IBC LIFE SCIENCES

A Part of bdp BIOPHARMA DEVELOPMENT & PRODUCTION

6TH ANNUAL BIOMANUFACTURING

2016年第6届亚洲生物制造年会

16 - 19 May 2016

Grand Hyatt Shanghai, China

2016年5月16日至19日 ▸ 上海金茂君悦大酒店

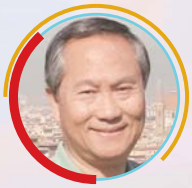
John Rasko
Immediate Past Chair, Advisory Committee on Biologicals,
Therapeutic Goods Administration (TGA)

Firelli Alonso
Senior Director, External Supply, BioTherapeutics Pharmaceutical Sciences,
Pfizer Biotech, United States

Claudia Lin
Vice President of Quality and Compliance,
Innovent Biologics, China

Xueming Qian
Chairman and CEO,
MabSpace Biosciences, China

Deepak Hedge
Product Development Director, Platform Technology Science China, GSK Shanghai R&D,
GlaxoSmithKline, China



Michael Lee
Plant Director,
JHL Biotech, China

Kim Wong
Director, Facilities & cGMP Support, BioProcess Research & Development,
Sanofi Pasteur Ltd, Canada

James Sayer
Director, Global Product Quality,
Amgen, United States

Frederic Rohmer
General Manager,
Lilly Suzhou Manufacturing, China

Wenzhi Tian
Founder and President,
ImmuneOnco Biopharma, China

Jun Xiang
Vice President of Biotechnology Institute of Shanghai CP Guojian,
Shanghai CP Guojian Pharmaceutical Co., Ltd, China

KEY TOPICS

- Batch vs. Continuous Manufacturing: How to Run Smoothly & Improve Product Quality?
- CMO Selection & Performance Management
- Cost Structure of Planning a New Biomanufacturing Facility
- Systematic Approach to Apply QbD & Risk Mitigation in Process Validation
- Establishing Biosimilarity with Analytical Similarity Plan
- Ensuring Contamination Control

WORKSHOPS

MONDAY | **16 MAY 2016**

A: **How Outsourcing & CMO Can Add Value**

B: **Risk Management & Quality Control Strategies for Biotech Products**

THURSDAY | **19 MAY 2016**

C: **Biologics Fill/Finish 101: Development History, Challenges & Opportunities**

NEW FEATURES

Breakfast Meet & Greet

Breakfast Workshop: CMO Selection & Performance Management

Site Tour to Genor Biopharma's NEW cGMP Production Facility

Co-located with:

5th ANNUAL CELL LINE DEVELOPMENT & ENGINEERING ASIA

7th ANNUAL BIOSIMILARS ASIA

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www.biomanufacturing-asia.com

6TH ANNUAL BIOMANUFACTURING

CONFERENCE DAY ONE

17 May 2016 TUESDAY

Breakfast Meet & Greet

BOOK SEPARATELY

7:00 to 8:30 **Breakfast Meet & Greet with Regulator**
John Rasko, *Immediate Past Chair, Advisory Committee on Biologicals*, **Therapeutic Goods Administration (TGA)**

8:00 **Main Conference Registration Opens & Morning Coffee**

8:50 **Welcome Address & Ice Breaker from IBC Asia**

9:00 **Chairperson's Opening Remarks**

Biopharma Visionary Keynote Sessions

9:10 KEYNOTE ADDRESS **Global Biopharma Policy & Market Trends**
- Rapid growth in biopharma: challenges and opportunities
- Emerging trends in biopharmaceutical production
- Where is biopharmaceutical manufacturing heading?

9:40 PANEL DISCUSSION **China's Biopharma: Opportunities & Biggest Challenges**
- Funding and investment difficulties in China are apparent, what are the reasons?
- CFDA outlook
  - ~ Review and approval speed of CFDA
  - ~ How cGMP guidelines have been implicated in real time operation, not during audition
  - ~ What it takes to get approval in US/EU from China?
- Manufacturing sciences
  - ~ GMP compliant manufacturing facility in China
  - ~ Operation excellence and improvement
  - ~ Product quality: how quality is evaluated by manufacturers?
  - ~ Choosing the right partner – suppliers and CMO's
- Different technologies: getting all the information required from the vendors

Panelists:
Claudia Lin, *Vice President of Quality and Compliance*, **Innovent Biologics**, China
Joe Zhou, *CEO*, **Genor Biopharma** & *Vice President*, **Walvax Group**, China
Wenzhi Tian, *Founder and President*, **ImmuneOnco Biopharma**, China
Bai Xianhong, *President*, **Biotech Pharmaceutical Co., Ltd**

10.30 **Morning Networking & Refreshment Break**

CMO vs. In-House Operations

11:45 **CMO vs. In-House: When Do You Need to Approach CMOs?**
- How do CMOs control the operations?
- Scheduling/ Timeline
- Meeting client requirements
- Cost issues: Viable option for the manufacturers?
- Challenges in transferability of analytical and formulation processes to CMO

Senior Representative, **Boehringer Ingelheim Biopharmaceuticals**

Single-Use vs. Stainless Steel Technologies

12:15 **Single-Use, Continuous Bioprocessing: Value Proposition & How to Get Started**
- The value proposition of integrated systems
- An update on the state of art and what is currently available
- Key features of an integrated purification unit at development scale and for GMP manufacturing

Rob Noel, *Business Development, Manager*, **Pall Life Sciences**, United Kingdom

12:45 CASE STUDY **New Directions in Biotech Facility Design: Impact of Hybrid Single Use & Stainless Steel for Larger Scale Facilities**
- Impact of hybrid technology
- CAPEX & OPEX
- Regulatory requirements and facility layout principles
- Multiproduct downstream flexibility
- Automation strategy for commercial and market supply
- ADC facilities

Niels Guldager, *Senior Technology Partner*, **NNE Pharmaplan**, Denmark

13:15 **Networking Lunch & VIP Tables**
VIP 1: **Qing Qiao Robin Tan**, *Head of Analytical Science*, **Shanghai CP Guojian Pharmaceutical**, China
VIP 2: **Yanshan Huang**, *CEO*, **Zhejiang Doer Biologics**, China
VIP 3: **Hongtao Lu**, *Executive Vice President, Scientific Research*, **Zai Laboratory**, China
VIP 4: **Frederic Rohmer**, *General Manager*, **Lilly Suzhou Manufacturing**, China
Exchange business cards and have an informal chat with the above guests during the networking lunch!

Cold Chain Management

14:30 **Increased Visibility to Drive Operational Excellence Throughput the Pharma Cold Chain**
- What is the promise of telemetry?
- Relevant and actionable data to secure decisions and minimise risks across the supply chain
- Case studies: real life pilots on RAP e2 containers using Envirotainer's integrated visibility solution

Steve Winyard, *Pharma Cold Chain Industry Expert*, **Envirotainer**

Batch vs. Continuous Manufacturing

15:00 PANEL DISCUSSION **Batch vs. Continuous Manufacturing: How to Run Smoothly?**
- Reducing process development time and manufacturing cost / Cost of good vs the other
- Impact on the facility design
- Impact on quality
- Control strategies
- Regulatory considerations
- PAT
- Cutting-edge technique and results of perfusion cell culture: regulation vs. approval of the produced medicine
  - ~ How to report batch / validation failure, with respect to contamination?
  - ~ Change of upstream and downstream process and its reporting and documentation
- Risk analysis and risk mitigation
- How to increase flexibility & facilitate the plant's growing needs of producing drugs?
- Pros & cons of different mode of operation
  - ~ Analysing which one is more suited for one type of product or environment or regulation
- Other new trends of continuous manufacturing
  - ~ Large vs. small molecule

Moderator:
Steven Lee, *CEO*, **DRL Biologics Singapore Operations Pte Ltd**, Singapore
Panelists:
Rob Noel, *Business Development, Manager*, **Pall Life Sciences**, United Kingdom
Suyamburam Sathasivam, *General Manager R&D Biotechnology*, **Sun Pharma**, India
Joe Zhou, CEO, **Genor Biopharma** & *Vice President*, **Walvax Group**, China
Kim Wong, *Director, Facilities & cGMP Support, BioProcess Research & Development*, **Sanofi Pasteur Ltd**, Canada
Hang Zhou, *Director of Biologics*, **Wuxi AppTec Biopharmaceuticals**, China

15:40 **Afternoon Networking & Refreshment Break**

Interactive Roundtable Discussions

16:10
- Moderator will kick-start the session with (10 min) opening/introduction of the topic/issue discussed and raise related concerns/challenges
- Participants will form a discussion to identify the top 3 solutions/strategies to resolve the challenge/issues (30 mins)
- Moderator will digest and summarise the key outcomes and strategies taking into account feasibility of the solution presented (5 min each Moderator)

Roundtable 1: Stainless Steel vs. Single-Use
Moderator: **Fei Jiang**, *Director, Business Development*, **3SBio Inc**, China

Roundtable 2: Operational Excellence in Biomanufacturing & Quality Control
Moderator: **Bill Huang**, **Lean Practitioner**

Roundtable 3: Successful Technology Transfer
Moderator: **Kim Wong**, *Director, Facilities & cGMP Support, BioProcess Research & Development*, **Sanofi Pasteur Ltd**, Canada

18:00 **Chairperson's Summary & End of Conference Day One**

19:00 **Networking Dinner!** BOOK SEPARATELY

6TH ANNUAL BIOMANUFACTURING

CONFERENCE DAY TWO

18 May 2016 WEDNESDAY

Breakfast Workshop

BOOK SEPARATELY

7:00 to 8:30

CMO Selection & Performance Management

- A large part of biopharmaceutical companies now rely on outsourcing partners for the development and manufacture of biological drug substance and drug product for clinical studies and commercial supply.
- The focus of this workshop will be on a key element in the development of a partnership between the Client (Contract Giver) and the CMO (Contract Acceptor) – the CMO selection process.
- The workshop will include a hypothetical interactive case study, offering the participants hands-on experience in selecting the appropriate CMO, based on proven externalization guiding principles. CMO performance management tools and metrics will also be discussed

Firelli Alonso, *Senior Director, External Supply, BioTherapeutics Pharmaceutical Sciences*, **Pfizer Inc.**, United States

9:00 Chairperson's Opening Remarks

Biomanufacturing Quality & Efficiency

9:10 CASE STUDY

Operating Manufacturing Process Efficiently & Making Compliance with Quality Regulation

Senior Representative, **Boehringer Ingelheim Biopharmaceuticals**

9:50

Virus Reduction/Removal Technology / Viral Clearance Technology

- Viral filtration and validation of the product with respect to viral freedom
- Viral safety for culture media
- Virus reduction technology, and its regulation

10:30 Morning Networking & Refreshment Break

Track A: Facilities

Facility Planning: Cost & Investment

11:30 CASE STUDY

Cost Structure of Planning a New Biomanufacturing Facility

- New facility cost comparison between US and China
- Options to reduce new facility cost
- Cost estimation model for new facility
- Cost comparison amoung using CMO, leasing a facility and building/operating a new facility

Jason Li, *Vice President*, **Genor Biopharma**, China

12:20 CASE STUDY

Key Aspects of a Site-to-Site Technology Transfer

- Ensuring facility fit of the receiving site
- How process and facility engineering work together
  - ~ Timing ~ Risk assessment
  - ~ Development of technologies and application

Suyamburam Sathasivam, *General Manager R&D Biotechnology*, **Sun Pharma**, India

Innovative Technologies

14:30

Disruptive/Innovative Biomanufacturing Technologies

- Revolution of Biomanufacturing technologies
- Key areas of Biomanufacturing technology innovation
- Economically disruptive technologies of the future

Steven Lee, *CEO*, **DRL Biologics Singapore Operations Pte Ltd**, Singapore

15:10 CASE STUDY

Single Use System Sterilisation Considerations & Best Practice to Ensure Product/Process Quality & Efficiency

James Sayer, *Director, Global Product Quality*, **Amgen**, United States

Commissioning, Qualification & Validation

16:20 CASE STUDY

Systematic Approach to Apply QbD & Risk Mitigation in Process Validation

- Developing QbD
  - ~ Designing & optimizing the process ~ Small scale vs. large scale
- Process validation: specification
- Quality attribute analytical
- Post approval process monitoring
- Life-cycle & raw material control
- In-process control vs. DP control
- Extractable & Leachable Quantification

Kim Wong, *Director, Facilities & cGMP Support, BioProcess Research & Development*, **Sanofi Pasteur Ltd**, Canada

17:00 CASE STUDY

Design & Qualification on Critical Utility System for Biomanufacturing Facility

- The economic and compliant system design for critical utility systems
- Its impact to Biomanufacturing facility and operation
- Project strategy
- Commissioning plan

Michael Lee, *Plant Director*, **JHL Biotech**, China

Track B: Production

Investigational New Drug (IND) Application

Antibody-Drug Conjugates Development & Manufacturing for IND Application

- Conjugation and purification process development from small-scale to pilot scale
- Challenges in preclinical studies for IND application in China
- Regulatory considerations in China

Jun Xiang, *Vice President of Biotechnology Institute of Shanghai CP Guojian*, **Shanghai CP Guojian Pharmaceutical Co., Ltd**, China

Process & Quality

CASE STUDY

Implementing Comparability Studies for Biological Products

- How does it change during scale-up process?
- What kind of method/model to use to prevent change of protein quality

Andrea Ji, *Senior Scientist, Late Stage Pharmaceutical Development*, **Genentech Inc, A member of Roche**, United States

13:00 Networking Lunch & VIP Tables

Bring your questions and visit the guests during the networking lunch!

VIP 1: Zhe Ru Zhang, *CEO*, **Shanghai JMT-Bio Inc**, China
VIP 2: Xueming Qian, *Chairman and CEO*, **MabSpace Biosciences**, China
VIP 3: Deepak Hedge, *Product Development Director, Platform Technology Science China, GSK Shanghai R&D*, **GlaxoSmithKline**, China

CASE STUDY

Establishing Biosimilarity with Analytical Similarity Plan

- How to establish acceptance criteria? Variability amongst the different sourced RMPs (reference medicinal product)?
- How to establish process related impurities and its comparison with innovator product?
- Statistical considerations
- In-vitro/Lab comparison vs. Clinical comparison
- Effect of age/shelf life of RMP (reference medicinal product)

Claudia Lin, *Vice President of Quality and Compliance*, **Innovent Biologics**, China

Trends in Quality Assurance Failures

- What are the key factors that led to plant closings in the last 18 months?
- What steps can we take to ensure our operations to not go down the path that leads to plant closure?
- What are current hot buttons for EMA and FDA inspections?

Scott Wheelwright, *CEO*, **Complya Asia**, China

15:50 Afternoon Networking & Refreshment Break

Cleaning & Sanitisation in Downstream Processing

- Implementation of suitable cleaning protocols
- Cleaning solutions
- Developing cleaning procedures

Ensuring Contamination Control

- Low endotoxin recovery
- Bioburden control
- Use of Isolators vs. Laminar Air Flow system

17:40 Chairperson's Summary

18:00 Presentation of Best Poster & Best Booth Award

WORKSHOPS & SITE TOUR

PRE-CONFERENCE WORKSHOPS: MONDAY 16 MAY 2016

WORKSHOP A

How Outsourcing & CMO Can Add Value

9am - 12pm

Senior Representative, **Boehringer Ingelheim Biopharmaceuticals**

WORKSHOP B

Risk Management & Quality Control Strategies for Biotech Products

2pm - 5pm

The goal of this workshop is to train QA, QC and operations managers in the following areas. After attending this course you will understand

- The concept of risk as used by regulatory authorities
- How to evaluate risk in process development, analytical methods, and facility validation
- How to manage risk to improve product safety and reduce production failures

KEY TOPICS TO BE DISCUSSED INCLUDE:

- Risk
  - ~ What do we mean by risk ~ How do we evaluate risk
  - ~ How do we measure risk ~ How do we control risk
- ICH Q10 and regulatory concepts of risk
- Risk management for process development and analytical methods
- Risk management for audits and inspections
- Risk management for qualification and validation

WORKSHOP LEADER:

Scott Wheelwright,*CEO*, **Complya Asia**, China

Scott is the founder of Complya Asia, a consultancy in China focused on helping clients meet international requirements for cGMP and Quality Assurance. Dr. Wheelwright is one of the founders of Innovent Biologics, a biopharmaceutical firm in China. Dr. Wheelwright has thirty years experience in bringing novel products to market with work experience that encompasses both large and small pharmaceutical, biotech and other life science companies. Dr. Wheelwright received his PhD in chemical engineering from the University of California at Berkeley and performed post-doctoral studies at the Max Planck Institute for Biophysics in Frankfurt, Germany. He is the author of a book on protein purification and has published numerous articles on manufacturing, process development, and bringing products to market. Dr. Wheelwright currently resides in Suzhou China.

POST-CONFERENCE WORKSHOP + SITE TOUR: THURSDAY 19 MAY 2016

WORKSHOP C

Biologics Fill/Finish 101: Development History, Challenges & Opportunities

9am - 12pm

Since the first batch of biologics, the field of drug fill/finish has grown substantially. When switching from API to biologics manufacturing, changes have been made to accommodate these valuable and vulnerable molecules. This workshop focuses on discussing the details and specifics of modern biologics fill/finish manufacturing.

KEY TOPICS TO BE DISCUSSED INCLUDE:

- Formulation development
- Drug product design and design space
- Sophisticated machineries/equipment
- Control methods
- Monitoring and control of particulates during manufacturing
- PAT for fill-finish operation
- Trends in material and area qualifications

WORKSHOP LEADER:

Feng He, *Senior Director and Quality Head*, **Genor BioPharma**, China

Dr. He joined Genor Biopharma in 2014, prior to which he had worked for Amgen Seattle for six years as Scientist and Senior Scientist, Drug Product Development. His working experience includes contract settings to deliver commercial formulation recommendations to clients, biophysical characterization, pre-formulation, and formulation of vaccine candidates including proteins, viruses and virus-like particles; formulation and lyophilization of bacteria-based pharmaceutical products; stability studies of macromolecular systems; characterization of protein-ligand interaction and refolding of recombinant biopharmaceuticals. He has a PhD in Biochemistry and Biophysics and M.A. in Mathematics at University of Kansas, B.S. Biosciences and Biotechnology in Shanghai JiaoTong University. Dr. He is now serving as adjunct professor in the department of pharmaceutical chemistry at the university of Kansas

SITE TOUR

Exclusive Site Tour to Genor Biopharma's NEW cGMP Production Facility

2pm - 6pm

SITE TOUR LEADER:

Jing Tian, *BD Manager*, **Genor Biopharma**, China

Jing Tian is currently BD Manager of Genor, a leading domestic company with global capability in R&D and manufacturing of therapeutic mAb. Her main responsibility is management of licensing in/out, CRO&CMO, as well as government affairs. She is currently project manager for a CMO project in collaboration with an international company. Prior to joining Genor, she served in T-mab BioPharma and handled diverse responsibilities spanning across biologic IND application supporting, funds application and project management, intellectual property protection, and enterprise image promotion. She received a M.S. degree in pharmacology and a B.S. degree in engineering from China Pharmacuetical University, where she was trained in biology and bioengineering.

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16 - 19 May 2016

Grand Hyatt Shanghai, China

2016年5月16日至19日 ▸ 上海金茂君悦大酒店

IBC's **6th Annual Biomanufacturing Conference** will examine the latest regulations, analyse new and existing facilities, introduce cost saving technologies, and discuss best practices to meet the growth of biologic products in Asia, with more focus in China. Key biological manufacturers will share their learnings, challenges and strategies to both advance and refine this developing industry. This conference also aims to provide a platform for key industry experts to have in-depth discussions on biomanufacturing facilities, process and quality.

Have your questions answered by industry experts such as:

- What kind of method to use to prevent change of protein quality?
- How to increase flexibility and facilitate the plant's growing needs of producing drugs?
- How do CMOs control the Biomanufacturing operations?
- What's the impact of new regulations in the design and implementation of facilities?
- How to establish process related impurities and its comparison with innovative product?

New & Fun Activities:

- Breakfast Meet & Greet
- Early Morning Workshop
- More Raffle Draws
- Networking Dinner
- Present a Poster and Win the People's Choice of Best Poster

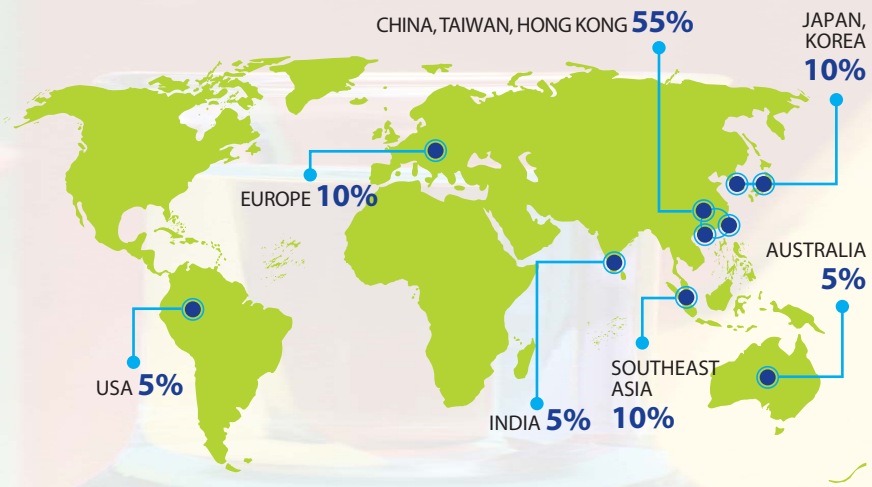
SPONSORSHIP OPPORTUNITIES

Contact: **Yvonne Leong**
+65 6508 2489
Yvonne.Leong@ibcasia.com.sg

WHO SHOULD ATTEND

BY INDUSTRY

Biopharmaceutical / Pharmaceutical / Biotechnology	45%
Technology and Solution Providers	20%
CMO	15%
Research Institutes	10%
Government	10%



BY JOB TITLE

CEOs / VPs / Directors / Heads of

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- Operations
- Downstream Processing
- Technologies / Scientific Technology
- Biologics
- R&D
- Quality & Regulatory Affairs / Quality Assurance / Quality Control
- Business Development / Product Development

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☐ Yes! I/We will attend the **6th Annual Biomanufaturing** • 16 – 19 May 2016, Grand Hyatt Shanghai, China

☐ I would like to purchase the conference presentations at SGD1000 + GST (SGD1070) per log in.

FEE PER DELEGATE	Super Early Bird Register & pay on or before 29 Jan 2016	Early Bird Rate Register & pay on or before 11 Mar 2016	Special Rate Register & pay on or before 8 Apr 2016	Normal Rate Register & pay after 8 Apr 2016
INTERNATIONAL COMPANIES – Global Headquarters Located Outside on Mainland China				
❑ **4-Day Package:** 2 Day Conference + All 3 Workshops + Site Tour	USD 2,795	USD 2,895	USD 3,095	USD 3,295
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❑ **2-Day Package:** 2 Day Conference Only	USD 1,795	USD 1,895	USD 2,095	USD 2,295
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❑ **4-Day Package:** 2 Day Conference + All 3 Workshops + Site Tour	CNY 7,500	CNY 8,000	CNY 8,500	CNY 9,000
❑ **3.5-Day Package:** 2 Day Conference + 2 Workshops + Site Tour	CNY 7,000	CNY 7,500	CNY 8,000	CNY 8,500
❑ **3-Day Package:** 2 Day Conference + ❑ 2 Workshops OR ❑ 1 Workshop+ Site Tour	CNY 6,500	CNY 7,000	CNY 7,500	CNY 8,000
❑ **2.5-Day Package:** 2 Day Conference + ❑ 1 Workshop OR ❑ Site Tour	CNY 6,000	CNY 6,500	CNY 7,000	CNY 7,500
❑ **2-Day Package:** 2 Day Conference Only	CNY 5,500	CNY 6,000	CNY 6,500	CNY 7,000

GOLD PASS: Add USD 150 / CNY 1000 to upgrade to Gold Pass and have access to all 3 conferences.

❑ **Breakfast Meet & Greet / Breakfast Workshop** Add USD 200 / CNY 1,300

❑ **Networking Dinner** Add USD 99 / CNY 650

❑ **Present a Poster** Add USD 50 / CNY 325

SPECIAL GROUP SAVINGS AVAILABLE!
Register a team of 3 or more delegates, and the 4th delegate attends for FREE!

DELEGATE DETAILS

Please photocopy for additional delegates

Name: Dr/Mr/Ms

Job Title:

Department:

Tel: | Mobile No.:

Email:

Who is Head of your Department? | Who is Head of Training?

Company Name:

Address: | Postal Code:

Main Business/Activity:

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(Please tick)

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☐ Payment by Credit Card. (AMEX, VISA or MasterCard accepted)

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Credit card contact: _____ Department: _____

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MAIL the attached registration form with your cheque to
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Email
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Web
www.biomanufacturing-asia.com

HOTEL INFORMATION

Grand Hyatt Shanghai, China
Jin Mao Tower, 88 Century Boulevard
Pudong, Shanghai 200121
Tel: +86 21 5049 1234 | Fax: +86 21 5049 8381
Contact Person: April Gu, Events Manager
Email: april.gu@hyatt.com

PAYMENT TERMS

Payment must be received 10 business days prior to the event. To take advantage of discounts with an expiry date, registration and payment must be received by the cut-off date.

- Payment by bankers draft or cheque in S$ or US$ should be made in favour of **"IBC Asia (S) Pte Ltd"** and mailed to:
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  c/o Informa Regional Business Services
  111 Somerset Road, TripleOne Somerset #10-05
  Singapore 238164
  Attn: The Accounts Receivable Team
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Should you be unable to attend, a substitute delegate is welcome at no extra charge. Cancellations must be received in writing at least 10 business days before the start of the event, to receive a refund less 10% processing fee per registration. The company regrets that no refund will be made available for cancellation notifications received less than 10 business days before the event.

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Please quote the name of the delegate, event title and invoice number on the advice when remitting payment. Bank charges are to be deducted from participating organisations own accounts. Please fax your payment details (copy of remittance advice, cheque or draft to +65 6508 2407).

Attendance will only be permitted upon receipt of full payment. Participants wishing to register at the door are responsible to ensure all details are as published. IBC assumes no further liability or obligation, beyond the refund of the paid registration fee, in the event of postponement or cancellation by IBC.

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