

2023 Annual Meeting Program (Japan Affiliate)

As of 2023/5/12

May 18 Annual General Meeting 9:30-10:20

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|----------------|-------------------|---------------|---|---------------------|---------------------------------|--|
| 5F Hall | 9:30-10:20 | 50 | | MC: Akihiro Matsuki | Head of Secretariat | |
| | | | Welcome | Hirokazu Kisaka | Chairman | |
| | | | Nomination and Election of AGM chairman | | | |
| | | | 2022 Activity Report | Akihiro Matsuki | Head of Secretariat | |
| | | | 2022 Financial Report | Tetsuro Noguchi | Treasurer | |
| | | | 2022 Internal Audit Report | Munetaka Hattori | Japan Affiliate Auditor | |
| | | | 2023 Action Plan | Akihiro Matsuki | Head of Secretariat | |
| | | | 2023 Budget Proposal | Tetsuro Noguchi | Treasurer | |
| | | | 2023 Election Results of Board & Officers | Toshio kawakita | 2023 Head of Election Committee | |
| Bylaw Revision | Hiroshi Yamaguchi | Past Chairman | | | | |

May 18 Annual Conference 10:30-17:20

| Venue | Time | minutes | Title | Speaker | Affiliation | Moderator | Affiliation |
|---------------|-------------|---------|--------------------------|--|---------------------------------------|--|---|
| 5F Hall | 10:30-10:35 | 5 | Orientation | MC: Daisuke Hirasawa | Chugai Pharma Manufacturing Co., Ltd. | | |
| | 10:35-10:45 | 10 | Opening Remarks | Welcome and Opening | Chair, ISPE Japan Affiliate | ISPE Japan Affiliate 2023 Chair | |
| | 10:45-11:05 | 20 | ISPE HQ Update | ISPE International Update & Strategic Planning | Thomas Hartman | ISPE President & CEO | |
| | 11:05-11:55 | 50 | Keynote Speech 1 | Promotion of Well-being in the 100-year life | Yoshihide Esaki | Director, Institute for Social Policy Issues | Hirokazu Kisaka ISPE Japan Affilaite Chairman |
| 2F Event Hall | 11:55-13:00 | 65 | Lunch (Luncheon Seminar) | | | | |
| 5F Hall | 13:00-13:50 | 50 | Keynote Speech 2 | The Present and Future of Digital Health | Naohisa Yahagi | Professor, Keio University, Graduate School of Media and Governance | Hiroshi Yamaguchi ISPE Japan Affiliate Past Chairman |
| | 13:50-14:40 | 50 | Keynote Speech 3 | MHLW Update | Fumi Yamamoto | Councilor for Pharmaceutical Affairs Minister. S Secretariat, MHLW | Junya Soma ISPE Japan Affiliate Vice Chairman |
| | 14:40-15:30 | 50 | Keynote Speech 4 | 2022 Annual Meeting Keynote session FDA Quality: The Key Ingredient for Stable Pharmaceutical Supply Chains | Michael Kopcha | Director, Office of Pharmaceutical Quality Center for Drug Evaluation and Research, FDA | |
| 2F Event Hall | 15:30-16:10 | 40 | Coffee Break | | | | |
| 5F Hall | 16:10-16:25 | 15 | ISPE HQ Update | ISPE International Update information on COP and Technical communities | Tim Postlethwaite | ISPE Director, Technical Communities | |
| | 16:25-17:15 | 50 | Special Lecture 1 | A Look To The Future of Regulated Drug Manufacturing | Robert Chew | Chairman and Chief Innovation Officer Commissioning Agents, INC. | Hirofumi Suzuki ISPE International Board of Director |
| | 17:15-17:20 | 5 | Closing Remark for Day 1 | | Akihiro Matsumi | Chairman, 2023 Annual Meeting Organizing Committee/ Japan Affiliate Head of Secretariat | |

May 19 Workshops 9:30-17:00

| Venue | Time | minutes | | Title | Speaker | Affiliation | Moderator | Affiliation |
|------------------|---|---------|-------|---|--------------------------------------|---|-------------------|---------------------------------------|
| 2 F Zuiun | 9:30-12:45 Workshop 1-1 SPP COP | | | | | | | |
| AM | Theme : It's time to explore the sterile frontier! | | | | MC: Hironobu Sunayama | SHIBUYA CORPORATION | | |
| | 9:30-9:40 | 10 | | Introduction of SPP COP | Kentaro Nakamura | SPP COP Leader, JGC JAPAN CORPORATION | NA | |
| | 9:40-10:40 | 60 | | The implications of Annex 1 for Aseptic Processing worldwide | Joerg Zimmermann | Vetter Development Service, Former chair of the ISPE | Kentaro Nakamura | SPP COP Leader, JGC JAPAN CORPORATION |
| | 10:40-11:30 | 50 | | When to consider single-use system risks and direction of risk reduction ~ Overview of how and when risk reduction measures are reflected in single-use specifications ~ | Susumu Sugiyama Norioki Masai | FUJIFILM Corporation Shionogi Pharma Co., Ltd. | Seiji Shimura | Nihon Pall Ltd. |
| | 11:30-11:45 | 15 | Break | | | | | |
| | 11:45-12:45 | 60 | | Impact of robotics and automation in aseptic manufacturing | Shiobu Ito Michiyoshi Ono | Toray Engineering Co.,Ltd. Pharma Solutions Co., Ltd. | Ken Nagai | Airex Co., Ltd. |
| | 12:45-13:45 | 60 | Lunch | (Mini-Luncheon Seminar) | | | | |
| 2 F Zuiun | 13:45-17:00 Workshop 1-2 SPP COP | | | | | | | |
| PM | Theme : It's time to explore the sterile frontier! | | | | MC: Hironobu Sunayama | SHIBUYA CORPORATION | | |
| | 13:45-14:45 | 60 | | The Ideal of Sterile Drug Manufacturing from FDA Form 483s | Toshihide Takemoto | KANTO CHEMICAL CO.,INC. | Kiyoshi Mochizuki | X Pro Associates |
| | 14:45-15:35 | 50 | | An investigation of the relationships between air velocity and air flow pattern around the manufacturing equipment Part II | Fumihito Takashima Yoshinari Sano | OSHITARI LABORATORY,INC. NITTA CORPORATION | Minoru Tamura | Airex Co., Ltd. |
| | 15:35-15:55 | 15 | Break | | | | | |
| | 15:55-16:45 | 50 | | Report on Isolators and RABS survey in 2023 | Kimihiko Yatsu Mirai Tamukai | KANTO CHEMICAL CO.,INC. HIKARI PHARMACEUTICAL CO.,LTD. | Ken Nagai | Airex Co., Ltd. |
| | 16:45-16:55 | 10 | | Introduction of the seminar of the new ISPE Sterile Product Manufacturing Facilities Baseline Guide, 3rd edition (Japanese version) | Atsushi Osao | FUJIFILM Engineering CO.,LTD | NA | |
| | 16:55-17:00 | 5 | | Closing remarks | Hironobu Sunayama | SHIBUYA CORPORATION | NA | |

| Venue | Time | minutes | | Title | Speaker | Affiliation | Moderator | Affiliation |
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| 2 F Heian | 9:30-12:45 Workshop 2 FoF | | | | | | | |
| AM | Theme : Facilities of the future Smart Factory | | | | MC: Akihiro Matsuki | Mitsubishi Chemical Engineering Corporation | | |
| | 9:30-10:00 | 30 | Lecture 1 | Facilities of the future Smart Factory | Hirkazu kisaka | Kyowa Kirin Co.,Ltd | | |
| | 10:00-10:30 | 30 | Lecture 2 | Digital Transformation Activity Report | Rei Kobayashi | DAIICHI SANKYO PROPHARMA CO.,LTD | | |
| | 10:30-11:30 | 60 | Lecture 3 | Smart Factory | Yoshiyuki Yamashita | Professor, Tokyo University of Agriculture and Technology | | |
| | 11:30-11:45 | 15 | Break | | | | | |
| | 11:45-12:30 | 45 | Panel Discussion | Panel Discussion | Hideaki Hosaka Shuheii Wakamatsu Makoto Kaneko Koji Kawano Takehisa Kanemaru | Chugai Pharma Manufacturing Co., Ltd. Chiyoda Corporation Siemens K.K. Mitsubishi Chemical Engineering Corporation JGC JAPAN CORPORATION | | |
| | 12:45-13:45 | 60 | Lunch | (Mini-Luncheon Seminar) | | | | |
| 2 F Heian | 13:45-17:00 Workshop 6 Containment COP & EHS COP | | | | | | | |
| PM | 13:45-16:15 Workshop 6-1 Containment COP | | | | | | | |
| | Theme : Risk Based Approach for manufacturing of highly potent products | | | | MC :Shinichiro Matsunaga | Takeda Pharmaceutical Company Limited | | |
| | 13:45-14:30 | 45 | Special Lecture | PDE setting for drugs without toxicological information | Tae Hyashi | Chemicals Escaliation Reseach Institute | Shinichiro Matsunaga | Takeda Pharmaceutical Company Limited |
| | 14:30-15:15 | 45 | Containment COP | Aiming to improve the usability of PEEM-DB : 2022 Activity Report | Yuko Tanaka Yutaro Ishikawa | Nara Machinery Co., Ltd. Sumika Chemical Analysis Service, Ltd. | Yohei Sasaki | TAKENAKA CORPORATION |
| | 15:15-15:30 | 10 | Break | | | | | |
| | 15:30-16:15 | 45 | Special Lecture | High Potent Drug Products Building at Shionogi Pharma - Introduction of Construction Case - | Yuta Hamabe | Shionogi Pharma Co., Ltd. | Munetaka Hattori | Pharmaceutical consultant |
| | 16:15-17:00 Workshop 6-2 EHS COP | | | | | | | |
| Theme : Seeking the Well-Being of EHS (Occupational Health, Safety and Environment) in pharmaceutical industry | | | | MC: Ayumi Hasegawa | Ono Pharmaceutical Co., Ltd. | | | |
| 16:15-17:00 | 45 | EHS COP | How should be controlled and promoted EHS activity ? | Tomoyuki Hasegawa | Ono Pharmaceutical Co., Ltd. | Nobuaki Kato | Chugai Pharmaceutical Co., Ltd. | |

| Venue | Time | minutes | Title | | Speaker | Affiliation | Moderator | Affiliation |
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| 2 F Fukuju | 9:30-12:45 Workshop 3 ATMP COP | | | | | | | |
| AM | Theme : An approach from the new modality area for the realization of well-being | | | | MC: Tsutomu Igarashi | ATMP COP Leader, Takeda Pharmaceutical Company | | |
| | 9:30-9:45 | 15 | Introduction | COP activities & today's agenda | Tsutomu Igarashi | ATMP COP Leader, Takeda | | |
| | 9:45-10:35 | 50 | Key Note | -Japan-U.S. ATMP collaboration session- ATMP Guidance Development and Industry Trends | Erich Bozenhardt | ATMP COP(USA) Chair, United Therapeutics Inc. | Tsutomu Igarashi | ATMP COP Leader, Takeda Pharmaceutical Company |
| | 10:35-10:45 | 10 | Break | | | | | |
| | 10:45-11:45 | 60 | Lecture 1 | Trend of manufacturing processes and facility plans for cell therapy products | Tetsuro Hatsuoka | Kajima Corporation | Tsutomu Igarashi | ATMP COP Leader, Takeda Pharmaceutical Company |
| | 11:45-11:55 | 10 | Break | | | | | |
| | 11:55-12:45 | 50 | Lecture 2 | Overview of "ISPE GUIDE: ATMPs Autologous Cell Therapy" | Ryu Ueda | Chiyoda Corporation | Tsutomu Igarashi | ATMP COP Leader, Takeda Pharmaceutical Company |
| | 12:45-13:45 | 60 | Lunch | (Mini-Luncheon Seminar) | | | | |
| 2 F Fukuju | 13:45-17:00 Workshop 7 BIO COP | | | | | | | |
| PM | Theme : The Latest Information on Global Engineering Standard for Biopharmaceutical Manufacturing Facility ~Introduction to ASME BPE 2022~ | | | | MC: Takashi Kaminagayoshi | BIO COP Leader, Takeda | | |
| | 13:45-14:00 | 15 | Introduction | COP Activities & Today's Agenda | Takashi Kaminagayoshi | BIO COP Leader, Takeda | | |
| | 14:00-14:50 | 50 | Lecture 1 | Positioning of ASME BPE & Initiatives in BIO COP ※Recorded | Masashi Oda Ken Kimbrel | Hitachi Plant Services Chair, ASME BPE Standards Committee, VNE Corporation | Takashi Kaminagayoshi | |
| | 14:50-15:05 | 15 | Break | | | | | |
| | 15:05-15:55 | 50 | Lecture 2 | Overview of ASME BPE 2022 | Makoto Sekine | B.E.Marubishi | Osamu Shirokizawa | |
| | 15:55-16:10 | 15 | Break | | | | | |
| | 16:10-17:00 | 50 | Lecture 3 | Detailed description of single-use technology related contents | Iyo Terashima | Thermo Fisher Scientific | Shuji Ninomiya | |

| Venue | Time | minutes | Title | | Speaker | Affiliation | Moderator | Affiliation |
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| 2 F Togen | 9:30-12:45 Workshop 4 : API COP | | | | | | | |
| AM | Theme :Practice and Issues of Process Simulator in the Pharmaceutical Industry ~First step toward a digital strategy~ | | | | MC: Natsumi Iwanaga | | | |
| | 09:30-09:40 | 10 | Opening Remarks | Opening Remarks from COP Leader | Muneki Kishida | Mitsubishi Tanabe Pharma Corporation | | |
| | 09:40-10:20 | 40 | Lecture1 | Systematic and emotional ways of process modeling | Sanghong Kim | Tokyo University of Agriculture and Technology | Yoshio hidaka | Takeda Pharmaceutical Company Limited |
| | 10:20-11:00 | 40 | COP Activity Report | API×Process Simulation ~ Report on Modeling of Virtual API "HMCIN" ~ | Makoto Nakaya | Yokogawa Electric Corporation | Ayako Nakajima | Q&EHS Solutions Corporation |
| | 11:00-11:10 | 15 | Break | | | | | |
| | 11:10-12:00 | 50 | Lecture2 | Digital design and operation of robust drug substance manufacture processes: Industry cases & value statements ※Recorded | Niall Mitchell Shigeru Kashiwaya | Siemens Process Systems Engineering Ltd., London, UK | Masaaki Nakata | Siemens Process Systems Engineering |
| | 12:00-12:40 | 40 | Lecture3 | Combining artificial intelligence and simulation modelling for drug substance manufacturing | Motoki Irikura | Chiyoda Corporation | Yu Sagae | Eisai Co., Ltd |
| | 12:45-13:30 | 45 | Lunch | | | | | |

| Venue | Time | minutes | Title | | Speaker | Affiliation | Moderator | Affiliation |
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| 2 F Horai | 9:30-12:45 Workshop 5 IP COP | | | | | | | |
| AM | Theme : Multifaceted Good Practice in Clinical Supply | | | | | | | |
| | 09:30-09:35 | 5 | | IP-COP Introduction | Yoshihiko Sato | IP-COP Chair, Mitsubishi Logistics Corporation | — | — |
| | 09:35-10:20 | 45 | Lecture1 | The GAP between Regulations and Actual activities in Investigational product, and the proposals | Yoshihiro Sawada | IP-COP Regulatory & Customs WG Lead, Astra Zeneca K.K. | Chika Ishihara | Marken Japan Limited. |
| | 10:20:-10:55 | 35 | Lecture2 | Direct to Patient (Japan local and Global status update) | Minoru Mihara | IP-COP DtP/DfP WG Lead, Marken Japan Limited. | Naoya Okamura | Mitsubishi Logistics Corporation |
| | 10:55-11:00 | 5 | Break | | | | | |
| | 11:00-11:55 | 55 | Lecture3 | Current situations and issues of outsourcing in clinical supply (Insurance, Customs clearance, Destruction, and Subcontracting) | Kenichi Kuchiki | IP-COP Outsourcing WG Lead, Mitsui-Soko Holdings Co.,Ltd. | Yoshihiko Sato | Mitsubishi Logistics Corporation |
| | 11:55-12:40 | 45 | Lecture4 | Future label with 2D-code on Investigational Products: Current status and prospect for digitalization | Hitomi Okuhara | IP-COP 2D-code WG Lead, Bayer Yakuhin, Ltd. | Claire Tsukada | Pfizer R&D Japan G.K. |
| | 12:40-12:45 | 5 | | IP-COP Closing | Yoshihiko Sato | IP-COP Chair, Mitsubishi Logistics Corporation | — | — |
| | 12:45-13:45 | | Lunch | | | | | |