions.

5:15 Immunogenicity of Clotting Factors: Predictive Methods and Risk Factors
Matthias Germer, Ph.D., Senior Director, Preclinical Research, Biotest AG, Germany
The most important adverse event in the substitution of coagulation factors in hemophilia patients is formation of inhibitory antibodies. Product, patient and treatment characteristics have now been identified as most relevant risk factors. The in-depth understanding of the immunological response allows us to minimize the patient risk by adequate patient monitoring and adaptation of individualised treatment schemes. Predictive immunogenicity tests might help us to develop unique novel products.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:45 Close of Conference Day One

PROTEIN & ANTIBODY ENGINEERING

8:00 am Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Arvind Rajpal, Ph.D., Vice President, Protein Engineering, Rinat, USA

ADC, BISPECIFICS AND COMPLEX BIOLOGICS

9:00 Enzymatic Conjugation of Payloads to Antibodies for the Generation of Next-Generation ADCs

Unpublished Data

Ulf Grawunder, Ph.D., CEO, NBE-Therapeutics, LLC., Switzerland
Conventional conjugation of toxic payloads to antibodies for the generation of ADCs has the disadvantage that the site for conjugation and the drug-to-antibody ratio (DAR) cannot easily be controlled and chemical conjugation may be associated with limited yield of the desired ADC product. NBE-Therapeutics has developed a novel, enzymatic payload conjugation technology that allows precise control of conjugation site and drug-to-antibody ratio. Data in connection with this technology will be presented.

9:30 Location Matters: Site of Conjugation Modulates Stability and Pharmacokinetics of Antibody-Drug Conjugates

Arvind Rajpal, Ph.D., Vice President, Protein Engineering, Rinat, USA
To understand the role of conjugation site, we developed an enzymatic method for site-specific antibody-drug conjugation using microbial transglutaminase. We show that the conjugation site has significant impact on ADC stability and pharmacokinetics in a species-dependent manner. These differences can be directly attributed to the position of the linkage rather than the chemical instability, as was observed with a maleimide linkage. With this method, it is possible to produce homogeneous ADCs and tune their properties to maximize the therapeutic window.

10:00 Sponsored Presentations *(Opportunities Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Quantum Dot - Conjugated Antibodies as Diagnostic and Therapeutic Tools for Cancer Imaging and Treatment

Unpublished Data

Weiming Xu, Chief CEO, Molecular Biology, London Biotech Ltd., United Kingdom
By conjugating Qdots with small antibody fragments targeting membrane-bound proteins in cancer, such as GRP78, we demonstrated that the Quantum dot-antibody retains its immunospecificity and its distribution can be monitored by visualization of multi-color fluorescence imaging both *in vitro* and *in vivo*. Moreover we have shown for the first time that Qdot-GRP78 scFv bioconjugates can be efficiently internalized by breast cancer cells and possess biological anti-tumour activity, showing its potential for cancer treatment.

11:30 COVA322: A Novel, Bispecific TNF/IL-17A Inhibitor for the Treatment of Inflammatory Diseases Moving towards the Clinic

Unpublished Data

Michela Silacci, Director Discovery Research, Covagen AG, Switzerland
We will present COVA322, a bispecific TNF/IL-17A inhibitor, blocking the activity of both cytokines *in vitro* and *in vivo* with picomolar inhibition potencies. The fusion of the anti-IL-17A Fynomer to the fully human anti-TNF antibody does not alter the favorable biophysical properties of the antibody. Furthermore, data from preclinical development confirm the overall IgG-like expression profiles of bispecific FynomAbs. Through its unique mode-of-action of inhibiting simultaneously TNF and the IL-17A/A homodimer, COVA322 has game changing potential in the treatment of inflammatory diseases.

12:00 pm Next-Generation Bi-Specific Antibodies for Autoimmunity and Oncology

Tariq Ghayur, Ph.D., Senior Research Fellow, Global Biologics, Abbvie, USA
This presentation will provide a brief description of dual variable domain (DVD) – Ig within the context of various bi-specific formats, as well as the process which we have developed to select lead DVD-Ig candidates. Novel applications and therapeutic opportunities for bispecific antibodies will also be presented.

12:30 Networking Luncheon in the Exhibit Hall with Poster Viewing

ANALYTICAL CHARACTERIZATION & STABILITY

8:00 am Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Weiguo Dai, Ph.D., Scientific Director/Janssen Fellow, Johnson & Johnson, USA

FORMULATION AND STABILITY

9:00 Theory and Practice in Addressing Particulate and Aggregation Issues for Developing High Quality Therapeutic Protein Products

Unpublished Data

Li Shi, Ph.D., CEO, Shanghai Zerun Biotechnology, PR China
The biggest barrier for the acceptability of biological products is the lack of the world's confidence on the quality of current products made in China. China's goal of building up the world's confidence would be based on our achieving high quality and control of product dosage form and manufacturing process. This presentation will discuss how to address parts of the critical quality issues of protein-based biologics, the particulate and aggregation issues from both theoretic and practical points of view.

9:30 Parenteral Delivery of High-Dose Monoclonal Antibody: Challenges and Advances

Weiguo Dai, Ph.D., Scientific Director/Janssen Fellow, Johnson & Johnson, USA
There is an increasingly unmet need for the delivery of high-dose biologics. However, development of high concentration biologics formulations for subcutaneous or intramuscular route has always been a significant challenge. In recent years there has been great progress in the development of novel approaches to deliver high-dose biologics through subcutaneous route. The presentation will discuss the key challenges and approaches in this hot area. The presentation will focus on the latest advances in the development of formulation approaches and delivery devices and provide the case studies to discuss advantages and limitations of the approaches.

10:00 Sponsored Presentations *(Opportunities Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 The Role of Sub-Visible Particle Analysis in Biologics Development – What You Need to Know to Meet Current Regulatory Expectations and Why It Can Improve Your Chances for Successful Product Development

Case Study

Unpublished Data

Danny Chou, Pharm.D., Ph.D., MBA, Senior Research Scientist, Biologics, Gilead Sciences, USA
Despite the technical limitations of current particle detection technologies, it is generally agreed that the best strategy to ensure product quality and patient safety is to utilize complementary technologies in order to obtain the most complete information while allowing one to verify data obtained by orthogonal methods. The goal of this presentation is to share the latest advances using the complementary/orthogonal approach to sub-visible particle characterization and what you can do to be prepared for the future.

11:30 Linker Stability and Aggregation of Antibody-Drug Conjugates

Unpublished Data

Andrea Ji, Ph.D., Senior Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.
This talk will cover elucidation of degradation pathway of the antibody-drug conjugates (ADC) linker, and the impact of linker stability on the safety, efficacy and shelf life of ADC products. The aggregation propensity of ADC molecules will also be discussed along with the formulation mitigation strategies.

12:00 pm Maximizing the Stability of Therapeutic Proteins and Peptides Using Recombinant Human Albumin

Case Study

Unpublished Data

Mark Perkins, Ph.D., Product Manager, Application Development, Novozymes Biopharma UK Ltd., United Kingdom
The challenges of formulating a therapeutic protein are many, including a susceptibility to aggregation, oxidation, and surface adsorption. With these challenges in mind formulators are increasingly interested in technologies that can improve biotheraputic stabilization; in particular with difficult to stabilize molecules. Recombinant human albumin is a technology that can work with these candidates and in this presentation I will give examples of the application of this molecule to stabilize a variety of peptide and protein drugs.

12:30 Networking Luncheon in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION *All Conference Participants Welcome*

1:45 Chairperson's Opening Remarks
Li Shi, Ph.D., Shanghai Zerun Biotechnology, PR China

1:50 CHO Cell History and CHO Genetics & Genomics for Manufacturing – Insights, Questions, Opportunities
Florian M. Wurm, Ph.D., Professor, Biotechnology, Swiss Federal Institute of Technology Lausanne (EPFL) and Founder, CSO, ExcellGene SA, Switzerland
CHO cells have been used in culture for more than 50 years. Only "recently" from the 80s on they have become the most successful manufacturing technology for recombinant proteins. This talk will cover the earlier and later history of these cells, and will discuss their unique genetics, their phenotypical adaptability and the reasons for their overall popularity and productivity. In addition, the complexities of immortalized cells as production hosts will be discussed and opportunities and challenges to use genomics data for their improvement will be presented.


2:30 Evolution of ADC by Design - A Journey of Protein Medicinal Chemistry Using an Expended Genetic Code
Ho Sung Cho, Ph.D., CTO, Ambrx USA and Feng Tian, Ph.D., Director, EuCODE Technology and Head, Ambrx China
Technologies essential to ADC development have evolved - from polyclonal murine antibodies to fully human monoclonal antibodies; from non-specific conjugation toward site-specific conjugation. Ambrx is using its proprietary Protein Medicinal Chemistry™ platform to create novel site-specific combinations of antibody, linker, and drug, to optimize the therapeutic potential of ADCs. Furthermore, we are using an innovative business model - partnering with Zhejiang Medicines Co. and Wuxi - to develop our first clinical candidate in China. This presentation will provide a summary of our recent experiences.

FIRST PUBLIC ANNOUNCEMENT
3:10 Developing the First Fully Human mAb in China Using the OmniRat™ Transgenic Technology
Chris Chen, Ph.D., Senior Vice President and CTO, Biologics Services, Wuxi Apptec, PR China
Developing fully human mAbs using transgenic animals has emerged as a dominant technology for therapeutic monoclonal antibodies. However, this technology has not been applied for mAb discovery in China. By collaborating with Open Monoclonal Technology Inc, we have successfully developed the first fully human mAb using the OmniRat™ technology. This case study will highlight the entire mAb discovery process from antigen generation to identification of mAb candidate for cell line development. Technical challenges and lessons learned will be discussed.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

4:15 Breakout Discussions
Breakout discussions are facilitated, small-group discussions which encourage interactive participation leading to problem-solving and future collaborations around focused topics. Attendees will discuss novel technologies, complex challenges or exciting ideas ranging from protein & antibody research to scaling up and CMC issues. Each breakout discussion will be facilitated by a moderator with attendees from diverse disciplines sharing a common interest in a specific discussion topic.

Discussion topics include:

- Making Therapeutic Antibodies against Multispan Transmembrane Proteins
- Development of Novel Biotherapeutics
- Development of Engineered Protein Scaffolds
- Antibody Engineering to Make Effective ADCs
- Bispecific Constructs and Their Future Developments
- Collaboration between Biopharmaceutical Industries in China and Foreign Academic Scientists
- Cell-Free Production of Membrane Proteins and Other Difficult Targets
- New Expression Platforms for Manufacturing Cell Line Development
- Setting Up DAR Specifications for Clinical Production
- The Future of Biotherapeutic Stabilization: Protein Engineering or Formulation?
- Supply Chain Challenges
- ADC - CMC and Manufacturing Strategy
- Establishing Own Manufacturing Facilities vs CMOs – What is the Value Proposition?
- Minor Variant Characterization and Mass Spec Application in China's Biotech Industries

5:15 Close of Conference Day Two

To submit a discussion topic or to volunteer as a moderator, please contact **Mimi Langley** at **mlangley@healthtech.com**

OPTIMIZING PROTEIN EXPRESSION

8:30 Morning Coffee

8:50 Chairperson's Opening Remarks
Ning Gao, Senior Scientist, AstraZeneca R&D Boston, USA

PROTEIN EXPRESSION STRATEGIES

9:00 FEATURED PRESENTATION
From Gene to Protein: A Review of Strategies for the Production of Recombinant Proteins to Support Small Molecule Drug Discovery

Ian Hunt, Ph.D., Head, Protein Sciences (Cambridge), Center for Proteomic Chemistry, Novartis Institutes for Biomedical Sciences, USA

Case Study

This presentation will review some of the general strategies for the production of milligram quantities of protein which are fit for purpose (e.g. choice of expression systems, construct design, small-scale expression testing, large scale expression and purification, protein characterization). We will also explore the instrumentation to expedite identification of soluble proteins and will look at what are the challenges and trends facing protein sciences, utilizing case studies from various projects.

9:30 Dynamics of Protein Expression

Ning Gao, Senior Scientist, AstraZeneca R&D Boston, USA

Case Study

Recombinant technology has led to some revolutionary changes in protein production. Solubility and functionality are our primary goals, while speed and yield are critical factors in success. As many different affinity tags have been developed to simplify purification procedures, protein expression has been playing an important role during protein production process. Using a right expression system for our specific needs is crucial in drug discovery. I will give an overview of protein design, expression, purification and characterization with a few case studies of challenging proteins.

10:00 Sponsored Presentation
Speaker to be Announced

Sponsored by MaxCyte

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Modulation of Cell-Free Expression Conditions for the Production of High Quality Membrane Protein Samples: Case Studies of G-Protein Coupled Receptors and Mray Translocases
Frank Bernhard, Ph.D., Lab Head, Institute of Biophysical Chemistry, Goethe University Frankfurt, Germany

We will present systematic screening processes for the development of optimized and target specific membrane protein production conditions by implementing cell-free expression technologies as well as a variety of new hydrophobic environments. We present examples of the functional characterization of (i) human endothelin receptors known as key players in blood pressure regulation, of (ii) various MraY translocases, polytopic membrane integrated enzymes essential for bacterial cell wall biosynthesis, and of (iii) the crystallization of cell-free expressed membrane proteins as new approach for structure based drug design.

11:30 Protein Expression Optimization by Evolutionary Design of Experiments (eQbD)
Davide de Lucrezia, Ph.D., CEO, Explora Biotech SRL, Italy

Case Study

Unpublished Data

Heterologous protein expression requires the simultaneous optimization of several parameters. Current design of experiments methodologies do not allow to tackle high-dimensional problems and to tackle multiple objectives simultaneously. Latest innovation in evolutionary algorithm circumvent these limitations and provide effective solution to protein expression optimization. We will present the latest innovation in evolutionary algorithm to tackle multiobjective optimization of culture media and process variables for heterologous protein expression optimization.

12:00 pm High-Titer Cell Line Development

Weidong Jiang, Ph.D., CSO and Vice President, Henlius Biopharmaceuticals Inc., USA

Case Study

Using high expression vector systems, we developed a fast and efficient way to construct high-titer cell lines that are suitable for scale-up bioreactors. Starting from 96-well screening post-transfection to 24-deep well fed-batch shaker screening, which mimics closely to bioreactor conditions, we have generated more than 2-5 g/L yield in shake flasks for 5 antibody projects in a period of just over a year. A detailed case study will be presented for our cell line development.

12:30 Networking Luncheon in the Exibit Hall with Poster Viewing

QUALITY, SCALABILITY AND CMC STRATEGIES

8:30 Morning Coffee

8:50 Chairperson's Opening Remarks
Scott M. Wheelwright, Ph.D., Principal Consultant, Complya Asia Co., Ltd., PR China

SCALABILITY AND MANUFACTURING

9:00 FEATURED PRESENTATION
Boehringer Ingelheim Pioneers International Biopharmaceuticals' Move to China

Johannes Salzbrunn, Head, GMP Downstream/Fill & Finish, Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd., PR China

The unmet need for novel therapeutics is pushing the demand for capacities in high professional GMP production. Boehringer Ingelheim is expanding its global network of CHO derived production and makes use of highly interchangeable production formats to ensure a seamless transfer of skills and knowledge between the sites. Using disposable products makes the GMP production both versatile and easy to access. This talk will discuss the opportunities and challenges of building the BI's first cGMP manufacturing site in China.

9:30 CHO Processes for Manufacturing: High Yield, Robustness and Quality - Scale-Down and Up
Maria J. De Jesus, Ph.D., COO, ExcellGene SA, Switzerland

CHO cells continue to present challenges when trying to establish high yielding manufacturing processes. We have identified the most critical steps in the value chain from the DNA in a vector and the final manufacturing process. Innovative technologies, materials, procedures and bioreactors, all along this value chain, allow us to establish high yielding manufacturing cell culture processes in very short time and at cost far below the typical industry standard. The presentation will share some of the insights gained and discuss opportunities for further improvements.

10:00 Sponsored Presentations *(Opportunities Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

QUALITY AND COMPLIANCE

11:00 Challenges for Quality and Compliance in Asia

Scott M. Wheelwright, Ph.D., Principal Consultant, Complya Asia Co., Ltd., PR China

Case Study

Unpublished Data

What kind of challenges have companies located in Asia run into in manufacturing? In this discussion we look at various documented issues related to manufacturing compliance faced by companies around the world, with a focus on problems encountered in Asia.

11:30 Achieving Quality and Compliance Excellence in BioPharma Lifecycle
Michael Lee, Vice President, Operations, DesigneRx Pharmaceuticals, Inc.

Compliance coverage needs to include: materials system, equipment & facilities, production, laboratory, packaging & labeling and the quality system. Operation excellence can be achieved by an integrated team to look after: quality culture, maintain the state of control in operation, root cause investigations, product lifecycle management, process performance and capability management, making QC (reactive) and QA (preventive/proactive) as integrated partners, continual improvement and variability reduction.

12:00 pm A Perspective on US FDA Expectations of GMP in Early Development
Dan Klassen, BSc, President, Klassen Consulting, LLC & Associates, USA

It is generally understood that varying levels of GMP compliance are required in early development stages of the product lifecycle. It is not well understood what the expectations of Regulatory Authorities for varying levels of compliance are at the various stages. There are, in fact, expectations related to GMP concepts and regulations for all levels of early development, from the earliest R&D, to Preclinical safety, and all phases of Clinical development. This presentation will discuss the expectations of the US FDA including those of the regulatory submission CMC reviewers, inspectors, as well as the Agency in general, based on the experiences and opinion of the speaker.

12:30 Networking Luncheon in the Exhibit Hall with Poster Viewing

OPTIMIZING PROTEIN EXPRESSION

1:40 Chairperson's Remarks
Changlin Dou, Ph.D., CTO, Luye Biologics R&D, PR China

CELL LINE DEVELOPMENT & CELL CULTURE

1:45 FEATURED PRESENTATION
Integrating Cell Line Development, Upstream Processing and Downstream Processing to Efficiently Eliminate Product Related Impurities during Development of Complex Therapeutic Proteins
Ingo Gorr, Ph.D., Principal Scientist, Cell Culture Research, Large Molecule Research, Roche Diagnostics GmbH, Germany
In this presentation a fast but elegant strategy for cell line selection and development of a manufacturing process for a novel IL2-based immunocytokine for cancer therapy will be described. Here, only CLD, USP and DSP together are capable of reducing critical impurities. Intriguing strategies to achieve a high quality therapeutic protein in combination with accelerated timelines are highlighted.

2:15 A High-Throughput Automated Platform for the Development of Manufacturing Cell Lines
Shuangping Shi, Ph.D., Group Lead (Cell Line Development), BioProcess Development, Merck & Co., USA
The fast-growing biopharmaceutical industry demands speedy development of highly efficient and reliable production systems to meet the increasing requirement for drug supplies. We report here an integrated high-throughput and automated platform for development of manufacturing cell lines for the production of protein therapeutics. The combination of BD FACS Aria™ Cell Sorter, CloneSelect™ Imager, TECAN Freedom EVO™ liquid handling system and ambr™ microscale bioreactor system has enabled a high-throughput and more efficient cell line development process.

2:45 Sponsored Presentations *(Opportunities Available)*

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Improving Cell Line Stability Using Selective Pressures to Enhance Antibody Expression
Case Study
Changlin Dou, Ph.D., CTO, Luye Biologics R&D, PR China
Cell line generation and selection prior to process development is most crucial to ensure stable long-term expression of antibody in mammalian cell cultures. This talk will review some technologies utilized in cell line development and present a case study on how we solved a cell line stability problem at Luye Biologics.

4:15 Cell Culture Advances Enabling the Development of Platform Technologies for Biosimilar mAb Manufacturing
Rustom Mody, Ph.D., Senior Vice President and Head, R&D, Lupin Ltd., India
Advances have been made in cell culture technology which has enabled the development of platform technologies for manufacture and scale-up of monoclonal antibodies that can deliver high product titers over 5 g/L. However, significant challenges remain in controlling scale-up-associated-heterogeneity and biosimilarity. Some of the factors that can influence biosimilarity are quite complex and poorly understood. The talk focuses on risk-based approaches that can be used as platform technologies.

4:45 Improve Cell Culture Productivity by Hydrolysate Replacement
Case Study
H.Fai Poon, Ph.D., Director, Cell Culture, Hisun Pharmaceuticals, PR China
Currently, more than 75% of mAb production processes in China contain hydrolysate. While hydrolysate provides many benefits to mAb production (i.e. high titer, universality etc), it also increases the risk of inconsistant production processes. Here, we present a case study in which we replaced the hydrolysate in the basal medium of our production process. By such media optimization, we achieved higher productivity and more consistent product quality.

5:15 Close of Conference

QUALITY, SCALABILITY AND CMC STRATEGIES

1:40 Chairperson's Remarks
Marie M. Zhu, Ph.D., Director, Process Sciences, Technical Operations, Agensys Inc., an affiliate of Astellas Pharma, Inc., USA

CMC STRATEGIES

1:45 FEATURED PRESENTATION
CMC Strategies for Antibody-Drug Conjugates
Vaughn B. Himes, Ph.D., Executive Vice President, Process Sciences and Technical Operations, Seattle Genetics, USA
The first of this new generation of ADCs, ADCETRIS® (brentuximabvedotin), received accelerated approval by FDA in 2011, and a number of new agents are in clinical development. Due to the hybrid nature of ADCs, the supply chain can be complex. CMC strategies for developing manufacturing processes and product quality characterization will be discussed. Key factors in Seattle Genetics' selection of manufacturers for clinical and commercial production of ADCs, as well as future trends for ADC manufacturing will also be presented.

2:15 Antibody-Drug Conjugates: Challenges and Critical Considerations for Developing Early-Phase Clinical Manufacturing Processes
Case Study
Unpublished Data
Marie M. Zhu, Ph.D., Director, Process Sciences, Technical Operations, Agensys Inc., an affiliate of Astellas Pharma, Inc., USA
Developing a scalable and robust ADC process that generates ADC products with desired drug-to-antibody ratio and consistent product quality attributes is important for clinical manufacturing. We will share the challenges experienced during developing ADC processes. Further, through case studies, we will discuss critical aspects in ADC process development and will elucidate development strategies that resulted in successful process scale-up and tech transfer for ADC production.

2:45 Sponsored Presentations *(Opportunities Available)*

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Control Strategies for Antibody-Drug Conjugates Drug Product Manufacturing
Shan Jiang, Ph.D., Director, Formulation and Fill/Finish, Seattle Genetics, Inc., USA
Antibody-drug conjugates (ADCs) have unique attributes that pose challenges in the development and manufacturing. A control strategy for ADC drug product (DP)-related critical quality attributes (CQA) was developed based on the assessment of product quality attribute criticality and process capability. Appropriate and multiple levels of control assure these quality attributes can be consistently maintained by the DP manufacturing process.

4:15 QbD Considerations in Purification Process Development
Yiming Yang, Ph.D., Senior Scientist, Shire Pharmaceuticals, Inc., USA
Quality by Design (QbD) is a concept of building quality into the process and product in a systematic, science, and risk based manner. QbD principles were used in developing a late phase purification process to produce a therapeutic protein. Practical considerations for the QbD implementation were discussed. A case study is presented to better explain the QbD considerations and implementation. The case study described a design of experiment (DoE) study to define design space. Also, a process control strategy was developed to better control the process performance and product quality.

4:45 Designing Cross-Species Reactive Fast Follow-On Antibody Therapeutics to Shorten the Time from Discovery to IND Filing
Unpublished Data
Xueming Qian, Ph.D., Chairman and CEO, R&D, Mabspace Biosciences Co. Ltd., China
Developing IP protected fast follow-on antibodies against clinically validated targets should be a key focus for China. By employing a tolerance breaking technology we generated therapeutic neutralizing antibodies with cross-species reactivity for validated targets. This property provides strong IP protection due to their distinct epitope spaces and enables rapid preclinical evaluation in rodent / NHP for the candidate molecule. This approach shortens the timeline and lowers the cost from discovery to IND filing. Examples of this strategy will be discussed.

5:15 Close of Conference

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CONFERENCE SCHEDULE

Tuesday-Wednesday (April 1-2, 2014)
- Track 1: Protein & Antibody Engineering
- Track 2: Analytical Characterization & Stability

Wednesday-Thursday (April 2-3, 2014)
- Track 3: Optimizing Protein Expression
- Track 4: Quality, Scalability & CMC Strategies

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