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26-28 February 2019
Hilton Tokyo Bay
Tokyo, Japan

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Hidenari Yamada

Department Manager,
API Process Development,
Chugai Pharmaceutical, *Japan*



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PRE-CONFERENCE WORKSHOPS • TUESDAY, FEBRUARY 27

9:00 am - 5:00 pm

PRE-CONFERENCE WORKSHOP #1: PREPARING FOR AN FDA INSPECTION

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

PRE-CONFERENCE WORKSHOP #2: THE ESSENTIALS OF TECHNOLOGY TRANSFER

Virtually every company will need to outsource certain factors over the course of its drug product development; whether it be analytical and process development, cGMP contract manufacture, characterization and viral clearance testing, validation, regulatory support etc. This is underpinned by Technology Transfer.

Principal junctures of Technology Transfer can occur between pre-clinical to first into human (FIH), successive clinical stages and through to commercial manufacture.

Technology transfer elements can be complex and in today's fast-moving field of drug development there can be no room for error, with associated cost and delay implications. Technology transfer lies directly on the critical path and therefore must be right 'first time'. Demonstration of Product Comparability forms an essential element of certain technology transfer situations and which is essential in ensuring an exacting clinical product and meeting regulatory expectation.

In this workshop we will examine essential technology transfer as it applies to multiple product types (recombinants, biologics, vaccines, cellular and gene therapy products, conjugates etc.) and

- The nature of the challenge
- Strategy
- The 'nuts and bolts' of technology transfer
- Application to different product types recombinants, mAbs, biologics, ATMPs, biosimilars etc.
- Considerations of early and late stage transfers
- Pre-clinical to FIH
- cGMP manufacture
- The importance of the quality target product profile
- Ensuring Product Comparability
- Change control
- Regulatory compliance and health authority expectation
- Managing risk
- Sourcing and selection of a CMO partner
- Project management
- Technical and Quality agreements, protocols and reports
- Dealing with issues and how to get things back on track
- In licensing
- Commercial strategy
- Common pitfalls

The workshop will incorporate a mix of interactive modules, real life case studies, key topic points for discussion plus will provide model examples of actual technical quality agreements, technology transfer protocols and reports.

Richard Dennett, Senior Director Regulatory Affairs CMC, PPD, France

8:00	<i>Registration and Morning Coffee</i>	
	PLENARY SESSION	
8:45	Chairperson's Opening Remarks and Welcome to BPI Asia	
9:00	KEYNOTE ADDRESS: Viral Safety Approach (and/or) Process Control and Validation Strategies - Updates for Amgen Singapore Facility Amgen Representative to be Determined	
9:30	KEYNOTE ADDRESS: Implementation of Continuous Manufacturing Facility to Increase Flexibility and Capacity – A Case Study of an Antibody Continuous Process Scale-up We have established a POD based disposable continuous manufacturing GMP facilities in Hangzhou, China. The innovative design of the facility provides highly flexible and efficient biologics manufacture, with speed and cost advantage. This continuous manufacturing facility is designed to meet all international GMP rules by FDA, EMEA, Japan and cFDA. Two 500L lines are in operation now, and can be expanded to a total of 6x500L capacity within 6-9 months for large scale end to end processing. We will share the issues and challenges for the implementation from a green field to a full GMP operation of the new facility. A case study of technology transfer and scale-up GMP production for FDA IND filing supply will be provided. A case study of continuous perfusion process development of an antibody with a yield of 2 g/L/day will be presented. It is our mission to design and apply innovative technologies to provide biotherapeutics drugs that not only meet international quality standards, but also are affordable to patients in China and around the world. Jerry Yang , Senior Vice President, Process and Product Development, Hangzhou Just Biotherapeutics Co., China	
10:00	PLENARY PANEL DISCUSSION: Next Generation Bioprocessing, Digitalization and Facilities of the Future • What do the future strategies for bioprocessing look like? • Reducing manufacturing footprint through process improvements and changes • Improving production efficiency, reducing costs and increasing capacity to increase speed to market • Process intensification • Evaluating new platforms and technologies for increased flexibility in commercial manufacturing <i>Panelists:</i> Weichang Zhou, Ph.D. , Chief Technology Officer, Senior Vice President, Biologics Development and Manufacturing, Wuxi Biologics, China	
10:30	<i>Networking Refreshment Break in the Exhibit & Poster Hall</i>	
	TRACK ONE: CELL LINE DEVELOPMENT AND UPSTREAM PROCESSING	TRACK TWO: DOWNSTREAM PROCESSING
	Cell Line Development and Engineering	Innovative Approaches and Technologies in Downstream Processing
11:10	Chairperson's Remarks	Chairperson's Remarks
11:15	Accelerating Timelines from Early Candidate Selection to Production Cell Lines Thomas Jostock , Science and Technology Lead / Principal Fellow, Novartis, Switzerland	Featured Presentation – Analysis of Economic Drivers for Integrated & Continuous Bioprocessing of mAbs CASE STUDY NEW DATA Günter Jagschies, Ph.D. , Senior Director, Strategic Customer Relations, GE Healthcare, Germany
11:45	Target Integration Technology for Bioproducts Manufacturing Chugai introduced target integration technology in cell line development for manufacturing recombinant therapeutic proteins. To shorten project time line is strongly desired in pharmaceutical industry, however, process of cell line development currently takes at least a few months and is extremely tedious. Target integration-based cell line development is attractive as the plasmid vectors integrate into predetermined active sites in genomes. Kunihiko Kodaira , CLD Group Manager, API Process Development Dept., Chugai Pharmaceutical Co., Ltd., Japan	Innovative Strategies for Enhancing HCP Clearance in Clarification and Downstream Processing CASE STUDY NEW DATA Benoit Mothes , DSP Skill Center Head, DSP Breakthrough Technologies Skill Center, BioPharmaceutics Development, Sanofi, France Fabien Rousset, Ph.D. , Head of Bioseparations, Daicel, Chiral Technologies Europe, France
12:15	Sponsored Scientific Track Presentation	Sponsored Scientific Track Presentation
12:45	<i>Luncheon in the Exhibit & Poster Hall</i>	

	TRACK ONE: CELL LINE DEVELOPMENT AND UPSTREAM PROCESSING	TRACK TWO: DOWNSTREAM PROCESSING
	Upstream Processing – Process Intensification, Perfusion Systems and Cell Culture Media Development	Downstream Development for Novel Modalities
1:55	Chairperson's Remarks	Chairperson's Remarks
2:00	Intensification of a Multi-Product Perfusion Platform for Rapid Process Development The Intensified Perfusion Platform (IPP) at Sanofi has minimized the need for extensive development work and optimization in early stage. Challenges in achieving high cell density and sustainable volumetric productivity, comparisons between fed batch and intensified perfusion, technology readiness for single use bioreactor scale-up, development of perfusion scale down systems, and integration of at-line and online analytics will be discussed. Shawn Barrett , Associate Director, Sanofi R&D, USA	Overcoming Downstream Challenges for Fc Fusion Proteins Ijeoma Ikechukwu , Senior Scientist, Downstream Process Development, Patheon
2:30	Media Development for Intensified Seed Train Expansion Including N-1 Perfusion Media composition plays a critical role for biopharmaceutical production as well as seed train expansion. We could show that the right combination of media, specifically designed for their purposes, in a seed train including a perfused N-1 step can increase productivity in the final perfused production step, indicating that specific companion media combinations can increase productivity gains with these intensified process formats. Mona Bausch , Scientist in Perfusion Systems R&D, Merck Life Science, Germany	Scalable Purification Platform Development from the Cell-Free Expression System for Site-Specific Antibody Drug Conjugates Julie Hang, Ph.D. , Associate Director, Downstream Process Development, Sutro BioPharma Inc., USA (INVITED)
3:00	New Technologies for Improving and Controlling Product Quality, Expression, Timelines and Yield in Upstream Process Development Niki Wong , Principal Research Scientist, AbbVie Operations Singapore Pte Ltd, Singapore	Sponsored Scientific Track Presentation
3:30	<i>Networking Refreshment Break in the Exhibit & Poster Hall</i>	
	PLENARY SESSION	
4:00	Continuous BioManufacturing: Past, Present, and Future Sadettin Ozturk, Ph.D. , Senior Vice President, Process and Analytical Development, MassBiologics, USA	
4:30	Continuous Manufacturing in Monoclonal Antibody Development Karen Wen, Ph.D. , President, Mycenax Biotech Inc., Taiwan	
5:00	iLDC Based Continuous Process, Future Direction on CMC of Next Generation ADCs Gang Qin , President, GeneQuantum Healthcare (Suzhou) Co., Ltd., China	
5:30	<i>Close of Day One and Cocktail Reception in Exhibit Hall</i>	

8:00	<i>Registration and Morning Coffee</i>	
9:00	Chairperson's Opening Remarks	
	PLENARY SESSION	
9:10	KEYNOTE ADDRESS: Designing Cost Effective Next Generation Factory for Biologics – Case Study from Chugai Pharmaceutical Japan Reducing manufacturing cost is significant for increasing accessibility to biologics for patients. And increasing manufacturing start-up speed and flexibility is a key under an uncertain business environment. This presentation covers concept of Next Generation Factory to aim reduction of manufacturing cost from several hundred dollars to several ten dollars. Key features of the factory are small footprint with continuous manufacturing and automation. Hiddenari Yamada, Deputy Department Manager of API Process Development Department, Chugai Pharmaceutical Co., Ltd., Japan 	
9:50	PANEL DISCUSSION: Market Trends and Implications for Bioprocessing in Asia • Critical review of the biopharmaceutical market in Asia • Innovation in biopharma pipelines – What can be expected in terms of therapeutic areas and product types • Trends towards in house manufacturing or CDMO? • Single use vs stainless steel facilities • Continuous processing vs fed batch • Impact of biosimilars • Regulatory developments and impact on bioprocessing • Strategies to improve the bioprocessing capabilities in Asia • How is the bioprocessing industry in Asia going to be in 2020? <i>Moderator: Scott Wheelwright, Ph.D., Principal Consultant, Complya Asia Co., Ltd., China</i>	
10:30	<i>Networking Refreshment Break in the Exhibit & Poster Hall</i>	
	TRACK ONE: ANALYTICAL, QUALITY CONTROL AND SINGLE USE SYSTEMS	TRACK TWO: TECHNOLOGY TRANSFER AND BIOMANUFACTURING STRATEGIES
	Real-Time Process Monitoring Methods & Single Use Systems	Technology Transfer and Scale Up – Case Studies and Lessons Learned
11:10	Chairperson's Remarks	Chairperson's Remarks
11:15	CASE STUDY: Use of Multivariate Data Analytics For Real Time Process Monitoring And Controls Denise Tan, Principal Engineer, Process Development, Amgen Singapore Manufacturing Pte Ltd, Singapore	Technology Transfer Lead Time Reduction at Roche Joe Runner, Senior Manufacturing Technical Specialist, Global Technology Acceleration Team, Genentech, USA
11:45	PANEL DISCUSSION: Best Practices for Ensuring Quality Control for Single Use Systems Panelists: Denise Tan, Principal Engineer, Process Development, Amgen Singapore Manufacturing Pte Ltd, Singapore	Re-Purposing Equipment for Scale-Up Capacity at Reduced Cycle Time and Capital Expense Paul Kubera, Vice President, Process Technology, ABEC, Inc., USA
12:15	Sponsored Scientific Track Presentation	Sponsored Scientific Track Presentation
12:45	<i>Luncheon in the Exhibit & Poster Hall</i>	

	TRACK ONE: ANALYTICAL, QUALITY CONTROL AND SINGLE USE SYSTEMS	TRACK TWO: TECHNOLOGY TRANSFER AND BIOMANUFACTURING STRATEGIES
	Quality Control Methods for Biopharmaceuticals – Challenges and Key Considerations	Economic Analysis, Drivers, and Strategies in Biomanufacturing
1:55	Chairperson's Remarks	Chairperson's Remarks
2:00	Considerations and Strategies in Creation of GMP Master and Working Cell Banks to Meet FDA, EMA and NMPA Expectations Liming Shi, Senior Director, QC, CMAB Biopharma Inc., China	Economic Analysis and Drivers for Continuous Processing Facilities Yuki Abe, Ph.D., Senior Consultant Engineer, Biopharm Services Ltd., United Kingdom
2:30	Quality Systems – The Key to Compliance and Ensure Long Term Product Success Claudia Lin, Ph.D., Founder & CEO, JADE BioMedical	Overcoming the Challenges on Fc Fusion Protein Manufacturing Kenneth Kang, Ph.D., Head, Manufacturing, Yifan/Generon, China
	PLENARY SESSION	
3:00	Implementation of BPOG's Biomanufacturing Technology Roadmap: Progress, Challenges and Prospects Akihiro Yanagita, Group Manager, Chugai	
3:30	<i>Networking Refreshment Break in the Exhibit & Poster Hall</i>	
	Regulatory Perspectives - Impact of Evolving Global Regulatory Landscape on Bioprocessing	
4:00	Government Reforms to the Drug Registration Process and How They Affect Biopharmaceutical Manufacturing in China Scott Wheelwright, Ph.D., Principal Consultant, Complya Asia Co., Ltd., China	
4:30	Regulatory Perspective for Successful ADC Development and Case Studies Wen Jin Wu, Ph.D., Senior Investigator, Office of Biotechnology Products, US Food and Drug Administration (FDA), USA	
5:00	<i>Close of Main Conference</i>	

HIGHLIGHT YOUR COMPANY'S EXPERTISE AT BPI ASIA 2019

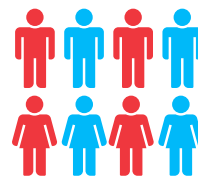
BPI Asia bridges multiple stages of development to share innovative ideas that improve the cost and quality of process, product development, and manufacturing.

Attendees of BPI Asia will get to experience and influence the paradigm shift of developing and manufacturing biopharmaceuticals through collaborative efforts across departments and stages of development. As a sponsor of BPI Asia, partner with leading bioprocess decision makers in need of solutions towards commercially successful biologics.

BPI ASIA HIGHLIGHTS

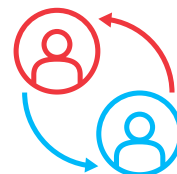
200+

Attendees



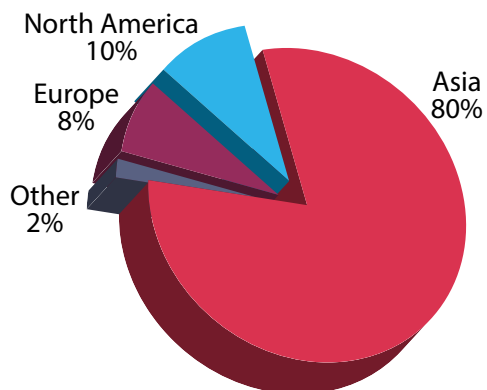
8+

Hours of Networking

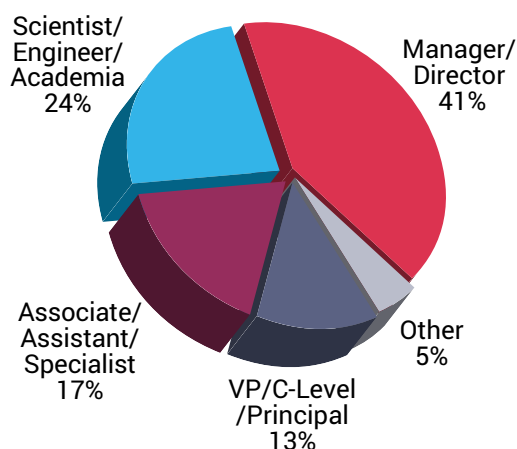


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ACADEMIC/GOVERNMENT RATES*	SAVE 500 USD Register by November 9, 2018	Standard Rate
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Industry Poster	150 USD	
Academic/Government Poster	0 USD	
Networking Dinner in Tokyo (February 26)	120 USD	

*Academic/Government rates are extended to full-time employees of government, universities and university-affiliated hospitals only.

All prices noted above are in USD

****Select one Pre-Conference Workshop:**

- Workshop #1: Preparing for an FDA Inspection
- Workshop #2: The Essentials of Technology Transfer



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