May 24: Annual General Meeting 9:30-10:30

4F Main Hall | 09:30-10:30
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09:30-10:30 Annual General Meeting | MC: Akihiro Matsuki
Welcome | Hirofumi Suzuki
Nomination and Election of AGM chairman | Akihiro Matsuki
2017 Activity Report | Hiroshi Sakai
2017 Financial Report | Hirono Matsuki
2017 Internal Audit Report | Ayako Nakajima
2016 Action Plan | Hiroshi Sakai
2016 Budget Proposal | Hiroshi Sakai
2016 Election Results of Board & Officers | Katsuhiko Kaneda

As of 2018/05/08

May 24: Annual Conference 10:40-17:50

Venue | Time | Event | Title | Speaker | Affiliation | Moderator | Affiliation
---|---|---|---|---|---|---|---
4F Main Hall | 10:40-11:20 | Opening Remarks 1 | | Akihiro Matsuki | | ISPE Japan Affiliate Chairman | ISPE Japan Affiliate
5F Main Hall | 10:40-11:20 | Opening Remarks 2 | | Timothy P. Howard | | Chair, ISPE International | ISPE International
4F Main Hall | 11:20-12:10 | Keynote Speech 1 | | Sau (Larry) Lee | | Deputy Director, Emerging Technology Team Chair Office of Testing and Research/DPIQ/FDA | Ayako Nakajima
4F Main Hall | 12:10-13:10 | Lunch | | | | | Isupin Nakamura
5F Main Hall | 13:10-13:55 | Keynote Speech 2 | | Kenta Harimoto | | Director, International Business Promotion Office, Healthcare Industries Division | Shigeru Nakamura
5F Main Hall | 13:55-14:40 | Special Lecture 1 | | Christian Wiedeling | | Senior Director Global Accounts | Shigeru Nakamura
5F Main Hall | 14:40-15:25 | Special Lecture 2 | | Andreas Flueckiger | | Chief Occupational Health Officer | Shigeru Nakamura
4F Main Hall | 15:25-16:10 | Coffee Break | | | | | Shigeru Nakamura
5F Main Hall | 16:10-17:00 | Special Lecture 3 | | Naohisa Yahagi | | Associate Professor, Graduate School of Media and Governance | Hiroshi Yamaguchi
5F Main Hall | 17:00-17:50 | Keynote Speech 3 | | Yoshino Motoda | | Senior Scientist (for Quality) Pharmaceutical 
Management Division, Pharmaceutical & Medical Devices Agency | Ayako Nakajima
5F Main Hall | 18:00-20:00 | Networking Party | | | | | Shigeru Nakamura

May 25: Workshops 9:15-17:00

| Venue | Time | Title | Speaker | Affiliation | Moderator | Affiliation
---|---|---|---|---|---|---
1F Zunun | 09:15-12:30 | Workshop 1-1: CONTAINMENT COP | MC: Koji Yamaura | | | 
| 9:15-9:45 | Workshop 1-2: Introduction of Containment COP Activities | Koji Yamaura | | | 
| 9:45-10:15 | Workshop 1-3: Practical Aspects of Containment | Andreas Flueckiger | | | 
| 10:15-10:45 | Break | | | | | 
| 10:45-11:15 | Workshop 1-4: Case Study of Risk Assessment of OSD Manufacturing | Masahiro Yamamoto | | | 
| 11:15-12:30 | Workshop 1-5: Current Status and a Sample of Pharmaceutical Equipment Exposure Measurement - Updated Data Base (PEEM 2018) | Haruka Futamura / Syunsuke Kumakura | | | 
| 12:30-13:00 | Lunch | | | | |
**2f Zushi**

**13:30-17:00 Workshop 1** - CONTAINMENT COP

- **13:30-14:00** 30 Containment COP Introduction of PDE Setting Roundtable in Japan
  - Shinichiro Matsuura
  - Shunji Kato
  - Takeda Pharmaceutical Company Limited

- **14:00-14:45** 45 Containment COP Progress of PDE Setting Roundtable Activity
  - Tatsuya Hasegawa
  - Otsu Pharmaceutical Company Limited

- **14:45-15:00** Break

- **15:00-16:00** 60 Special Lecture Determining Occupational Exposure Limit (OEL) and Permitted Daily Exposure (PDE) values
  - Elke Weber
  - Occupational Health Specialist
  - F. Hoffmann-La Roche Ltd. Basel

- **16:00-16:30** 30 Special Lecture PDE Derivation Based on the Concepts of Toxicology and Risk Assessment
  - Yosuke Hirose
  - Director, Division of Risk Assessment
  - National Institute of Health Sciences

- **16:30-17:00** 30 Special Lecture ASSESSMENT AND CONTROL OF DNA REACTIVE (MUTAGENIC) IMPURITIES IN PHARMACEUTICALS
  - Masayuki Horina
  - Director, Division of Genetics and Mutagenesis
  - National Institute of Health Sciences

**3f Heian**

**9:15-12:30 Workshop 2** - BIO COP

- **9:15-9:30** 15 Lecture Introduction of BIO COP
  - Sei Murakami
  - BIO COP Leader

- **9:30-10:10** 40 Lecture SPE Guide: Biopharmaceutical Process Development and Manufacturing
  - Fumi Nakahori
  - Kansai Pharmaceutical Corporation

  - Teru Ogawa
  - Chugai Pharmaceutical Co., Ltd.

- **10:50-11:15** 15 Break

- **11:05-11:45** 40 Lecture SPE Guide: Biopharmaceutical Process Development and Manufacturing
  - Akira Takeda
  - Chugai Pharmaceutical Co., Ltd.

- **11:45-12:30** 45 Lecture Made-in-Japan Platform Technology for Therapeutic Antibody Manufacturing - Perspective for Project iMAB
  - Yuichi Osumi
  - Graduate School of Engineering, Osaka University

- **12:30-13:30** 60 Lunch

**2f Heian**

**13:30-17:00 Workshop 5** - SPP COP

- **13:30-13:40** 10 Fast Talk into the trend of Sterile pharmaceutical processes
  - Koji Kawasumi
  - K.T.MFG.CO., LTD.

- **13:40-14:25** 45 Lecture 1 Top tip: Not to Use Single-use System When Planning New Production Lines
  - Seiji Shimura
  - Pall Corporation

- **14:25-14:50** 25 Lecture 2 Lessons learned from FDA 483s issued for sterile Products Processing
  - Kiyoshi Mochizuki
  - Nippon Suisan Co., Ltd.

- **14:50-15:00** 10 Break

- **15:00-15:45** 45 Lecture 3 Outline of the draft revision of PIC/S Annex 1 on RAMS
  - Kenji Kosaka
  - Takeda Pharmaceutical Co., Ltd.

- **15:45-16:30** 45 Lecture 4 Report of air flow pattern studies
  - Yasuuki Ando
  - Astellas Pharma Inc.

- **16:30-17:00** 30 Lecture Topics of revision draft of EU and PIC/S GMP Annex 1
  - Kenji Nakamura
  - GSC CORPORATION

**2f Fukui**

**9:30-12:30 Workshop 1** - API COP

- **9:30-9:35** 5 Welcome Remarks
  - Akira Kunimatu

- **9:35-10:20** 50 Lecture1 The manufacturing industry will be redefined with continuous manufacturing
  - Takesi Sato
  - TAKASAGO CHEMICAL CORPORATION

- **10:20-10:50** 30 Lecture2 A case study of continuous manufacturing in mock-up API (HMCIN) plant
  - Tomohiro Mizusako
  - TAKASAGO CHEMICAL CORPORATION

- **10:55-11:10** 15 Break

- **11:10-11:35** 20 Lecture3 The Feature of Small Continuous Crystallizer and Examples of Crystallization
  - Ryo Hara
  - TOUGU CORPORATION

- **11:35-11:50** 20 Lecture4 Features of Mi reactor and Continuous reactors
  - Tsuyoshi Kada
  - NISSAN ENGINEERING CO., LTD.

- **11:50-12:10** 20 Lecture5 The role of PAT in the continuous processes of pharmaceuticals
  - Yuki Harasawa
  - METTLER TOLEDO

- **12:10-12:30** 20 Lecture6 Introduction of an approach for pharmaceutical continuous manufacturing by CONTINUOS pharmaceuticals
  - Masahiro Kawano
  - GSC CORPORATION

- **12:30-13:30** 60 Lunch

**2f Fukui**

**13:30-17:00 Workshop 2** - API COP

- **13:30-14:20** 50 Lecture? Movement on continuous manufacturing of APIs and the effort in DAICHI SANKYO
  - Hiroshi Nagasu
  - DAICHI SANKYO COMPANY, LIMITED

- **14:30-15:15** 50 Lecture1 Innovation of API Production Using Few First Syntesis
  - Shu Nakayama
  - Department of Chemistry, School of Science, Tohoku University

- **15:30-16:15** 30 Lecture2 Continuous manufacturing of API - issues and the challenge
  - Yukari Sato
  - Tsubasa Shimizu
  - Takeda Pharmaceutical Co., Ltd.

- **16:20-16:45** 5 Special Lecture
  - Hiroshi Nagasu
  - TEI PROJECT SERVICES CORPORATION
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<th>Time</th>
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<th>Speaker(s)</th>
<th>Sponsor(s)</th>
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<tr>
<td>9:15-12:30</td>
<td>Workshop 1:YP (Workshop for Young Professionals)</td>
<td>Yoshihiko Sato</td>
<td>Astubi Corporation</td>
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<td>9:15-12:30</td>
<td>Introduction about YP</td>
<td>Yoshihiko Sato</td>
<td>Astubi Corporation</td>
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<td>10:00-11:00</td>
<td>URS report from team (3 team)</td>
<td>Takahito Takehashi</td>
<td>KEDANOHANO CO., LTD.</td>
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<td>11:10-12:10</td>
<td>Group work</td>
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<td>Workshop 4:IP COP</td>
<td>Yoshihiko Sato</td>
<td>Pfizer Japan Inc.</td>
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<td>Yoshihiko Yamauchi</td>
<td>C&amp;Q COP</td>
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<td>Yoshihiko Yamauchi</td>
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<td>Workshop 8:PACKAGING COP</td>
<td>Manami Takahashi</td>
<td>Mitsubishi Logistics Corporation</td>
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