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# CELL LINE DEVELOPMENT & ENGINEERING ASIA

Advancing Asia's Capabilities in Quality Biopharma Development

21 – 23 February 2012 | Grand Hyatt Shanghai, China

## Academic Keynote Speaker:

### Prof Michael Betenbaugh

Professor and former Chair of Department,  
Chemical and Biomolecular Engineering,  
Johns Hopkins University, USA

## Industry Keynote Speaker:

### Dr Jianguo Yang

Principal Scientist,  
Genzyme / Sanofi Aventis, USA

## Why You Should Attend:

- Asia's **FIRST** and **ONLY** conference focused on **Cell Line Development and Engineering** from the leading company with established events in US and Europe
- Featuring case studies from biopharma, research institutes and biotechs to **review available technologies, products and suppliers and to discuss cost effective and quality process development**
- The most comprehensive event highlighting **key challenges in cell line development and engineering including** best practices, improving cell banking, optimising selection process and subsequent cell line development, IP and regulatory issues
- **Explore collaboration opportunities** with Asian biopharma and regional as well as global partners
- **Learn from international experts**, identify challenges and gaps in cell line development
- Review **regulations** from US, Europe and Asia

## PLUS! Expert Presentations from:



### Dr Lin Zhang

Associate Research Fellow,  
Pfizer, USA



### Dr Ralf Schumacher

Head of Biologics Research, Pharma  
Research and Early Development,  
Roche Diagnostics, Germany



### Dr Zhiwei Song

Senior Scientist,  
BTI A\*Star, Singapore



### Dr Cheng Liu

Chief Executive Officer,  
Eureka Therapeutics, USA



### Dr Chichang Lee

Executive Director,  
Sincere Pharmaceuticals, China



### Dr Steven Lee

Global Head of Biologics,  
Luye Pharmaceuticals, Singapore



### Dr Rustom Mody

Executive Vice President,  
Intas Biopharmaceuticals, India



### Dr Baoping Wang

Vice President and Head of R&D,  
Novo Nordisk, China



### Dr Weidong Jiang

CSO and Vice President,  
Henlix Biopharmaceuticals, USA



### Dr Yang Yuan Sheng

Research Scientist,  
BTI, A\*Star, Singapore



### Dr Feng Gao

Chief Operating Officer,  
AutekBio (Beijing), China



### Dr Noelle Sunstrom

Chief Executive Officer,  
Neuclone, Australia



### Dr Emmanuel Guerevitz

Chief Executive Officer,  
Amagino Biotechnology, Israel



### Dr Shun Luo

President,  
JS Biosciences, China



Post-conference Workshop: 23 February  
**Solutions for Asia Biologic Development**

## Key themes and issues include:

- Examining the Business and Regulatory Landscape
- Cell Line Development Approaches for Biosimilars
- Addressing Timeline Bottlenecks in Development
- Implementing Successful Cell Line Strategies
- Screening and Automation, Clone Selection, Expression and Cell Line Stability
- Optimizing Process Development

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8:30 **Registration and Morning Coffee**

8:50 **Chairperson's Opening Remarks**  
**Dr Jianguo Yang, Principal Scientist,**  
**Genzyme / Sanofi Aventis, USA**

### Keynote Sessions

9:00 **Overview on Advances and Challenges in Cell Line Development**

**KEYNOTE** Therapeutic protein/antibody products are mainly produced from mammalian cell lines. Production cell line is one of critical factors for productivity and quality during any therapeutic recombinant protein/antibody product development. Though various new technologies have been developed and applied during production cell line development, many challenges still remain. This presentation is an overview for the major challenges, including vector and host engineering, clone selection and cell line stability, cell banking, platform medium and process development, product quality assessment and their future trends.

**Dr Jianguo Yang, Principal Scientist,**  
**Genzyme / Sanofi Aventis, USA**

9:40 **Cell Lines Development for Antibody Production**

This session describes the challenges regarding the selection of production cell lines expressing therapeutic antibodies or antibody-derived complex molecules. Proper transfection, propagation, sub-cloning and further characterization of cells is as essential as scrutinizing the antibodies isolated from the respective supernatants in order to identify the most suitable monoclonal production cell line allowing stable expression of high titers and excellent antibody quality without sequence variances. Excellent growth and metabolic parameters and the fit between production cell line and medium are further key-prerequisites for maintenance of constant product quality and process consistency during up-scaling. Therefore, close monitoring of cell properties, fermentation parameters and product qualities are mandatory.

**Dr Ralf Schumacher, Head of Biologics Research, Pharma Research and Early Development, Roche Diagnostics, Germany**

10:10 **Keynote Panel Discussion: Cell Line and Antibody Development: Is China Ready to Compete and Lead?**

- PANEL**
- Is it all about biosimilars?
  - Opportunities and challenges
  - Regulatory concerns and updates

**Dr Baoping Wang, Vice President & Head, Novonordisk R&D, China**

**Dr Chichang Lee, Executive Director, Simcere Pharmaceuticals, China**

**Dr Steven Lee, Head of Global Biologics, Luye Pharma, Singapore**

**Dr Ralf Schumacher, Head of Biologics Research, Pharma Research and Early Development, Roche Diagnostics, Germany**

**Dr Jianguo Yang, Principal Scientist, Genzyme / Sanofi Aventis, USA**

10:50 **Morning Refreshments**

11:20 **Creating Value through Partnerships**

**Dr Steven Lee, Head of Global Biologics,**  
**Luye Pharma, Singapore**

### Cell Line Development Approaches for Biosimilars

11:50 **Biosimilars: A Once-in-a-lifetime Opportunity for Chinese Bio/Pharma**

In the developed markets, pharmas are facing serious challenges; high R&D cost, low productivity, complex and complicated marketing and reimbursement, fast approaching patent expiration amongst others. In developing markets such as China and India, these challenges can be great opportunities. Although China has become the world's 2nd biggest economy, very few Chinese companies can afford the R&D budgets of Big Pharma. Biosimilar have become a focal point recently, driven by increasing pressures from escalating healthcare costs. This presents potential to enter the biopharmaceutical business. What experiences and lessons can Chinese contenders learn from Euro-American biopharma? This session will outline the advantages and disadvantages that China already has to develop biosimilars. Strategies that China should adopt to develop a new national industry sector, biopharmaceuticals, will be presented.

**Dr Shun Luo, President, JS Biosciences, China**

12:20 **Engineering Mammalian Cells Using Dual Expression Cassettes for Expression of Biosimilar Monoclonal Antibody**

**Dr Rustom Mody, Executive Vice President,**  
**Intas Biopharmaceuticals, India**

12:50 **Optimization of Signal Peptides for the Expression of Recombinant Antibodies in CHO Cells**

**CASE STUDY**

The first step in the synthesis of a secretory protein involves the translocation of the nascent protein to the ER followed by crossing the membrane into the ER lumen. A hydrophobic peptide at the N-terminal of the protein is responsible for initiating this step. The heavy chain of human Ig usually has a 19-amino acid signal peptide while the human kappa light chain contains a 21-amino acid signal peptide. Eight heavy chain signal peptides and two light chain signal peptides have been compared for their impact on antibody secretion.

**Dr Zhiwei Song, Senior Scientist, Bioprocessing Technology Institute, A\*Star, Singapore**

13:20 **Networking Lunch**

### Addressing Timeline Bottlenecks in Development

14:30 **Reducing Time Lines of Cell Line Production**

Current expression systems and methods used to produce therapeutic mAbs in CHO cells will be discussed that improve expression, and shorten the process of developing and isolating high-producing cell lines. MAbs and biosimilars mAbs are often derived from a common framework allowing for the establishment of platform processes that can be used to develop multiple molecules with minimal process alterations. Achieving maximum production of these molecules under developmental time constraints is discussed through improved methods of selecting high-producers and methods for increasing production.

**Dr Noelle Sunstrom, Chief Executive Officer, Neulone, Australia**

15:00 **Cell-in-a-Box® Technology: Development of a Cell Based Product for Clinical Trials**

This session presents a technology which allows living cells to be encapsulated into bio-inert polymer beads. Cell-in-a-Box® and Bac-in-a-Box™ technologies allow both living eukaryotic and bacterial cells to be encapsulated in order to protect, store, isolate and transport them. We have developed a genetically modified cell line which was approved through the European Medicines Agency (EMA) for a phase III. Some of the applications include long term therapy for diabetes, cardiovascular disease, degenerative diseases, cancer etc.

**Dr Brian Salmons, Chief Executive Officer, SG Austria, Singapore**

15:30 **Afternoon Refreshments**

16:00 **Exploring Different Strategies of Production for Cell Line Development Between Biosimilar and New Biological Drug Development**

To successfully and rapidly launch the product to the market, different strategies of production cell line generation (CLG) and process determination (PD) are implied to meet different requirements between biosimilar and new drug development. In this presentation, the current available services of CLG and PD will be reviewed. Various development strategies will be explored and compared to meet different requirements between biosimilar and new drug development.

**Dr Feng Gao, Chief Operating Officer, AutekBio (Beijing), China**

### Implementing Successful Cell Line Strategies

16:30 **Accelerate and Streamline Biotherapeutic Development Using Cell Culture Platforms**

**CASE STUDY**

Development of biotherapeutics is a complex process including cell line development, process development scale up, preclinical and clinical studies. The speed, quality and cost of biologic development are the key measurements and success factors of a biopharmaceutical company or a biological program. Good platforms will support cell line and different processes as well as their transitions. Many factors such as scalability, quality measurements, success rate and cost/effort must be considered and optimized. Examples of different approaches and their results will be analyzed to give some principles and guideline on platform developments.

**Dr David Zhao, Chief Operating Officer, JS Biosciences, China**

17:00 **Vector design for enhancing generation of monoclonal antibody producing CHO cell lines**

**CASE STUDY**

Selection of high producers and maintenance of long term production stability are two major challenges for generation of cell lines expressing monoclonal antibodies (mAb). We have developed an optimized tricistronic vector and novel anti-silencing promoters to address these two challenges. The performance of our newly developed vector and promoters for generation of mAb producing CHO cell lines will be presented.

**Dr Yang Yuan Sheng, Scientist, Bioprocessing Technology Institute, A\*Star, Singapore**

17:30 **Chairperson's Remarks and End of Day One**

9:00 **Chairperson's Opening Remarks**  
**Prof Michael Betenbaugh**, Professor and former Chair of Department, Chemical and Biomolecular Engineering, Johns Hopkins University, USA

9:10 **Glycosylation and Genomics: Techniques and Technologies to Optimize Cell Line Development and Quality**  
Visit [www.cellineasia.com](http://www.cellineasia.com) for updates.  
**Prof Michael Betenbaugh**, Professor and former Chair of Department, Chemical and Biomolecular Engineering, Johns Hopkins University, USA

KEYNOTE

### Screening and Automation, Clone Selection, Expression and Cell Line Stability

9:50 **Screening Methods to Increase Prediction of Cell Line Behavior in Bioreactors**  
Visit [www.cellineasia.com](http://www.cellineasia.com) for updates.  
**Dr Weidong Jiang**, Chief Scientific Officer and Vice President, Henlix Biopharmaceuticals, USA

10:30 **Morning Refreshments**

11:00 **Technology Spotlight**  
This session is presents an opportunity for technology providers to showcase their expertise and how this can support the cell line development. For Inquiries, contact [Yvonne.leong@ibcasia.com.sg](mailto:Yvonne.leong@ibcasia.com.sg) / +65 6508 2489

11:30 **3D Cell Cultures in Serum Free Media Using Nanotubes Structures as Scaffold**  
The developments of Nano scale substance such as carbon nanotubes (CNTs) for medical applications allow us to think about solution to obtain cells and tissue in 3D. This presentation shows how CNTs combined in a 3D structure could be used as scaffolds for cell culture in a serum free-media to avoid artifacts. CNT scaffolds were formed on polycarbonate membranes by vacuum filtration and cell proliferation and morphology were investigated using a screening method based on direct analysis under photonic and electronic microscopy. Osteoblast cells, Chondroblast cells, Fibroblast cells on 3D CNTs showed excellent proliferation with extension of cell morphology in all directions and following the "grid" structure. These results suggest that CNTs can be used as scaffolds with excellent affinity for cell adhesion and becoming a valid 3D structure to imagine production of tissue in culture  
**Dr Emmanuel Guerevitz**, Chief Executive Officer, Amagino Biotechnology, Israel

12:10 **Networking Lunch**

13:30 **Title to be Advised**  
Visit [www.cellineasia.com](http://www.cellineasia.com) for updates.  
**Dr Lin Zhang**, Associate Research Fellow, Pfizer, USA



### Optimizing Process Development

14:10 **A Novel Technology for the Rapid Generation of Cell Lines with Superior Productivity Characteristics**  
Cloning of highly-secreting recombinant cell lines is critical for biopharmaceutical therapeutic protein manufacture, but faces numerous challenges – including the fact that the secreted protein does not remain associated with the producing cell. This problem is solved by a novel, automated and user-friendly technology for bioprocess development which incorporates improvements in instrumentation; no comparable methods allowed for incorporation of as wide a range of physiological parameters for cell selection. This process allowed several serial subcloning steps to be performed within days of one another, resulting in rapid generation of clonal populations with significantly increased and more stable homogeneous antibody secretion. CHO cell lines with specific antibody secretion rates of >80 pg/cell per day were routinely obtained using this cloning approach.  
**Dr Rodney E. Thompson**, Board of Directors, FJS Biopharmaceutical, USA

14:50 **Afternoon Refreshments**

15:20 **Technology Spotlight**  
This session is presents an opportunity for technology providers to showcase their expertise and how this can support the cell line development. For Inquiries, contact [Yvonne.leong@ibcasia.com.sg](mailto:Yvonne.leong@ibcasia.com.sg) / +65 6508 2489

15:50 **Cell Line Glycosylation Engineering for ADCC Enhancement of Therapeutic Antibody**  
ADCC (Antibody-Dependent Cell-mediated Cytotoxicity) is a major mechanism of action for therapeutic antibodies for treatment of cancer and autoimmune diseases. Enhancement of ADCC activity has the potential for improving antibody drug efficacy, lower dosing, and expansion of patient population. A novel approach has been developed through glycosylation engineering in mammalian cells (CHO) to produce antibodies with enhanced ADCC. The new technology generates a unique glycosylation pattern, which enables the engineered antibody to have favorable biophysical properties, such as increased binding affinity to its Fc receptor CD16, resulting in enhanced ADCC (10-100x fold). The engineered CHO cell line has been adapted to culture in serum-free and suspension conditions suitable for future scale-up culture under cGMP facility. This is a leading technology for development of next generation therapeutic antibodies with better efficacy at a lower cost.  
**Dr Cheng Liu**, Chief Executive Officer, Eureka Therapeutics, USA

16:30 **ROUNDTABLE DISCUSSIONS:**

- What can be done to push innovation in cell line development beyond the current boundaries? What are the drivers and barriers to further optimization?
- Strategies for implementing automated systems in cell line and antibody research
- What is the economic potential of therapeutic antibodies in the future and where should your next investment be?

17:30 **Closing Remarks & End of Conference**



This workshop will run from 09:00 – 12:30, with a mid morning refreshment break. Registration begins 30 minutes before the workshop commences.

## Solutions for Asia Biologic Development

### Background and Objectives:

Materials and technologies for cell culture, down-stream purification and biologic formulation become hurdles for Asian biologic development. Most of these products need to be imported. The objectives of the workshop are to present Asian (especially China) biologic development needs and supply situation; present current strategy and efforts in this area; describe the future supply chain and efforts of materials and technologies for Asia biologic development.

### Who Should Attend:

Senior management, scientists and supply chain management of Chinese and other Asian biologic and biopharmaceutical companies and institutes

### Brief Outline:

Tools and materials for biopharmaceuticals and biologics are critical for the efficiency, quality, speed and cost of biotherapeutics and vaccine development and manufacturing. For years, the majority of the tools and materials for Asian biologic development and manufacturing have been imported. The long supply time, lack of support and price presented hurdles for China and other Asian countries. We will present and discuss the future and plan for development and manufacturing of high quality materials and tools for biologics to meet international standards in Asia.

### Discussions will include:

- Vector design strategies
- Transfection method choice and transient expression
- Single cell cloning method
- High throughput technologies for clone selection
- Cell line stability vs. productivity
- Productivity vs. product quality
- Cell bank method

### About your Workshop Leaders:



**Dr. David (Xiaojian) Zhao**  
Chief Operating Officer, JS Biosciences China

Dr Zhao worked as director of R&D at EMD Chemicals, an affiliate of Merck KGaA and led cell culture development effort in Merck KGaA. He improved recombinant protein and vaccine production with new cell line development, media optimization and feeds using mammalian cell culture. He managed the cell culture product portfolio for annual multi-million dollar new product revenue of bioproduction business and launched over 10 products at Invitrogen where he evaluated and transferred many new technologies and developed the company's cell culture technology platforms.

Dr Zhao received a Ph.D. in Biochemistry from Colorado State University at Fort Collins of Colorado and postdoctoral training in molecular biology, protein chemistry and immunology at University of Colorado and the Blood Research Institute of Southeast Wisconsin. His research efforts were focused on genetics, immunology and protein structures.

He has over 15 year's industrial experience in cell culture, media development, process development, genomics, proteomics, bioinformatics, assay development, protein chemistry, enzymology, automation and instrumentation. He launched over 50 biotechnical products and published over 25 papers during his career and has 5 patents in assays, instruments and microarray area.



**Dr. Shun Luo**  
President, JS Biosciences, China

Dr. Shun Luo was formerly Scientific Director in Cell Science and Technology of Process and Product Development at Amgen. He is an expert in industrial scale mammalian cell culture media and process development. Previously, he was Group Leader for biotechnology pioneer Genentech and was R&D Head at JRH Biosciences in Lenexa, Kansas. He received his doctoral degree in Microbiology and Immunology from Virginia Tech after completing a master's degree in Biochemistry at Oregon State.

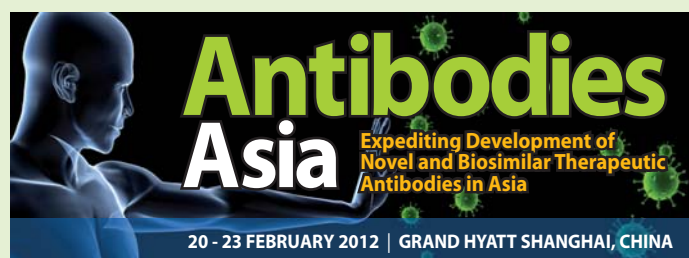
**Do you provide technology to support cell line development in Asia?**

**Limited Sponsorship & Exhibition Opportunities:**

- Showcase the latest in technology
- Meet senior decision makers in Asia, particularly in the fast-developing China market
- Position your brand as a market leader to stand out amidst the competition
- Generate leads, make new business and strengthen existing accounts

This is Asia's only dedicated Cell Line Development & Engineering event which brings you closer to the China market. For inquiries, [contact Yvonne.Leong@ibcasia.com.sg](mailto:contact.Yvonne.Leong@ibcasia.com.sg) / +65 6508 2489

### Co-located with:



The 4th Annual Antibodies Asia Summit 2012 is the region's premier conference on Antibodies Research & Development. Top scientists from pharma/biotech, universities and research institutes will convene in Shanghai to discuss the challenges, trends and collaboration opportunities in conducting Antibodies Research in Asia.

### Call for Poster Presentations:

Poster sessions offer a unique opportunity to have your scientific research projects displayed at this conference. **Submit your abstract.** You must be a confirmed attending delegate to qualify to present a poster. Submit abstract of 100 words or less, written in English to [elle.quan@ibcasia.com.sg](mailto:elle.quan@ibcasia.com.sg). Deadline for submission is 23 January 2012.

### Who should attend:

#### By Job Title

**Chief Executives, Scientists, Directors, General Managers and Heads of:**

- Antibody Research and Development
- Antibody Technology
- Immunology
- Cancer / Autoimmune Research
- Biopharmaceutical Research
- Licensing
- Business Development
- Antibody Purification
- Biopharmaceuticals
- Biotech

#### By Industry

- Biopharmaceuticals
- Biotech
- CMOs
- Academics and Research Institutes
- Technology Providers/Contract Service providers
- Venture Capitalists

#### By Country

- North Asia
- South East Asia
- Australia & Pacific
- USA
- Europe
- India

### Plus Workshop on: Optimisation and Comparability of Antibody Glycosylation

Featuring the latest antibody research and development, industry trends and updates and ways to expedite your antibody pipeline into revenue-generating biologics. [www.antibodiesasia.com](http://www.antibodiesasia.com)

# CELL LINE DEVELOPMENT & ENGINEERING ASIA

Advancing Asia's Capabilities in Quality Biopharma Development

As Asia becomes a biologics and biosimilars powerhouse, there is a growing demand for cell lines to be used for clinical and industrial purpose. Find out the trends, updates and success stories from Chinese companies that have taken the internal cell line development route as well as from international experts talking about increasing efficiency and speed of development while reducing costs and achieving process optimization.

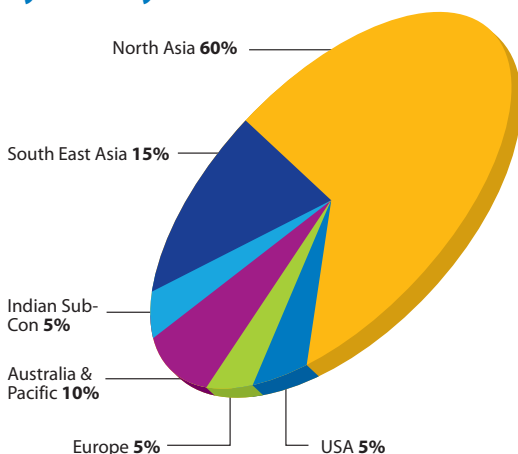
**CELL LINE DEVELOPMENT & ENGINEERING ASIA** brings together experts and top scientists from biopharmas, biotechs, CMOs and research institutes as well as leading technology providers from Asia and globally. **The region's 1st and ONLY focused Cell Line Development and Engineering Asia** provides a forum where industry experts share lessons learned through case studies, strategic discussion groups and interactive roundtables to collectively collaborate and provide solutions to your most pressing challenges. Bring back new ideas to do better business.

## Who should attend:

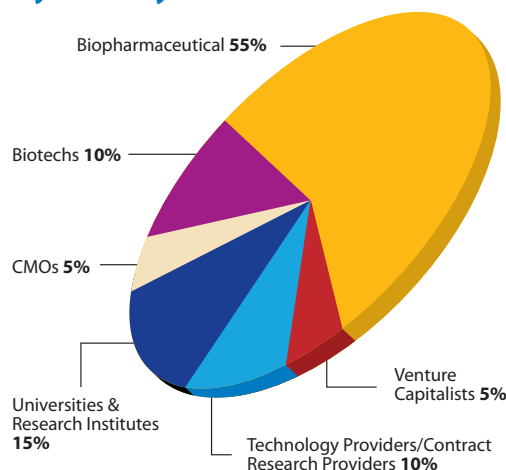
### By Job Title :

- Directors, VPs, CEO
- Head of Process Development
- Head of R&D
- Head of Bioprocess/Biotechnology
- Scientists
- Researchers
- QA/QC Specialists
- Bioprocess Engineers

### By Country:



### By Industry:



*"Best Conference related to cell line development, very well organized" ~ Biogen Idec*

*"Interesting talks combined with good possibilities for discussion" ~ Cellmed*

## About our Exhibitor:



TAP Biosystems (formerly The Automation Partnership) provides advanced automation systems and services to improve productivity in life science research, development and production applications.

TAP's focus is in four key application areas:

- Bioprocess development
- Discovery research
- Regenerative medicine
- Cell-based testing

TAP will be showcasing the ambr system (advanced micro bioreactor) for cell line selection and process optimisation and Fill-It, the automated screw-cap cryovial filling system for creating cell banks and reagent stocks.

## PAST ATTENDING COMPANIES IN THE SERIES INCLUDE:

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