CAMBRIDGE HEALTHTECH INSTITUTE'S 3RD ANNUAL

PEGS CHINA

Protein & Antibody Engineering and Development Summit

APRIL 5-7, 2016

GRAND HYATT SHANGHAI, PUDONG
SHANGHAI, CHINA

第三届中国蛋白与抗体工程及研发峰会

REGISTER BY
JANUARY 15
& SAVE **¥1000**

2016 CONFERENCE PROGRAMS:

- Protein & Antibody Engineering
  蛋白质与抗体工程
- Analytical Characterization of Biotherapeutics
  生物药物特性分析
- Next-Generation Cancer Biotherapeutics
  新一代肿瘤生物治疗
- Protein Aggregation & Stability
  蛋白质聚集和稳定性
- **Seminar:** Clinical and Regulatory Strategies for Domestic and Global IND and BLA Filings
  生物制品临床和监管战略

Keynote Speakers


Alain Beck, Ph.D., Senior Director, Antibody and ADC Physico-Chemistry, Centre d'Immunologie Pierre Fabre


Andrew Bradbury, MBBS, Ph.D., Research Scientist and Group Leader, Biosciences Division, Los Alamos National Laboratory


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


Paul W.H.I. Parren, Ph.D., Senior Vice President & Scientific Director, Genmab


Weikang Tao, Ph.D., Vice President & CEO, R&D Center, Jiangsu Henrui Medicine Co., Ltd.


Peter M. Tessier, Ph.D., Associate Professor, Chemical & Biological Engineering, Rensselaer Polytechnic Institute


Salvador Ventura, Ph.D., Professor, Biochemistry and Molecular Biology, Institute of Biotechnology and Biomedicine, University of Barcelona

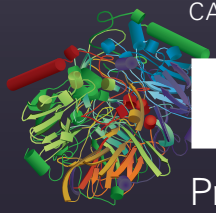

Herren Wu, Ph.D., Chief Technology Officer, MedImmune/AstraZeneca

Premier Sponsor
proteinsimple

Corporate Sponsor
Avacta LIFE SCIENCES

Organized by Cambridge Healthtech Institute

PEGSummitChina.com



CAMBRIDGE HEALTHTECH INSTITUTE'S 3RD ANNUAL

PEGS CHINA

Protein & Antibody Engineering and Development Summit

APRIL 5-7, 2016

GRAND HYATT SHANGHAI, PUDONG
SHANGHAI, CHINA

PEGS China: The Quintessential Protein & Antibody Engineering and Development Summit

Join your peers and leading players in the worldwide biopharmaceutical industry to develop and foster collaboration among international and domestic China companies and institutions.

Companies in China are increasingly being perceived as competitors and potential partners in novel biotherapeutics development. Local conglomerates are setting up biotherapeutic arms; multi-nationals are localizing research and development; innovative returnees are starting up new biotech ventures; and universities are spinning off novel ideas and training future generations in the protein sciences. All these are making China a fertile ground for the growth of novel biotherapeutics.

In its third year, "***PEGS China: Protein and Antibody Engineering & Development Summit***" returns to Shanghai for 3 days of inspiring presentations and case studies featuring the latest trends and future potential of China's biotech industry.

This year's event is comprised of four content-driven conferences with over sixty global speakers, plus a new seminar on clinical & regulatory strategies for global and domestic IND and BLA filings. In addition, dedicated exhibit hall and poster viewing hours will provide invaluable opportunities for networking, deal-making and ideas exchange.

- 3 Days, 4 Conferences, 1 Seminar
- 60+ Presentations from Industry Experts Featuring Case Studies and Unpublished Data
- 200+ Global Participants

Track 1:
Protein & Antibody Engineering
蛋白质与抗体工程

Features top researchers sharing their insight in the design and optimization of protein and antibody molecules, and discussing the cutting-edge technologies and creative approaches they used to overcome the challenges along the way.

Track 2:
Analytical Characterization of Biotherapeutics
生物药物特性分析

Showcases cutting-edge tools, techniques and approaches to evaluate structure-function relationships, determine physio-chemical properties and analyze higher order structures of novel biologics as well as biosimilars.

Track 3:
Next-Generation Cancer Biotherapeutics
新一代肿瘤生物治疗

Presents strategies to develop next-generation ADCs, bispecific and multi-specific antibodies, novel engineered antibodies with increased properties, as well as approaches to overcome the challenges in developing immunotherapy antibodies.

Track 4:
Protein Aggregation & Stability
蛋白质聚集和稳定性

Invites scientists to explore the mechanisms of aggregation, predict aggregation propensity, conduct stability studies, and compare tools for the characterization and quantification of these aggregates and particles.

Seminar: Clinical and Regulatory Strategies for Domestic and Global IND and BLA Filings
生物制品临床和监管战略

Explores opportunities and options for developing new products, and investigates strategies that have been used and that are available for successful international development.

CONFERENCE AT-A-GLANCE

Tuesday AM	**JOINT OPENING PLENARY** (T1 AND T2)	
Tuesday PM	**T1:** Protein & Antibody Engineering	**T2:** Analytical Characterization of Biotherapeutics
Wednesday AM		

Wednesday PM	**JOINT PLENARY SESSION** (T3 AND T4 AND SEMINAR)		
Thursday	**T3:** Next-Generation Cancer Biotherapeutics	**T4:** Protein Aggregation & Stability	**Seminar:** Clinical & Regulatory Challenges for Domestic and Global IND and BLA Filings

JOIN THE PEGS COMMUNITY ONLINE

SPONSORSHIP & EXHIBIT OPPORTUNITIES

AGENDA & BREAKFAST PRESENTATIONS

Showcase your solutions to a guaranteed, highly-targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, branding, registrations and use of the mailing list.

INVITATION-ONLY VIP DINNER/HOSPITALITY SUITE

Select your top prospects from the conference pre-registration list for an evening of networking at the hotel, or at a choice local venue. CHI will extend invitations, conduct follow-up and confirm attendees.

EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

OTHER OPPORTUNITIES INCLUDE:

- Conference Tote Bags
- Badge Lanyards
- Notebooks
- Literature Distribution
- Exhibit Hall Reception
- Networking Luncheon

LOOKING FOR ADDITIONAL WAYS TO DRIVE LEADS TO YOUR SALES TEAM?

CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Whitepapers
- Web Symposia
- Custom Market Research Surveys
- Podcasts

For sponsorship and exhibit information, please contact:

Companies A-K:

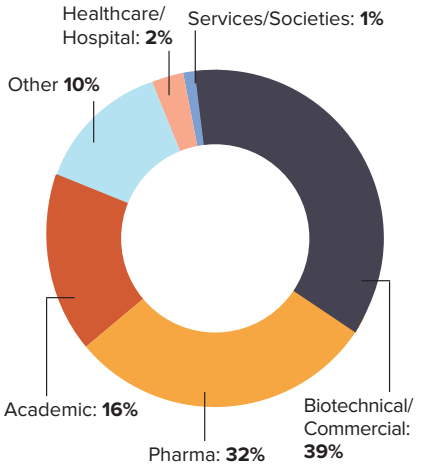
Jason Gerardi
Manager, Business Development
T: 781-972-5452
E: jgerardi@healthtech.com

Companies L-Z:

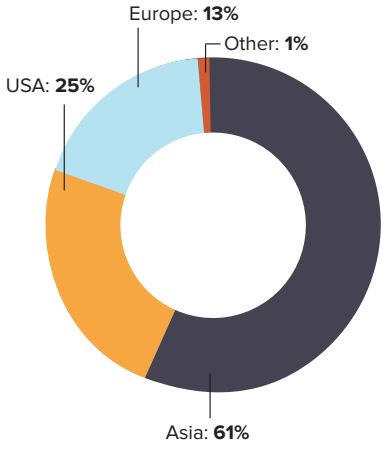
Carol Dinerstein
Director, Business Development
T: 781-972-5471
E: dinerstein@healthtech.com

2014-2015 ATTENDEE DEMOGRAPHICS

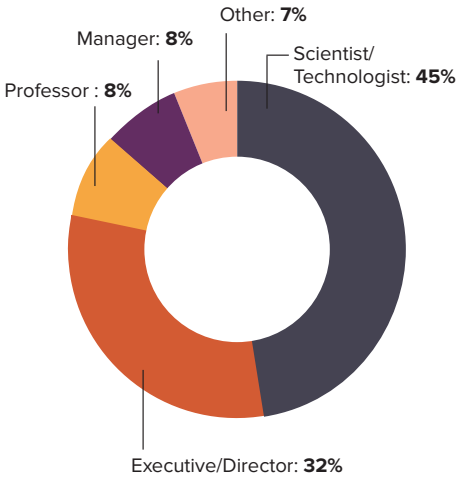
COMPANY TYPE



GEOGRAPHIC LOCATION



COMPANY TITLE



Premier Sponsor

proteinsimple

Corporate Sponsor

Avacta LIFE SCIENCES

GROUP DISCOUNTS: REGISTER 3 AND 4TH IS FREE!
Discount applies to attendees from the same organization registering for the same event. All registrations must be submitted together to qualify for the discount.

ALUMNI DISCOUNT - SAVE 20%:
CHI appreciates your participation at our events. 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.

TRACK 1:
PROTEIN & ANTIBODY ENGINEERING
蛋白质与抗体工程

TRACK 2:
ANALYTICAL CHARACTERIZATION OF BIOTHERAPEUTICS
生物药物特性分析

7:30 am Registration and Morning Coffee 注册和咖啡早茶

JOINT PLENARY SESSION

8:50 Chairperson's Opening Remarks 主席开幕词
Mitchell Ho, Ph.D., Chief, Antibody Therapy Section, National Cancer Institute, NIH

ND **9:00 Improved Methods for Designing and Evolving Antibodies** 抗体设计和进化的改良方法
Peter M. Tessier, Ph.D., Richard Baruch M.D. Career Development Associate Professor, Chemical & Biological Engineering, Rensselaer Polytechnic Institute

The biotech industry has seen an explosion in the development of therapeutic antibodies in the last decade. The advantages of antibodies are compelling. Nevertheless, there are many challenges associated with antibody selection and engineering that require key technical advances to simplify the rapid and reliable generation of potent antibody therapeutics. I will discuss our progress in addressing some of these challenges, including the design, evolution and selection of antibodies with high affinity, stability and solubility.

ND **9:30 Engineering Principles to Generate Multivalent Antibody-TRAIL Fusion Proteins** 多价抗体-TRAIL融合蛋白的制造工程原则
Roland Kontermann, Ph.D., Professor, Biomedical Engineering, Institute of Cell Biology and Immunology, University of Stuttgart

Fusion of TRAIL to antibody fragments has been shown to allow for a targeted delivery and the selective induction of tumor cell death. We have engineered optimized single-chain derivatives of TRAIL (scTRAIL), which were employed to develop novel multivalent antibody-scTRAIL fusion proteins with improved properties. These multivalent fusion proteins were generated employing either scFv-driven homodimerization or various separate homodimerization modules. Targeting and controlled dimerization of scTRAIL fusion proteins provides a strategy to enforce apoptosis induction, together with retained tumor selectivity and good *in vivo* tolerance.

10:00 Coffee Break 茶歇

10:30 Chairperson's Remarks
Mitchell Ho, Ph.D., Chief, Antibody Therapy Section, National Cancer Institute, NIH

RATIONAL DESIGN AND ENGINEERING

10:35 Design Principles for Bispecific IgGs – Opportunities and Pitfalls of Artificial Disulfide Bonds
双特异IgGs的设计原则-人工二硫键面临的机遇和困难
Itai Benhar, Ph.D., Professor, Molecular Microbiology and Biotechnology, Tel-Aviv University

We present a solution for correct pairing of heavy and light chains of bispecific IgGs, an engineered disulfide bond between the antibodies' variable domains that asymmetrically replaces the natural disulfide bond between CH1 and CL. Bispecific IgGs where the artificial disulfide bond is placed in the CH1-CL interface are also discussed. Examples will be provided for some of these bsAbs and future directions of the study will be discussed.

ND **11:05 Therapeutic Enzymes for the Treatment of Leukemia: Molecular Engineering and *in vitro* Evolution of L-Asparaginases**
血癌的治疗酶：分子工程和L-天冬酰胺酶的体外进化
Manfred Konrad, Ph.D., Research Director, Enzyme Biochemistry, Max Planck Institute for Biophysical Chemistry

L-asparaginases (L-ASNase) of bacterial origin are FDA-approved enzyme drugs for the treatment of acute lymphoblastic leukemia, despite eliciting adverse side effects, in particular immunogenicity. This talk highlights the rational design and molecular engineering of human homologues to replace bacterial enzymes. We developed a high-throughput screening platform to identify enzyme variants displaying improved catalytic activities, and packaged L-ASNases into microcapsules to enhance protein stability and prevent exposure to the immune system.

11:35 Expression, Structural and Functional Studies of the Human Cannabinoid Receptor CB2
人体大麻素受体CB2的表达、结构和功能研究
Alexei Yeliseev, Ph.D., Staff Scientist, Group Leader, LMBB, NIH/ NIAAA

Human cannabinoid receptor CB2 is an important target for pharmaceutical drug development. High resolution structural studies are necessary for rational design of specific ligands targeting this receptor. Furthermore, CB2 was site-specifically labeled by selectively targeting reactive cysteine residues and incorporation of unnatural functional groups through codon reassignment which allows preparation of receptor samples for various spectroscopic studies. Studies of the structural dynamics of CB2 bound to a variety of cannabinoid ligands, in detergent micelles and in lipid bilayers of various compositions are in progress.

12:05 Sponsored Presentation *(Opportunity Available)* 赞助商演讲(可选)

12:35 Networking Luncheon in the Exhibit Hall with Poster Viewing
海报展示/ 午餐

10:30 Chairperson's Remarks
Li Shi, Ph.D., CEO, Shanghai Zerun Biotechnology Co., Ltd

CHARACTERIZATION AND SELECTION OF COMPLEX BIOMOLECULES

ND **10:35 Analytical Characterization and Control Strategies for ADC** ADC的特性分析和控制策略
Heyi Li, Ph.D., Senior Principal Scientist and Group Leader, Biotherapeutics, Pfizer, Inc.

An antibody-drug conjugate (ADC) is typically produced by chemically linking a small molecule cytotoxin (drug) with a cancer-specific monoclonal antibody. This presentation provides an overview of control strategies and analytical and biochemical characterizations for ADCs. The talk will briefly discuss the critical quality attributes (CQAs), analytical control strategies, and provide examples of characterizations of ADCs from two common conjugation chemistries (Lysine and Cysteine). The characterizations include drug-antibody ratio (DAR), drug distribution, purity/impurity and potency.

11:05 Bio-Conjugation Approaches to Generate Bispecific Antibodies
制造双特异抗体的偶联方法
Julie Q. Hang, Ph.D., Senior Scientist, Protein Chemistry, Genentech, Inc.

Various forms of bispecific antibodies are generated by the expression of engineered antibodies or antibody fragments. Bio-conjugation of two bispecific Fab arms provided an efficient approach to produce a stable bispecific molecule, which carries the similar conformation and biological activities as the native F(ab')2. We also developed an orthogonal bio-conjugation approach to produce bispecific molecules through copper-less clicking reactions. Generation of multivalent bispecific molecules was also explored in bio-conjugation.

11:35 An Integrated Approach to Candidate Selection during Biologics Drug Development 生物制药过程中的候选株甄选综合方法
Steffen Hartmann, Ph.D., Global Head, Integrated Biologics Profiling, Novartis Pharma AG

The presentation will provide an overview of our integrated biologics profiling process at Novartis Biologics. The right state-of-the-art cell line development is combined with developability assessment encompassing a variety of methods from *in silico* tools to identify sequence liabilities to high throughput expression and biophysical profiling to '*in vivo* fitness' assessment as well as formulation assessment and *in vitro* tools for assessing immunogenicity risks. This enables the organization to select the best biologics candidate for each project for further development.

12:05 Sponsored Presentation *(Opportunity Available)*
赞助商演讲(可选)

12:35 Networking Luncheon in the Exhibit Hall with Poster Viewing
海报展示/午餐

TRACK 1:
PROTEIN & ANTIBODY ENGINEERING
蛋白质与抗体工程

1:55 Chairperson's Remarks
Yu Zhou, Ph.D., Associate Adjunct Professor, Anesthesia, University of California, San Francisco

DEVELOPABILITY AND OPTIMIZATION

CS **2:00 Glycooptimization of Antibodies Results in Improved Clinical Efficiency** 改良临床效率的抗体结果的糖多肽优化
Lars Stoeckl, Ph.D., Associate Director, R&D, Glycotope GmbH

Glycosylation is one of the major post-translational modifications of biotherapeutics that depends on the cell line used for production. We have generated a set of glyco engineered human cell lines for the high yield production of fully human glycooptimized antibodies. Two Biobetter antibodies directed against approved targets and glycooptimized with respect to manifold improvement of anti-cancer activity, half-life elongation, removal of immunogenic components are in clinical development. Case studies including results from clinical Phase I studies will be presented.

2:30 Rational Strategy to Stabilize Early Stage Biologic Candidates to Enhance Developability and Enable Successful Transfer from Research into Development
稳定早期生物候选株的理性策略，来提高可展性，并将研究成功转化成制药
Danny K. Chou, PharmD., Ph.D., President, Compassion BioSolution

The goal of this presentation is to describe a platform approach to identifying the optimal solution conditions that can stabilize biologics candidates in the discovery/candidate selection stage in a high throughput fashion, whereby, using a very limited amount of protein and commonly available equipment, the development team can assist the drug discovery team in candidate selection and re-engineering of molecules prior to transition into full-scale development.

CS **3:00 Viscosity Modulation of Antibodies by Design**
通过设计来进行抗体的粘度调节
Satish D. Singh, Ph.D., Research Advisor, Biotherapeutics Pharmaceutical Sciences, Pfizer, Inc.

Proactively eliminating or mitigating development challenges can reduce the time and resources required for taking a molecule from discovery to clinic. A common development challenge for mAbs is high viscosity of their concentrated solutions. Viscosity in solution depends on intermolecular (self-) interactions, which are determined by the sequence and structural properties. Understanding the molecular origins of these interactions can help to select or design mAb candidates with low viscosity.

3:30 Sponsored Presentation *(Opportunity Available)* 赞助商演讲(可选)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing
茶歇 / 海报展示

NEW AND EMERGING TARGETS

ND **4:40 Gypican-3 as a Liver Cancer Target for Antibody-Based Therapies** Gypican-3用作抗体疗法的肝癌靶
Mitchell Ho, Ph.D., Chief, Antibody Therapy Section, National Cancer Institute, NIH

Glypican-3 (GPC3) is expressed in hepatocellular carcinoma. Our lab has developed human monoclonal antibodies therapeutically targeting GPC3 that inhibit Wnt/Yap signaling pathways known to be important for liver cancer pathogenesis. Furthermore, we have demonstrated that a GPC3-targeted immunotoxin can cause regression of human liver cancer xenografts in mice. Its mechanism of action appears to involve both inhibition of cancer signaling (Wnt/Yap) and reduction in protein synthesis.

5:10 Targeting the Intracellular Proteome with Antibodies against Peptide/MHC Complexes Presented on the Cell Surface: Making the Intracellular Targets Visible to Antibody Therapy
细胞内靶向蛋白质组在细胞表面抗 Peptide/MHC 复合体的抗体：实现细胞内的抗体靶向治疗
Yoram Reiter, Ph.D., Professor and Head, Molecular Immunology, Biology, Technion-Israel Institute of Technology

The ability to generate T-cell receptor-like (TCRL) antibodies which bind HLA-peptide complexes on the surface of cells opens new possibilities for developing new therapeutic modalities. These antibodies can bind specifically to, and kill, the diseased cells, transforming disease-specific targets expressed inside malignant cells into targets that can be recognized on the cell surface by soluble TCRL antibodies. This approach expands the pool of novel therapeutic antibodies beyond the limits of currently available antibodies.

5:40 Welcome Reception in the Exhibit Hall with Poster Viewing 晚宴

6:40 Close of Day

TRACK 2:
ANALYTICAL CHARACTERIZATION OF BIOTHERAPEUTICS
生物药物特性分析

1:55 Chairperson's Remarks
Heyi Li, Ph.D., Senior Principal Scientist and Group Leader, Biotherapeutics, Pfizer, Inc.

EVALUATING STRUCTURE-FUNCTION RELATIONSHIPS

» **2:00 KEYNOTE PRESENTATION: CUTTING-EDGE MASS SPECTROMETRY METHODS FOR ANTIBODY, BIOSIMILAR, BISPECIFIC AND ANTIBODY-DRUG CONJUGATES STRUCTURAL ASSESSMENT**
主题演讲：抗体的尖端质谱法，双特异性生物仿制和抗体药物共轭结构的评估

CS ND *Alain Beck, Ph.D., Senior Director, Antibody and ADC Physico-Chemistry, Centre d'Immunologie Pierre Fabre, France*

A plethora of new mass spectrometry (MS) methods are used for antibody structural characterization and for biosimilarity assessment. In addition, these techniques are used to design and optimize more sophisticated and potent antibody derivatives such as ADCs (OptimADCs), bi- and multispecific antibodies, and controlled mixture of antibodies. Case studies based on state-of-the art MS methods such as Native and Ion-Mobility MS, Top-Down Sequencing, Proteomics and Sheathless Capillary Electrophoresis–Tandem MS will be presented and discussed.

2:30 Protein Bioanalytical and Biophysical Characterization and Comparability 蛋白的生物分析和生物物理表征和可比性
Li Shi, Ph.D., CEO, Shanghai Zerun Biotechnology Co., Ltd

With the latest advances in analytical technologies, most biological products can now be extensively characterized in terms of their identity, heterogeneity and impurity profile. The currently available biophysical and bioanalytical methods can characterize the primary, secondary and to some extent, the higher order structure of proteins. This session will discuss how to assess comparability of and process consistence of protein products using biophysical and bioanalytical characterization technologies.

3:00 Be Dynamic: How Physico-Chemical Techniques are Moving Forward to Meet Challenges in Biotherapeutics Characterization
不断前行：物理化学技术怎样前进迎接生物治疗药物特性的挑战
Luisa Iozzino, Ph.D., Associate Researcher, Protein Chemistry, Merck Serono S.p.A.

Biotherapeutics need in-depth characterization to be entirely understood. In particular, a better comprehension of higher-order structure will lead to safer and more effective biopharmaceutical products. Traditional spectroscopic techniques can be very useful for product characterization in a "dynamic mode". Case studies in which dynamic aspects on the structure of the product have been evaluated will be presented.

3:30 Sponsored Presentation *(Opportunity Available)* 赞助商演讲(可选)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing
茶歇 / 海报展示

BEST PRACTICES IN PROTEIN ANALYTICS

4:40 USP Analytical Methods and Approaches for Biologics
生物制剂的USP分析方法和途径
Jeff Zhu, Ph.D., Senior Director, Biologics and Biotechnology, USP-China

USP's USP-NF contains General Chapters and monographs that support the quality, safety, and potency of drug substances and products. This talk will explain the strategies used to prepare suitable monographs for biologics from multiple manufacturers and also highlight new test Chapters containing validated methods appropriate for many recombinant therapeutic products.

ND **5:10 Analytical Sciences: Eyes and Ears of Protein Therapeutics**
分析科学：眼睛和耳朵的蛋白疗法
Ziyang Zhong, Ph.D., Vice President, Product Development, Henlius Biotech Co. Ltd.

Analytical sciences is an integral part of drug R&D. It provides structural and biological evidences to the progress of any project. Several examples will be given to illustrate the important roles that AS played in protein therapeutics discovery and development. These range from analysis of binding kinetics, glycan profile, to amino acid sequence confirmation. Common techniques used in protein analytics, including LC/MS, SPR, and flow cytometry, will be discussed.

5:40 Welcome Reception in the Exhibit Hall with Poster Viewing 晚宴

6:40 Close of Day

TRACK 1:
PROTEIN & ANTIBODY ENGINEERING
蛋白质与抗体工程

8:30 am Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Herren Wu, Ph.D., CTO, MedImmune/AstraZeneca

ANTIBODY DISCOVERY AND LIBRARY GENERATION

» 9:00 KEYNOTE PRESENTATION: AT THE CROSSROADS: GETTING TO REPRODUCIBLE RESEARCH ANTIBODIES
主题演讲：站在十字路口：如何获得可重复研究的抗体

Andrew Bradbury, MBBS, Ph.D., Research Scientist and Group Leader, Biosciences Division, Los Alamos National Laboratory

Researchers all over the world routinely use antibodies, a critical class of commercially supplied reagents that are frequently unreliable. This situation affects reproducibility in biomedical research, wastes millions of dollars annually, and may affect clinical trials. This talk will provide an overview of the problem, argue that the time has come to express antibodies recombinantly and refer to them by their sequences, and provide possible ways to get to this ideal.

9:30 Therapeutic Antibody Discovery Using Multiple Tools
治疗性抗体发现使用多种工具
Yan Wu, Ph.D., Associate Director and Principal Scientist, Department of Antibody Engineering, Genentech, Inc.

10:00 Sponsored Presentation *(Opportunity Available)* 赞助商演讲 （可选）

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

11:10 Antibody Isotopes Diversity and Their Biomedical Potentials
抗体同位素的多样性及其生物医学潜力
Xiaoying Zhang, Ph.D., Professor, College of Veterinary Medicine, Northwest A&F University

Antibodies from different species (eg.: IgY, VHH, Bovine IgG, rabbit IgG, Lamprey—VLR) have different biological characters, and these may lead to special medicinal values. It is necessary to study, understand and utilize the antibodies from different species based on their unique advantages/characteristics. Such knowledge is becoming important source for antibody design, antibody engineering and antibody mimics.

11:40 Nature-Inspired Synthetic Human Ab Library
自然优化的人类合成抗体库
Yu Zhou, Ph.D., Associate Adjunct Professor, Anesthesia, University of California, San Francisco

Naïve human antibody CDR sequences were collated and used to design non-redundant synthetic CDRs matching the naturally occurring diversities. These synthetic non-redundant CDRs were inserted into the well expressing V-gene frameworks, and displayed to construct phage Ab library. Such phage Ab library was used to isolate high quality renewable antibodies (rAbs), which are essential reagents for determining how proteins function under normal and pathophysiological conditions.

12:10 pm Antibody Library Display on a Mammalian Virus: Combining the Advantages of Panning and Cell Sorting in One Technology
一个哺乳动物病毒抗体库的显示：平移和细胞分选优势结合的一种技术
Ernest S. Smith, Ph.D., Senior Vice President, Research & CSO, Vaccinex, Inc.

We have developed a new antibody selection technology that enables efficient expression of a library of human antibodies in full length IgG format on the surface of vaccinia virus, an enveloped mammalian virus. Various panning and magnetic bead based methods have been developed to screen the library of vaccinia-MAb virions and select recombinant vaccinia virus encoding specific antibodies. This technology ensures the selected antibodies are efficiently expressed and have favorable stability and specificity properties.

12:40 Networking Luncheon in the Exhibit Hall with Poster Viewing
午餐/ 海报展示

2:00 Close of Protein & Antibody Engineering
走进蛋白＆抗体工程

TRACK 2:
ANALYTICAL CHARACTERIZATION OF BIOTHERAPEUTICS
生物药物特性分析

8:30 am Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Joe Zhou, Ph.D., CEO, Genor BioPharma

ADVANCED METHODS AND APPROACHES IN BIOTHERAPEUTICS CHARACTERIZATION

9:00 Subvisible Protein Particles Mass Calculation with Improved Accuracy Using Microflow Imaging (MFI)
使用微流显微成像（MFI）技术提高显微蛋白颗粒质量计算精确性
Joy Zhou, Ph.D., Principal Scientist & Associate Director, Drug Product, Manufacturing Science & Technology, Shire Pharmaceuticals

Formation of subvisible particles (1–100 µm) is a major stability concern with protein therapeutics. However, particle numbers are often too low to permit for direct experimental protein content (mass) measurement. A novel, accurate, and easy-to-implement method using MFI was developed to calculate the mass of subvisible protein particles and testified with polystyrene standards and stressed mAb. This method improves estimations of protein particle mass and facilitates a better understanding of protein particle formation.

9:30 Use of Bio-Layer Interferometry (BLI)-Based Octet Platform for Biotherapeutic Drug Discovery & Development
生物膜层表面干涉技术（BLI）-基于八位位组平台在生物治疗药物的发现和研发中的应用
Vishal Kamat, Ph.D., Scientist, Biomolecular HTS Center, Therapeutic Proteins, Regeneron

10:00 Sponsored Presentation *(Opportunity Available)* 赞助商演讲 （可选）

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

COMPARABILITY AND BIOSIMILARITY ANALYSIS

11:10 Case Study of Genor BioPharma: Development and Commercialization Strategy of Therapeutic mAb in China
Genor biopharma案例研究：在中国治疗用mAb的研发和商业化战略
Joe Zhou, Ph.D., CEO, Genor BioPharma

Since 2009, Genor BioPharma has generated and tested working strategy of how to build up mAb pipeline of follow-on biologics/NME based on our sciences/technology in upstream, downstream and quality system. In this presentation, we demonstrate the positive future outlook of our current strategy using several mimic case studies such as CTA approval for GB221; comparability study approach with originators products; government funds obtained for GB221 and GB222; as well as our recent FOB commercialization through a Korea company.

11:40 Current Development in Analytical Tools and Approaches for Characterizing Biopharmaceuticals for Comparability and Implications for Biosimilars
当前开发的分析工具和方法对生物治疗药物和生物仿制药相似性的影响
Kate Zhang, Ph.D., Senior Director, Biopharmaceutical Development, Sanofi

With the continuing progress of analytical tools, the analytical assay could generate overwhelming amount of the data. A well-designed analytical strategy is essential to ensure the success of a comparability study which addresses the critical physical and chemical characteristics of bio-therapeutics.

12:10 pm Biosimilar mAb Higher Order Structure Comparability Analysis with Luminex Beads-Based Protein Conformational Array
生物仿制单克隆抗体高阶结构的相似性分析基于发光珠蛋白构象数组
Xing Wang, Ph.D., President, Array Bridge, Inc.

Biologics Higher Order Structure (HOS) is important to its safety and efficacy but difficult to define. A novel technology is developed using antibody arrays to analyze monoclonal antibody HOS, recently the technology has been adapted to the Luminex-based platform with much improved automation and throughput. Case studies will be presented to demonstrate the application of the Luminex-based antibody array in biosimilar as well as novel mAb development.

12:40 Networking Luncheon in the Exhibit Hall with Poster Viewing
午餐 / 海报展示

2:00 Close of Analytical Characterization of Biotherapeutics
走进生物治疗药物的特性分析

"This conference is very successful, in my opinion, for it not only invites the top scientists in the field of therapeutic antibody, but also this event gives a chance for local companies to present their scientific achievements. I enjoyed the talks very much. Thank you again for the organization."
…Senior Scientist, Roche R&D China Ltd

"Congratulations on a successful PEGS China meeting. I really enjoyed the conference and interactions with the attendees."
…Senior Scientist and Group Leader, Genentech, USA

"Thanks again for such a great PEGS China in Shanghai. I really enjoyed attending this very well organized conference! A job well done!"
…Director, High Throughput Biochemistry Lab, University of Zurich, Switzerland

"I really enjoyed the conference and made some great contacts."
…Associate Professor, Chemical Engineering, University of Queensland, Australia

TRACK 3:
NEXT-GENERATION CANCER BIOTHERAPEUTICS
新一代肿瘤生物治疗

TRACK 4:
PROTEIN AGGREGATION & STABILITY
蛋白质聚集和稳定性

1:00 pm Registration

JOINT PLENARY SESSION

THE PROMISE OF NOVEL CANCER BIOTHERAPEUTICS

2:00 Chairperson's Opening Remarks
Daotian Fu, Ph.D., General Manager, Livzon MabPharm

2:05 Developing Antibody-Drug Conjugates for the Treatment of Solid Cancers 抗体偶联药物治疗实体肿瘤的进展
Paul W.H.I. Parren, Ph.D., Senior Vice President & Scientific Director, Genmab
Therapeutic antibodies have revolutionized the treatment of cancer. However, many patients still fail to respond or become resistant to targeted treatment and novel innovative approaches to improve therapy are therefore required. Chemical engineering of antibodies, fueled by recent molecular insights, is providing important opportunities for the development of more potent antibody therapeutics. The progress in two antibody-drug conjugate programs from Genmab's portfolio will be highlighted.

2:35 Engineering the Next-Generation Antibody-Drug Conjugates for Cancer Therapy 用于癌症治疗的新一代抗体偶联药物
Herren Wu, Ph.D., CTO, MedImmune/AstraZeneca
Linking of highly potent cytotoxic warheads to tumor-targeting antibodies has the potential to attack tumors with missile-like precision and avoid toxicity to normal tissues. However, clinical observations indicate that the therapeutic window of most antibody-drug conjugates (ADCs) remains narrow. I will discuss our efforts in developing next-generation ADC technology which seeks to address the short-comings observed with current ADCs and help realize the full potential of this drug class to provide new breakthrough agents for the treatment of cancer.

3:05 Cancer Immunotherapy: Delivering the Promise 癌症免疫疗法：承诺的实现
Weikang Tao, Ph.D., Vice President & CEO, R&D Center, Jiangsu Henrui Medicine Co., Ltd.
Recent breakthroughs in treating different types of advanced-stage malignancies by harnessing self immunity against neoplastic cells showed a great promise of immunotherapy for cancer treatment. Various strategies have been employed to unleash, enhance or elicit anticancer immune reactions, which include T-cell checkpoint blockade, engineered T cells, BiTE, modified cytokines and cancer vaccines. This presentation will review recent progress in cancer immunotherapy and discuss some immunotherapeutic agents discovered and developed at HengRui Medicine Co., Ltd.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing 茶歇

CHALLENGES FOR NEW BIOLOGICS DEVELOPMENT IN CHINA

4:10 Update on Recent Regulatory Changes for Biologics Development in China 中国生物制剂研发的最新监管变化
Daotian Fu, Ph.D., General Manager, Livzon MabPharm
Over the past several years, the biotech industry in China has experienced tremendous growth, both in biosimilars and innovative biologics. In the meantime, the CFDA is also going through significant reforms with respect to guidance and the reviewing process for development of both biosimilars as well as innovative biologics. In this presentation, the author intends to provide an update on the recent development in CFDA's guidance for biologics development in China, and how the biotech industry can best position itself to take advantage of the recent regulatory changes.

4:40 PANEL DISCUSSION: Understanding the Clinical and Regulatory Pathways for New Biologics Development in China
小组讨论：了解中国生物制剂研发的临床和监管途径
Moderator: James Cai, Ph.D., Vice President, Global Regulatory Affairs, Access & Policy, Amgen Shanghai
Panelists:
Daotian Fu, Ph.D., General Manager, Livzon MabPharm
Weidong Jiang, Ph.D., CSO, Shanghai Henlius
Weikang Tao, Ph.D., Vice President & CEO, R&D Center, Jiangsu Henrui Medicine Co., Ltd.
Scott M. Wheelwright, Ph.D., CEO, Complya Asia

5:40 Close of Day

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 26, 2016.

Reasons you should present your research poster at this conference:

- Your poster will be showcased to our international delegation
- Receive ¥200 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

DEADLINE FOR POSTER SUBMISSION: **FEBRUARY 26, 2016**

TRACK 3:
NEXT-GENERATION CANCER BIOTHERAPEUTICS
新一代肿瘤生物治疗

8:30 am Morning Coffee

8:50 Chairperson's Opening Remarks
Ting Xu, Ph.D., CEO and President, AlphaMab Co.

IMMUNO-ONCOLOGY ANTIBODIES

ND **9:00 Challenges in Developing Immunotherapy Antibodies**
免疫抗体研发的挑战
Weidong Jiang, Ph.D., CSO, Shanghai Henlius
Cancer immunotherapy is the most exciting development for cancer treatment in recent years. Immuno checkpoints are the most popular targets for antibody drug development. We have developed anti-PD1 and anti-PD-L1 antibodies via different methodologies with success and failure. Both case studies will be presented to share our experience about how to obtain therapeutic antibodies from research to preclinical validation, including *in vitro* functional assays, *in vivo* animal model efficacy studies, and importance of affinity maturation for these antibodies.

9:30 Antibody-Cytokine Heterodimeric Fusion in Oncoimmunology - Efficacy, Characterization and Mode of Action
抗体细胞因子异二聚体融合技术在 Oncoimmunology 效能、特性和行动模式
Ting Xu, Ph.D., CEO and President, AlphaMab Co.
This presentation will examine strategies to booster immune status in non T-cell infiltrated tumor; cytokines for tumor immunotherapy and selection of right cytokines; as well as the design of heterodimeric antibody-cytokine fusion. Preclinical studies of two types of cytokines fusion, efficacy and mechanism will be presented.

Sponsored by Avacta LIFE SCIENCES

10:00 Cancer Biotherapeutics - Affimers: A Novel Scaffold for Biotherapeutics
治疗癌症生物药物的证实：生物治疗药物一种新型的基因支架
Amrik Basran, Ph.D., CSO, Therapeutics, Avacta Life Sciences
Affimers are a new protein scaffold with great potential for the generation of biotherapeutics. Based on the protease inhibitor Stefin A, large diverse libraries have been created by engineering in peptide loops into the scaffold backbone. Using phage display, we have identified competitive binders to a ranage of targets, including the immune check point, PD-L1. We have shown that the scaffold is amenable to being engineered with a range of half-life extension technologies, giving "IgG like" PK.

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

BISPECIFIC AND MULTI-SPECIFIC ANTIBODIES

11:00 COVA322: A Clinical-Stage Bispecific TNF/IL-17A Fynomab for the Treatment of Inflammatory Diseases
COVA322：一个临床阶段双特异性抗体TNF/IL-17A用于炎症疾病的治疗
Kristina Klupsch, Ph.D., Associate Director, Discovery Research, Covagen AG
Covagen develops bispecific FynomAbs by fusing its Fynomer binding proteins to antibodies resulting in therapeutics with novel modes of action and enhanced efficacy. FynomAbs have optimal physico-chemical and *in vivo* half-life properties, making them attractive as drug candidates. We will give an update about COVA322, a clinical-stage bispecific TNF/IL-17A inhibitor for the treatment of inflammatory diseases. In addition, FynomAbs with tailored anti-tumor effects will be presented.

11:30 Design of Multispecific Antibodies Modulating T-Cell Functions for Redirected Cytotoxicity 多特异性抗体设计调节T细胞的功能
Ji Jie Gu, Ph.D., Senior Principal Research Scientist, Global Biologics, AbbVie
With four DVD-Ig molecules currently in clinical development, we have furthered the DVD-Ig concept to the design of multispecific molecules to address additional unmet needs. In this presentation we will discuss: (1) improvement on DVD-Ig technology and beyond; (2) some basic structural and functional features of emerging multispecific molecules; and (3) how these molecules could be used to fine tune T cell functions for re-directed toxicity against tumor cells.

12:00 pm Bispecific Antibody Targeting of Nanomedicines for Cancer Therapy 用于癌症治疗的双特异性抗体纳米靶向药物
Christopher Howard, Ph.D., Senior Research Fellow, Australian Institute for Bioengineering and Nanotechnology, University of Queensland
A simple method to generate actively targeted nanomaterials using bispecific antibodies with dual specificity for nanomaterials and cancer targets such as Epidermal Growth Factor Receptor (EGFR) will be discussed. The design, expression, stability and target binding of the BsAbs will be outlined. The delivery of imaging agents and therapeutics to tumour sites using BsAb tethered nanomaterials will also be discussed.

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

TRACK 4:
PROTEIN AGGREGATION & STABILITY
蛋白质聚集和稳定性

8:30 am Morning Coffee

8:50 Chairperson's Opening Remarks
Danny K. Chou, Pharm.D., Ph.D., President, Compassion Biosolution

NEW FRONTIERS IN UNDERSTANDING PROTEIN AGGREGATION BEHAVIOR AND MECHANISMS OF ACTION

» 9:00 KEYNOTE PRESENTATION: DESIGNING PROTEIN SOLUBILITY 主题演讲：设计蛋白

Salvador Ventura, Ph.D., Professor, Biochemistry and Molecular Biology, Institute of Biotechnology and Biomedicine, University of Barcelona
One of the major challenges that one should face during the development of protein-based biopharmaceuticals is their inherent propensity to aggregate. Indeed, protein therapeutic agents are both stored and typically administered at very high concentrations. Under these conditions they can easily aggregate, impacting the product's developability, stability, formulation, and immunogenicity. I will discuss how computationally-assisted design of protein structures solubility is helping us to overcome these limitations.

9:30 Using *in silico* Tools to Predict the Propensities for Aggregation and for Viscosity 使用电脑模拟来预测聚集体的倾向
Bernhard Helk, Ph.D., Distinguished Fellow, Biologics Technical Development and Manufacturing, Novartis Pharma AG
Three *in silico* tools and their practical application to the prediction and characterization of protein-protein-interaction are demonstrated: SAP (Spatial Aggregation Propensity) identifies hydrophobic patches and is applied to engineer mAbs and ADCs with increased stability. DI (Developability Index) predicts aggregation propensities based on SAP and net charge. SCM (Spatial Charge Map) ranks mAbs according to viscosity. Case studies for predicting crystallization and viscosity of mAbs are presented.

10:00 Sponsored Presentation *(Opportunity Available)*
赞助商演讲（可选）

10:30 Coffee Break in the Exhibit Hall with Poster Viewing
茶歇 / 海报展示

11:00 Understanding Protein Aggregation – Opalescence, Turbidity and Particulates 了解蛋白聚集体-乳白光，混浊度和颗粒
Wei Wang, Ph.D., Senior Scientist, Global Biological Development, Bayer Healthcare
The large number of biological candidates in the pipeline demands an efficient product development process. However, many of these candidates are prone to aggregation. Depending on the aggregation pathways/mechanisms and/or extent, an aged solution of a biological product can possess different appearances - opalescence, turbidity, and/or presence of particles. This presentation discusses the similarities and differences of these appearances and the associated possible aggregation pathways/mechanisms.

11:30 Roles of Solution Composition on Protein Thermal Unfolding and Aggregation Kinetics
溶液组成对蛋白热致解折叠和聚集动力学的作用
Jifeng Zhang, Ph.D., Head, Drug Delivery and Device Development, MedImmune
Maintaining biophysical stability is an essential aspect in developing liquid formulation of therapeutic monoclonal antibody drug product. Solution conditions, e.g. pH, salt ion type and concentration, play important roles of determining antibody thermal stability and aggregation kinetics. In this presentation, the mechanistic pictures of protein-ion interactions and protein-protein interactions will be delineated to highlight their implications on thermal stability and aggregation kinetics.

12:00 pm Investigation of Product-Related Aggregation
与产品相关聚集的研究
Zhenyu Gu, Ph.D., Scientist III, Analytical Sciences, Alexion Pharmaceuticals
This presentation will examine the different methods for investigating protein aggregation and the potential root cause/mechanism for different aggregation.

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

TRACK 3:
NEXT-GENERATION CANCER BIOTHERAPEUTICS
新一代肿瘤生物治疗

1:45 Chairperson's Remarks
Weidong Jiang, Ph.D., CSO, Shanghai Henlius

EMERGING PLATFORMS FOR CANCER THERAPY

ND **1:50 Development of an Anti-HGF Antibody for Cancer Therapy**
Anti-HGF抗体治疗癌症的进展
Junho Chung, M.D., Ph.D., Professor, Biochemistry and Molecular Biology, Seoul National University

We developed an anti-HGF rabbit humanized antibody. In mouse xeno-graft models, this antibody effectively inhibited the growth of human glioblastoma, sarcoma and colorectal cancer cells. The pharmacokinetic property of the antibody was determined in primate and no drug-related toxicity was monitored. This antibody is now in phase I clinical trial (ClinicalTrials.gov Identifier: NCT02499224).

CS ND **2:20 Targeted Treatment of Cancer Using ADCs Containing Specifically Conjugated Prodrugs of Novel Cytotoxic Agents**
使用含有特异性的共轭前体药物的新型细胞毒性ADC药物靶向治疗癌症
Robert Y. Zhao, Ph.D., CEO and Chairman, Hangzhou DAC Biotech, Ltd.

This talk focuses on developing new generation ADCs using prodrug and specific conjugation methodology. Through the approaches of our proprietary prodrugs of novel cytotoxic agents, and novel specific linkages to the antibodies, our ADC drugs have shown much superior windows of antitumor activities both *in vitro* and *in vivo* than existing ADC drugs. This novel ADC platform would have broader applications in the treatment of cancer.

CS **2:50 A Novel Engineered VEGF Blocker with a Robust Anti-Tumor Activity** 一种具有强大的抗肿瘤活性的新型VEGF受体阻断剂
XiangYang Zhu, Ph.D., CEO, Huabo Biopharma (Shanghai) Co., Ltd.

A VEGF trap containing the second immunoglobulin-like domain of the VEGF tyrosine kinase receptor was fused to IgG1 Fc region, and a robust upstream and downstream process has been developed to assume enough materials for multiple clinical indications. Our results showed a strong anti-tumor activity in multiple animal models, indicated VEGF-Trap-mediated blockade may be superior to that achieved by other agents, such as monoclonal antibodies targeted against the VEGF receptor.

ND **3:20 GC1118, A Novel EGFR-Targeting Antibody, with a Distinct Binding Epitope and Efficacy**
GC1118，一种新型具有独特的结合表位和疗效的EGFR靶向受体
Jonghwa Won, Ph.D., Senior Research Director, Oncology Team, Green Cross Corp./Mogam Biotechnology Institute

Finding a differentiating factor is a key to position successfully into competitive, existing anti-cancer therapeutics. GC1118 has a distinct EGFR binding epitope and shows potent inhibitory activities on high-affinity EGFR ligands to which current antibodies have limited efficacy. Our study suggests that GC1118 would give prominent therapeutic effects on tumors refractory or resistant to current EGFR-targeting therapeutics. Potential hypothesis in working mechanism and clinical implications of GC1118 will be presented.

3:50 An Introduction to BoAn's Biologic Development Platforms
BoAn生物开发平台介绍
Changlin Dou, Ph.D., CTO & Senior Director, Antibody Technology Center, Luye Pharmacy Group

BoAn Biotechnology Com. is a wholly owned subsidiary of Luye group dedicated to biologic development. This talk will introduce BoAn's platform technologies in both new antibody drug discovery and biosimilar development.

4:20 Close of Conference

TRACK 4:
PROTEIN AGGREGATION & STABILITY
蛋白质聚集和稳定性

1:45 Chairperson's Remarks
Jifeng Zhang, Ph.D., Head, Drug Delivery and Device Development, MedImmune

AGGREGATION DURING PROCESSING AND FORMULATION

1:50 Investigating Mechanisms of Monoclonal Antibodies Particle Formation during Drug Product (DP) Processing
加工过程中单克隆抗体药物颗粒的形成机制的研究
Yuh-Fun Maa, Ph.D., Principal Engineer, Genentech, Inc.

Monoclonal antibody (mAb) particle formation observed during bottom mounted mixing and filling by piston pump was investigated to understand the root-cause mechanisms leading to protein degradation. The design of the mixer and the pump plays a critical role and any designs with contacting moving parts may grind the mAb molecules to immediately form particles. The impact of grinding on protein particle formation was assessed based on shear, local heat and cavitation.

2:20 Aggregation of Proteins during Bioprocessing: Mechanisms and Management Strategies 生物加工过程中蛋白质聚集：机制和管理策略
Danny K. Chou, Pharm.D., Ph.D., President, Compassion Biosolution

Protein aggregation is not only a challenge in the development of drug products, it is a significant barrier to cost-effective production of purified bulk drug substance. The goal of this presentation is to give some examples of how protein aggregation affects bioprocessing (e.g., purification including viral filtration), potential mechanisms, and how one may overcome this challenge.

CS ND **2:50 Detectability of Endotoxin Contaminations in Biologicals** 生物制剂中内毒素污染的检测能力
Johannes Reich, MSc, Ph.D. Student, Physical Chemistry, Universität Regensburg /Hyglos GmbH

In recent presentations and publications, the issue of Low Endotoxin Recovery (Endotoxin Masking) has been discussed. Thereby, formulated drug products often contain surfactants and buffer components in order to stabilize the active pharmaceutical ingredients (API). Interestingly, such components can affect the detectability of potential Endotoxin contaminations in common detection systems. Here, we show examples of masked Endotoxin in common product matrices and the applicability of dedicated demasking procedures.

3:20 Surfactants in Biotherapeutics: Impact, Analysis and Control
表面活性剂对生物治疗药物的影响分析和控制
Satish D. Singh, Ph.D., Research Fellow, Biotherapeutics Pharmaceutical Sciences, Pfizer, Inc.

Non-ionic surfactants in therapeutic protein formulations, added in small amounts, generally protect the protein from physical degradation at interfaces. The most popular surfactants are the polysorbates. The polysorbates can degrade by various mechanisms and the degradation products can also impact the stability of the protein. The importance of this excipient has led to a resurgence of interest in all questions related to their use in biotherapeutics, including analysis and control.

CS ND **3:50 Stability and Formulation Challenges for Biological Drug Products** 生物制剂产品稳定性和剂型的挑战。
Jun Xiang, Ph.D., Vice President, Pharmaceutical Science & Technology, Biotechnology Institute of Shanghai CP Guojian Pharmaceutical Co., Ltd.

Proteins and antibodies are "fragile" during processes, handling, storage, etc. A good formulation is critical for the stability of biological drug product to prevent any foreseeable or unforeseeable degradation. This presentation provides an overview of the possible challenges in the formulation development for biological drug products and will share some thoughts with case studies on overcoming these challenges to achieve a successful commercial launch of drug product.

4:20 Close of Conference

PEGS CHINA 2016 SCIENTIFIC ADVISORY BOARD

Danny Chou, Pharm.D., Ph.D., President, Compassion BioSolution, USA
Daotian Fu, Ph.D., General Manager, Livzon MabPharm, Inc., China
Weidong Jiang, Ph.D., CSO, Shanghai Henlius Biotech Co., Ltd., China
Wei Wang, Ph.D., Senior Scientist, Global Biological Development, Bayer Healthcare, USA
Jifeng Zhang, Ph.D., Head, Drug Delivery and Device Development, MedImmune, USA
Xiaoying Zhang, Ph.D., Professor, College of Veterinary Medicine, Northwest A&F University, China

Seminar: April 6-7, 2016

Clinical and Regulatory Strategies for Domestic and Global IND and BLA Filings

生物制品临床和监管战略

WEDNESDAY, APRIL 6, 2016

1:00 pm Registration

JOINT PLENARY SESSION

THE PROMISE OF NOVEL CANCER BIOTHERAPEUTICS

2:00 Chairperson's Opening Remarks
Daotian Fu, Ph.D., General Manager, Livzon MabPharm

2:05 Developing Antibody-Drug Conjugates for the Treatment of Solid Cancers 抗体偶联药物治疗实体肿瘤的进展
Prof. Paul W.H.I. Parren, Ph.D., Senior Vice President & Scientific Director, Genmab

Therapeutic antibodies have revolutionized the treatment of cancer. However, many patients still fail to respond or become resistant to targeted treatment and novel innovative approaches to improve therapy are therefore required. Chemical engineering of antibodies, fueled by recent molecular insights, is providing important opportunities for the development of more potent antibody therapeutics. The progress in two antibody-drug conjugate programs from Genmab's portfolio will be highlighted.

2:35 Engineering the Next-Generation Antibody-Drug Conjugates for Cancer Therapy 用于癌症治疗的新一代抗体偶联药物

Herren Wu, Ph.D., CTO, MedImmune/AstraZeneca

Linking of highly potent cytotoxic warheads to tumor-targeting antibodies has the potential to attack tumors with missile-like precision and avoid toxicity to normal tissues. However, clinical observations indicate that the therapeutic window of most antibody-drug conjugates (ADCs) remains narrow. I will discuss our efforts in developing next-generation ADC technology which seeks to address the short-comings observed with current ADCs and help realize the full potential of this drug class to provide new breakthrough agents for the treatment of cancer.

3:05 Cancer Immunotherapy: Delivering the Promise
癌症免疫疗法：承诺的实现

Weikang Tao, Ph.D., Vice President & CEO, R&D Center, Jiangsu Henrui Medicine Co., Ltd.

Recent breakthroughs in treating different types of advanced-stage malignancies by harnessing self immunity against neoplastic cells showed a great promise of immunotherapy for cancer treatment. Various strategies have been employed to unleash, enhance or elicit anticancer immune reactions, which include T-cell checkpoint blockade, engineered T cells, BiTE, modified cytokines and cancer vaccines. This presentation will review recent progress in cancer immunotherapy and discuss some immunotherapeutic agents discovered and developed at HengRui Medicine Co., Ltd.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

CHALLENGES FOR NEW BIOLOGICS DEVELOPMENT IN CHINA

4:10 Update on Recent Regulatory Changes for Biologics Development in China 中国生物制剂新制品的最新监管变化
Daotian Fu, Ph.D., General Manager, Livzon MabPharm

Over the past several years, the biotech industry in China has experienced tremendous growth, both in biosimilars and innovative biologics. In the meantime, the CFDA is also going through significant reforms with respect to guidance and the reviewing process for development of both biosimilars as well as innovative biologics. In this presentation, the author intends to provide an update on the recent development in CFDA's guidance for biologics development in China, and how the biotech industry can best position itself to take advantage of the recent regulatory changes.

4:40 PANEL DISCUSSION: Understanding the Clinical and Regulatory Pathways for New Biologics Development in China
小组讨论：了解中国新生物制剂研发的临床和监管途径

James Cai, Ph.D., Vice President, Global Regulatory Affairs, Access & Policy, Amgen Shanghai
Daotian Fu, Ph.D., General Manager, Livzon MabPharm
Weidong Jiang, Ph.D., CSO, Shanghai Henlius
Weikang Tao, Ph.D., Vice President & CEO, R&D Center, Jiangsu Henrui Medicine Co., Ltd.
Scott M. Wheelwright, Ph.D., CEO, Complya Asia

5:40 Close of Day

THURSDAY, APRIL 7, 2016

9:00 am - 4:30 pm

Clinical and Regulatory Strategies for Domestic and Global IND and BLA Filings

Instructor: Scott M. Wheelwright, Ph.D., CEO, Complya Asia

Drug development in China has progressed rapidly in recent years as novel therapies and biosimilars move forward in greater numbers each year. Companies are following multiple pathways to bring their products to patients in both domestic and foreign markets.

In this seminar we will discuss the opportunities and options for developing new products. In particular, we will investigate the options that have been used and that are available as we evaluate strategies for international development.

This course will cover the following topics:

- Why do we need a strategy?
- What does a development strategy include?
- What are our options for domestic regulatory approval (including novel drugs, biosimilars, and imports)?
- What foreign market development options are available (discussion on US, EU, Australia, South America, WHO and other options)?
- What is the common technical document (CTD) and how do we prepare it?
- What are our options for manufacturing and how do we evaluate and choose between them?
- What are the requirements for filing IND and NDA packages in foreign markets?
- Where do we go for help?
- How do we build and document our strategic plan?

At the conclusion of this seminar, active participants will understand:

- The options for drug development within China and internationally
- How to develop a coherent plan for drug development
- Basic requirements for preparation of regulatory applications
- How to prepare a "living" strategic plan that can be updated and adjusted to reflect company goals and to drive decision making

About the Instructor:

Scott M. Wheelwright, Ph.D., is an expert in developing drugs and bringing them to market in China and internationally. Dr. Wheelwright has lived in China for over five years where he has worked on numerous products under development. His previous US and international experience (he has also lived in India, Japan and Germany) includes bringing multiple drugs to market in multiple countries. He is the founder of Complya Asia, a consulting firm in China that works with Chinese firms to help them meet international standards for Quality Assurance and manufacturing. Dr. Wheelwright was one of the original founders of Innovent Biologics, a leading biosimilars company in China. Dr. Wheelwright received his Ph.D. from the University of California Berkeley and performed post-doctoral studies at the Max Planck Institute in Germany.