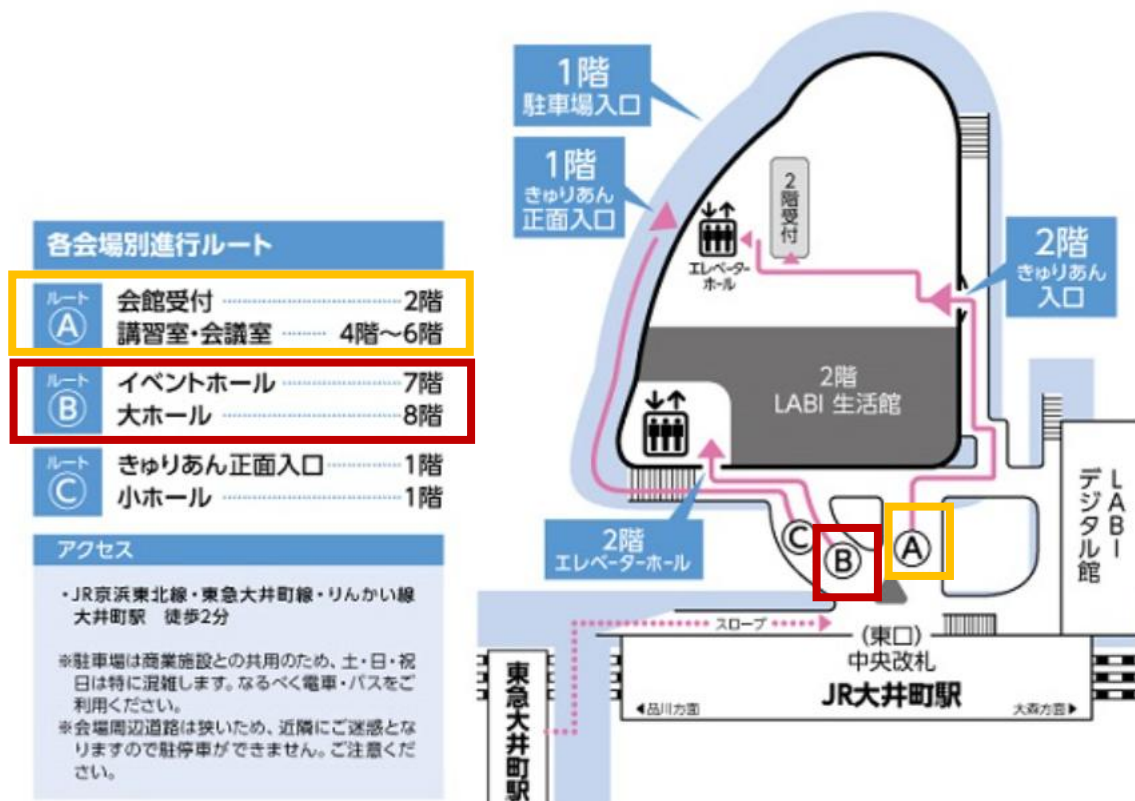


CONTENTS

【Venue Information】	P.2
【Conference Program】	P.4
【Workshops (WS)】		
WS-1-1/1-2 SPP Let's listen to your inner voice and take the first step!	P.5
WS-2 PHARMA4.0 Implementing Pharma 4.0 in the Field: What Does Implementation Theory Mean for Operating Digital in GxP?	P.6
WS-3 BIO Enhancing Global Competitiveness via Global Standards and Industry Collaboration ; Go Global, Go Standard, Go Bio!	P.7
WS-4 ATMP Capturing Emerging Global Trends in ATMP !	P.8
WS-5 CONTAINMENT / EHS Next-Generation Containment Strategy: Renovation, Validation, and IH	P.9
WS-6 API / SAM&GMP Technology Transfer in API Manufacturing: Current Status and Future Perspectives	P.10
WS-7 PHARMA PSE Expanding the Scope of Modeling: From Introduction to Practical Application	P.11
WS-8 C & Q ISPE Good Practice Guide \"Controlled Temperature Chambers - Commissioning & Qualification, Mapping and Monitoring\" 2nd Edition	P.12
WS-9 WIP Discovering Your Own Leadership Style– Diverse Leadership Journeys in the Pharmaceutical Industry	P.13
WS-10 IP Patient Centricity	P.14



[For attendees arriving on Day 1 (June 29)]

Conference Sessions / Networking Reception: Please use **Route B** shown in the figure on the left.

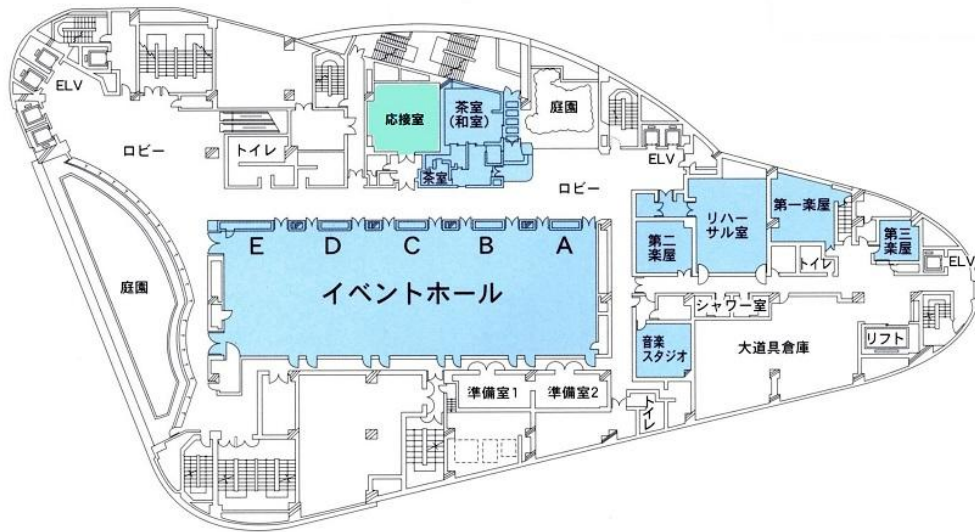
For the route guidance video, click [here](#).

[For attendees arriving on Day 2 (June 30)]

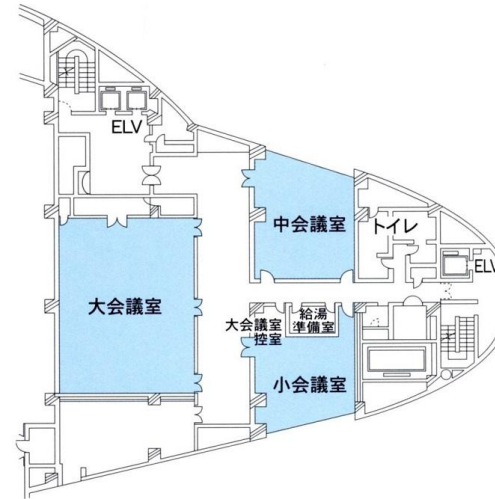
Workshop venues (4F-6F): Please use **Route A** shown in the figure on the left.

For the route guidance video, click [here](#).

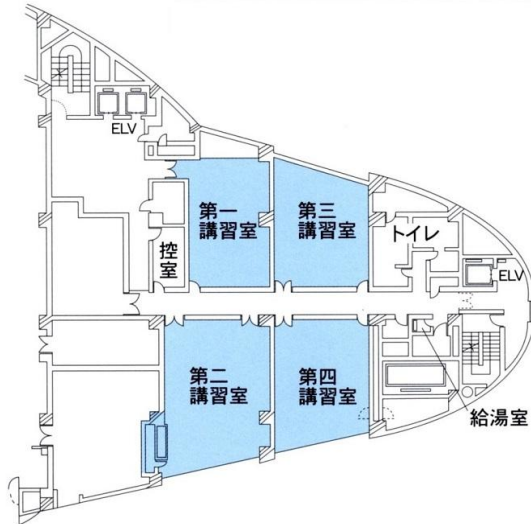
7F Event Hall



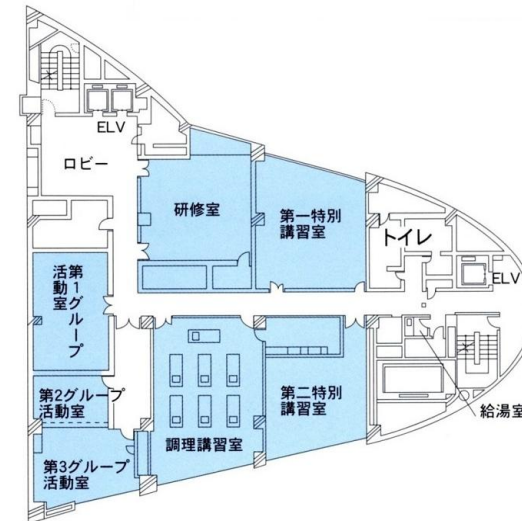
6F Conference Rooms



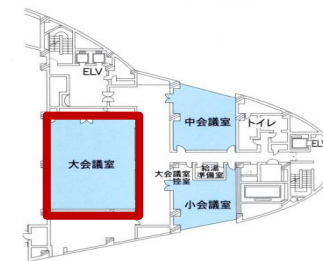
5F Conference Rooms



4F Conference Rooms

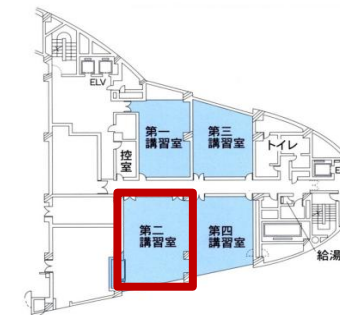


Time		Title	Speaker
11:00–11:05	Orientation	—	—
11:05–11:15	Opening Remarks	—	Yukinobu Maruyama (Chair, ISPE Japan Affiliate)
11:15–11:35	ISPE HQ Update	ISPE HQ Update (*)Video	Vivianne J. Arencibia (Chair, ISPE HQ)
11:35–12:20	Keynote Speech 1	Government Initiatives for Ensuring Thorough Manufacturing and Quality Control of Pharmaceuticals	Go Yamamoto (Director, Office of Compliance, Compliance and Narcotics Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare (MHLW))
12:20–13:40	Lunch (Luncheon Seminar + Sponsor Tabletop Exhibits)		
13:40–14:25	Special Lecture 1	Can AI Revolutionize Drug Discovery?	Dr. Yasufumi Okuno (Graduate School of Medicine, Kyoto University)
14:25–15:05	Special Lecture 2	Annex 1 – A Driver For Collaboration	Dr. Volker Storn (Roche Global MSAT &PO E2E Facility Solutions/ISPE-DACH Vice Chair)
15:05–15:40	Coffee Break (Sponsor Tabletop Exhibits)		
15:40–16:20	Special Lecture 3	Taking a Risk-based Approach to the Implementation of AI at Manufacturing Sites – what does this mean in practical terms?	Dr. Kevin O'Donnell (Market Compliance Manager, Health Products Regulatory Authority)
16:20–17:00	Keynote Speech 2	Implementing Manufacturing Management System with Advanced Technologies: Challenges and Insights	Kentaro Hara (Director, Office of Pharmaceutical Quality Management, Pharmaceuticals and Medical Devices Agency (PMDA))
17:00–17:40	Keynote Speech 3	Delivering Innovative Medicines at a World-Class Level – Chugai Pharma Manufacturing's Challenge Toward Becoming a Top Runner in Manufacturing –	Kenji Kamata (President, Chugai Pharma Manufacturing Co., Ltd.)
17:40–17:45	Closing Remark for Day 1	—	Tsutomu Igarashi (Vice Chair & Program Chair of the 2026 Annual Meeting, ISPE Japan Affiliate)

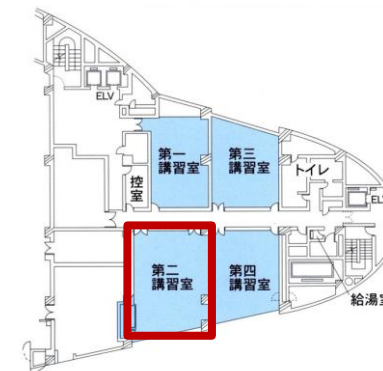


MC : Yuri Enomoto (MORIMURA BROS., INC.)

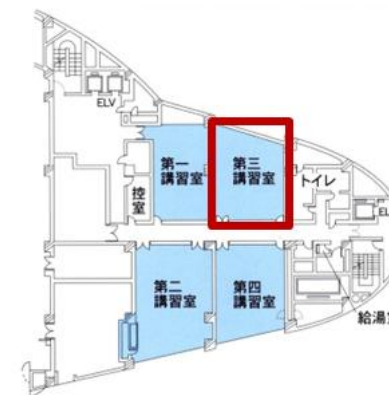
Time	minutes	Title	Speaker	Moderator
9:45-10:00	15	Introduction to COP Activities and Achievements	Kentaro Nakamura (SPP COP Leader, JGC Japan Corp.)	
10:00-10:55	55	Investigation Methods for Deviations in Environmental Monitoring	Shoji Takemoto (Takeda Pharmaceutical Co., Ltd.) / Haruka Tojima (Japan BCG Laboratory)	Takeshi Ono (Daiichi Sankyo Co., Ltd.)
10:55-11:10	15	Coffee Break		
11:10-12:00	50	Study on On-Site Leak Testing Procedures for 45H (H14) Filters	Katsuya Inoue (ASAHI KOGYOSHA CO., LTD.) Fumito Takashima (OSHITARI LABORATORY, INC.)	Koudai Chiba (Airex Co.Ltd.)
12:00-13:00	60	Annex 1: Current Hot Topics and Revision of the ISPE Baseline Guide for Sterile Facilities	Jörg Zimmermann (Vice President External Affairs, Vetter Development Service; Past Chair, ISPE)	Kentaro Nakamura (JGC Japan Corp.)
13:00-14:00	60	Lunch (Mini-Luncheon Seminar)		
14:00-14:05	5	Afternoon session opening remarks	Kentaro Nakamura (SPP COP Leader, JGC Japan Corp.)	
14:05-14:55	50	What Are the Risks and Benefits of PUPSIT Implementation?- Considerations Based on Case Studies and Survey Results for Single-Use and Multi-Use Systems -	Miyuki Hoshino (Merck Ltd.) Kohei Nakamura (Astellas Pharma Inc.)	Seiji Shimura (Global Life Sciences Technologies Japan K.K.)
14:55-15:30	35	2026 ISPE Aseptic Conference Presentation Report "Good Practices for Smoke Study in Aseptic Fill / Finish"	Takeshi Ono (DAIICHI SANKYO Co., Ltd.) / Masaru Fujita (Kyowa Kirin Co., Ltd.) / Kei Igarashi (Chugai Pharma Manufacturing Co., Ltd.)	Kentaro Nakamura (JGC Japan Corp.)
15:30-15:45	15	Coffee Break		
15:45-16:40	55	Material Transfer to Grade A with consideration for Annex 1	Satoshi Yodogawa (FUJIFILM Engineering Co., Ltd.) / Hiromitsu Nakanishi (DAIKIN APPLIED SYSTEMS Co.,Ltd.)	Hironobu Sunayama (SHIBUYA Corp.)
16:40-16:45	5	Closing remarks	Yuri Enomoto (MORIMURA BROS., INC.)	
16:45-17:00	15	Cleanup work	All	



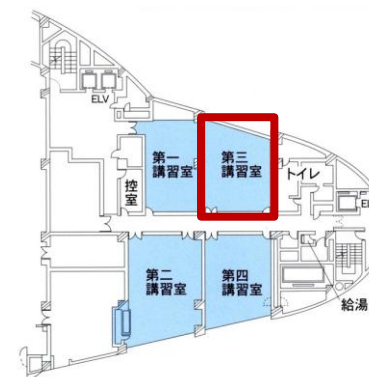
Time	minutes		Title	Speaker	Moderator
09:30-09:35	5		Workshop Announcement		Emiko YAMADA (Mitsubishi Chemical Engineering)
09:35-10:00	25	AMT WG	Physical AI × Robotics Transforming Pharmaceutical Manufacturing: Organizing Application Use Cases and Enabling Conditions	Masaoki OHYA (Daiichi Sankyo Co., Ltd.)	
10:00-10:10	10	AMT WG Q&A	Q&A		
10:10-10:30	20	AI/ML WG	Quality Risk Management for AI-enabled computerized systems	Daici TAKAHASHI (Pharma Planning Co., Ltd.)	Nobuhiro AOYANAGI (Green Willow Co., Ltd.)
10:30-10:40	10	AI/ML WG Q&A	Q&A		
10:40-10:50	10	Coffee Break			
10:50-11:10	20	P&P WG	Plug&Produce Technology Accelerating the Shift to Digital Factories and Future Outlook	Takashi YOSHIDA (Takeda Pharmaceutical Co., Ltd.)	Tsutomu IGARASHI (Takeda Pharmaceutical Co., Ltd.)
11:10-11:20	10	P&P WG Q&A	Q&A		
11:20-11:40	20	V4 WG	Digital Transformation of Validation From Legacy Approaches to Validation 4.0	Hiroyuki MIYAZAKI (Takeda Pharmaceutical Co., Ltd.)	Naoki SAKAMOTO (Taisei Corp.)
11:40-11:50	10	V4 WG Q&A	Q&A		
11:50-12:20	30	Guest lecturer	Pharma 4.0™ initiatives Implementing a Corporate Manufacturing Data Platform Content	Fumito IWASE (Takeda Pharmaceutical Co., Ltd.)	Hiroyuki MIYAZAKI (Takeda Pharmaceutical Co., Ltd.)
12:20-12:30	10	Q&A			
12:30-12:45	15		Pharma 4.0™ Activities Overview	Hiroyuki MIYAZAKI (Takeda Pharmaceutical Co., Ltd.)	
13:00-14:00	60	Lunch			



Time	minutes		Title	Speaker	Moderator
14:00-14:10	10	Introduction	COP activities and lecture content	Takashi Kaminagayoshi (BIO COP Leader, Takeda Pharmaceutical Co., Ltd.)	
14:10-14:50	40	Program1	Overview of ASME BEP 2026 Updates	Kazuya Nakagawa (Tec Project Services Corp.)	Keisuke Shibuya (Hitachi, Ltd)
14:50-14:55	5	Coffee Break			
14:55-15:15	20	Program2	Biocompatibility in ASME BPE (Temporary)	Tatsuhiko Kasai (Takeda Pharmaceutical Co., Ltd.)	Natsumi Ota (Hitachi Plant Services Co.,Ltd.)
15:15-15:45	30	Special Lecture	Latest Regulatory Trends for the Extractables & Leachables on Filters and Single-use systems including USP 665/1665	Chikako Yabuki (Merck)	Natsumi Ota (Hitachi Plant Services Co.,Ltd.)
15:45-16:05	20	Keynote Speech	Gaps Between Equipment Design Based on ASME BPE and Domestic Standards (Pressure Vessels) (Temporary)	Makoto Sekine (Marubishi Bioengineering Co.,Ltd.)	Toshiaki Izumi (Endress+Hauser Japan)
16:05-16:15	10	Coffee Break			
16:15-17:15	60	Panel discussion	JPMA/Bio COP Collaboration Panel Discussion "Keeping Japan's Biopant Construction Moving Forward: An Engineering Perspective on Challenges in Cost, Workforce, and Quality" (Temporary)	Takayuki Mizuno (Kajima Corp.) / Masahiro Kobayashi (Taisei Corp.) / Koichi Miyake (Obayashi Corp.) / Hideyuki Shimizu (Hitachi Plant Services Co.,Ltd.) / Naoto Kawaguchi (JGC Japan Corp.) / Rei Kurihara (Chiyoda Corp.)	Natsumi Ota (Hitachi Plant Services Co.,Ltd.) / Kamine Yu (Biopharmaceutical Facility Engineering & Consulting)



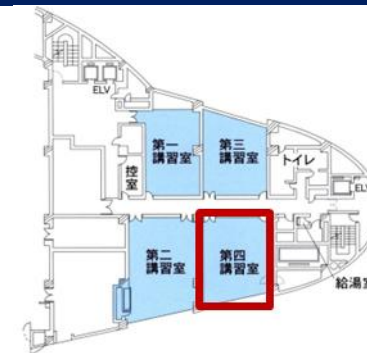
Time	minutes	Title		Speaker	Moderator
9:30-9:40	10	Introduction	COP activities and lecture contents	Ryo Ueda (Chiyoda Corp.)	
9:40-10:20	40	Keynote Speech	Keynote Speech (Tentative Title)	Yuto Takemoto (President and CEO, Quastella Inc.)	Kenichi Tahara (Takara Bio Inc.)
10:20-11:10	50	Special Lecture	Invited Lecture by APAC ATMP COP members (Tentative Titles)	Liu Shanshan (Fedegari Asia PTE LTD/ISPE International Board of Director) Zhang Peiqing (Cytiva/ISPE Singapore Affiliate President)	
11:10-11:25	15	Coffee Break			
11:25-12:05	40	Program 3	2026 ATMP COP Activity Report① Designing ATMP facilities considering the balance between cost and quality (Tentative Titles)	Toshihiko Hatanaka (Cytiva) Ryuichi Oyama (Chiyoda X-One Engineering Corp.)	Tetsuro Hatsuoka (Kajima Corp.)
12:05-12:45	40	Program 4	2026 ATMP COP Activity Report② - Comparison of decontamination methods in ATMP facilities - Initiative of wholesale business within ATMP supply chains	Tsuguru Eto (Validator K.K.) Chika Ishihara (Marken Japan)	Tetsuro Hatsuoka (Kajima Corp.)
13:00-14:00	60	Lunch			



Containment Session MC : Syunsuke Kumazawa (Toshiba Nanoanalysis Corp.)

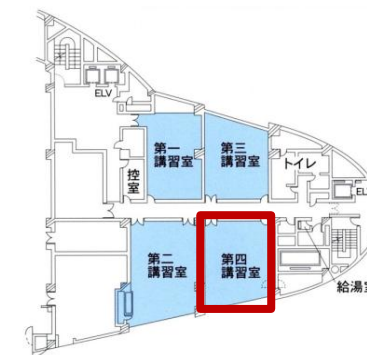
EHS Session MC : Ayumi Hasegawa (Ono Pharmaceutical Co.,Ltd.)

Time	minutes		Title	Speaker	Moderator
14:00-16:30 Containment					
14:00-14:45	45	Special lecture	Containment Design and Renovation Strategies in an R&D Pilot Plant	Naoya Ono (Kyowa Pharma Chemical Co., Ltd.)	Takao Odajima (Nichi-Iko Pharmaceutical Co., Ltd.)
14:45-15:15	30	Containment COP	Efforts to Correlate Airborne Transfer and Surface Material Data in Exposure Measurement.	Kazutoshi Sekiguchi (FandLa LLC)	Haruka Futamura (Airex Co., Ltd.)
15:15-15:45	30	Containment COP	Cleaning Validation Survey Results and Recommendations 1	Hiroaki Matsumoto (Office Kiseki Co., Ltd.)	Syunta Hashimoto (KIT Co., Ltd.)
15:45-16:00	15	Coffee Break			
16:00-16:30	30	Containment COP	Cleaning Validation Survey Results and Recommendations 2	Masahiro Hasegawa (Takeda Pharmaceutical Co., Ltd.)	Emi Miyata (Quascenta)
16:30-17:15 EHS					
16:30-17:15	45	EHS COP	Points to Communicate for EHS in Technology Transfer	Nobuaki Kato (CIMIC Co.,Ltd)	Ayumi Hasegawa (Ono Pharmaceutical Co.,Ltd.)



MC: Satoru Arai (Toray Industries, Inc.)

Time	minutes	Title		Speaker	Moderator
9:45-9:50	5	Introduction			
9:50-10:10	20	Presentation 1	Potential and Challenges of Applying Simulation to API Technology Transfer (Tentative)	Yuki Furusawa (Tanabe Pharma Factory Co., Ltd.)	—
10:10-10:30	20	Presentation 2	Case Studies on Technology Transfer in the SAM&GMP COP and Toward Better Technology Transfer (Tentative)	Masahito Watanabe (Kaken Pharmaceutical Co., Ltd.)	—
10:30-11:15	45	Presentation 3	Technology Transfer Activities and Process Chemistry (Tentative)	Takahiro Yoshikawa (Kongo Chemical Co., Ltd.)	Fumio Kishimoto
11:15-11:25	10	Coffee Break			
11:25-12:10	45	Presentation 4	TBD	Morio Wakisaka (Minophagen Pharmaceutical Co., Ltd.)	
12:10-12:55	45	Presentation 5	TBD	Osamu Hiruta (Tokyo University of Science)	
13:00-14:00	60	Lunch			



MC : Yasuaki Yabuki (AstraZeneca)

Time	minutes		Title	Speaker	Moderator
14:00-14:20	20	Presentation 1	Overview of Modeling and Recent Trends	Hirokazu Sugiyama (The University of Tokyo) Junu Kim (Auxilart)	Daisuke Yamakawa (Cytiva)
14:20-14:40	20	Presentation 2	Practical Applications of Modeling and Modality Expansion	Kazuo Okawa (Astellas)	
14:40-15:00	20	Presentation 3	Expectations for Modeling Based on Domestic and International Trends	Kozue Ugajin (PMDA)	
15:00-15:30	30	Panel Discussion		Speakers + Yoshihiro Matsuda (PMDA)	
15:30-15:45	15	Coffee Break			
15:45-16:45	60	Group Work	Introductory Modeling and Simulation Exercise (Open to Anyone with a Laptop)	Junu Kim (Auxilart)	Tomoyuki Taguchi (Chiyoda Corp.)



MC : Mayo Mimura (JGC Corp.)

Time	minutes	Chapter	Title	Speaker	Moderator
9:45-9:50	5	Introduction	Orientation and Introduction of C&Q COP	Mayo Mimura (JGC Corp.)	
9:50-10:00	10	Chapter 1 Chapter 2	Introduction Regulatory and Industry Guidance and Standards	Masahiko Yamaguchi (Kyoto Seisakusyo)	
10:00-10:15	15	Chapter 3 Chapter 4	Use Requirements Specification Types of Controlled Temperature Chambers	Ryohei Ogawa (TEC Project Service Corp.)	
10:15-11:15	60	Chapter 5	Commissioning and Qualification	Noboru Osaka (JGC Corp.) Masataka Tsuda (Kyowa Kirin Co., Ltd.) Mototsugu Mine (Catalent Shiga)	
11:15-11:30	15	Coffee Break			
11:30-12:30	60	Chapter 6 Chapter 7	System Monitoring Periodic Evaluation and Frequency of Thermal Mapping Studies	Masahiro Okuda (Shionogi Pharma Co., Ltd.) Tomoyuki Kuraishi (Pharma Planning Co., Ltd)	
12:30-12:45	15	Chapter 8 Chapter 9 Chapter 10	Maintenance Decommissioning Packaged Transport Systems	Akihiko Fukazawa (CHUGAI PHARMA MANUFACTURING Co., Ltd.)	
12:45-13:00	15	Q&A session	Questions & Answers	(ALL)	
13:00-14:00	60	Lunch			



Moderators: Wakako Kawada (Patheon by Thermo Fisher Scientific) / Emiko Yamada (Mitsubishi Chemical Engineering)

Time	minutes		Title	Speaker	Moderator
14:00-14:10	10	Introduction	Activities for Women in Pharma /About today's Workshop (goal)	Emiko Yamada (Mitsubishi Chemical Engineering)	Wakako Kawada (Patheon by Thermo Fisher Scientific)
14:10-15:00	50	Lectures	Diverse Leadership Stories (4 presentors)	Vivianne. A (Lonza) Leader 1 (TBD) Leader 2 (TBD) Leader 3 (TBD)	Wakako Kawada (Patheon by Thermo Fisher Scientific) Emiko Yamada (Mitsubishi Chemical Engineering)
15:00-15:40	40	Panel Discussion	Leadership Has Many Shapes	Vivianne. A (Lonza) Leader 1 (TBD) Leader 2 (TBD) Leader 3 (TBD)	Wakako Kawada (Patheon by Thermo Fisher Scientific) Emiko Yamada (Mitsubishi Chemical Engineering)
15:40-15:55	15	Coffee Break			
15:55-17:05	70	Roundtable Discussion	Designing Your Leadership Journey What Kind of Leader Do You Want to Be?	Group 1 ~5 (TBD)	Wakako Kawada (Patheon by Thermo Fisher Scientific) Emiko Yamada (Mitsubishi Chemical Engineering)
17:05-17:10	5	Closing	Key Takeaways from Today's Workshop	Wakako Kawada (Patheon by Thermo Fisher Scientific)	Emiko Yamada (Mitsubishi Chemical Engineering)



MC : Minoru Mihara (Marken Japan KK)

Time	minutes		Title	Speaker	Moderator
9:45-10:15	30	Panel Discussion	An Integrated Approach to Advancing Investigational Product Management and Supply (TBD)	WG Leaders or Speakers of the WG session	Tomoyuki Yamashita (Suvoda Software G.K.)
10:15-11:05	50	2D Code	TBD	Hitomi Okuhara (Bayer)	TBD
11:05-11:20	15	Coffee Break			
11:20-12:05	45	DDL WG	Digital Display Labels as an Emerging Tool for Modernizing Clinical Labeling	Yoshiharu Naka (Otsuka Pharmaceutical Co., Ltd.)	Atsushi Minami (Novartis Pharma K.K.)
12:05-13:00	55	HHC	Home Healthcare service as a part of DCT	Minoru Mihara (Marken Japan KK)	