

## 2012 Annual Meeting Program (Japan Affiliate)

Grand Prince Hotel Hiroshima 23-1, Motoujina-machi, Minami-ku, Hiroshima-shi, Hiroshima 734-8543 TEL:082-256-1111

As of April 25

### April 12 Annual General Meeting 10:00~10:30

|                                    |    |   |   |                         |
|------------------------------------|----|---|---|-------------------------|
| 10:00-10:30 Annual General Meeting |    | MC: Shigeru Nakamura                    | Head of Secretariat/Shimizu Corporation |                         |
| 10:00-10:30                        | 30 | Welcome                                 | Tatsuro Miyagawa                        | Chairman                |
|                                    |    | Nomination and Election of AGM chairman |   |                         |
|                                    |    | 2011 Activity Report                    | Shigeru Nakamura                        | Head of Secretariat     |
|                                    |    | 2011 Financial Report                   | Kenzo Toyoshima                         | Treasurer               |
|                                    |    | 2011 Internal Audit Report              | Takeshi Takashima                       | Japan Affiliate Auditor |
|                                    |    | 2012 Action Plan                        | Shigeru Nakamura                        | Head of Secretariat     |
|                                    |    | 2012 Budget Proposal                    | Kenzo Toyoshima                         | Treasurer               |
|                                    |    | Election Results of Board & Officers    |   | Executive Director      |

### April 12 Annual Conference 10:50~18:00

| Time        | Minutes | Downloads         | Title   | Speaker                       |   | Moderator          |                                  |
|-------------|---------|-------------------|---|-------------------------------|---|--------------------|----------------------------------|
| 10:50-11:10 | 20      | Welcome Remarks 1 |   | 2012 Japan Affiliate Chairman | ISPE Japan Affiliate  |                    |                                  |
|             |         | Welcome Remarks 2 |   | Nancy Berg                    | ISPE International  |                    |                                  |
| 11:10-12:00 | 50      | Keynote Speech 1  | Preparation for PIC/S accession: Challenges and Prospects                 | Shingo Sakurai                | PMDA  | Tetsuhiro Takarada | Mochida Pharmaceutical Co., LTD. |
| 12:00-13:00 | 60      | Lunch             | Luncheon Seminar & Table Top Exhibition                                   |                               |   |                    |                                  |
| 13:00-13:50 | 50      | Keynote Speech 2  | Recent regulatory trend in US (Video)                                     | Ilisa Bernstein               | FDA   | Kenzo Toyoshima    | SSP CO., LTD.                    |
| 13:50-14:40 | 50      | Special Lecture 1 | MedImmune in Frederick, Maryland: Our 2011 FOYA-winning Plant (Tentative) | Andrew Skibo                  | MedImmune   | Tatsuro Miyagawa   | CMIC CMO CO., LTD.               |
| 14:40-15:10 | 30      | Coffee Break      |   |                               |   |                    |                                  |
| 15:10-16:00 | 50      | Special Lecture 2 | PIC/S: Benefits for Japan Handling PIC/S Inspections                      | Helena Baião                  | PIC/S   | Munetaka Hattori   | Towa Pharmaceutical Co., Ltd.    |
| 16:00-16:50 | 50      | Special Lecture 3 | Revised Annex 11 -a GAMP and PIC/S Perspective                            | Sion Wyn                      | Conformity Ltd.   | Masayuki Akutagawa | Yamatake Corporation             |
| 16:50-17:10 | 20      | Break             |   |                               |   |                    |                                  |
| 17:10-18:00 | 50      | Special Lecture 4 | Pharma Industry Update and Astellas's Target                              | Masafumi Nogimori             | Astellas Pharma Inc. Representative Director, Chairman of the Board | Takeshi Furukawa   | Astellas Pharma Inc.             |
| 18:00-20:30 | 150     |                   | 10th Anniversary Party  |                               |   |                    |                                  |

### April 13 Workshops 9:00~16:30

>Please choose one Workshop in the morning and one workshop in the afternoon. The registration fee covers the entire two-day program, including the Networking Party

|                        | Time  | Minutes     | Downloads                               | Title  | Speaker  |  | Moderator                                     |  |
|------------------------|---|-------------|---|--|--|--|---|--|
| 13-Apr<br>Friday<br>AM | <b>9:00-16:30 Workshop 1 : PQLI, SAM&amp;GMP, API COP</b>                                 |             |   |  | MC: Jyunya Souma   | GlaxoSmithKline K.K.   |   |  |
|                        | <b>Approach for QbD by Q-quartet</b>  |             |   |  |  |  |   |  |
|                        | 9:00-9:40   | 40          | PQLI SAM&GMP API 1 & PQLI SAM&GMP API 2 | PQLI Update  | John Lepore/Roger Nosal  | Merck/Pfizer   | Yoshihito Ikeda                               | Seikagaku Co.                              |
|                        | 9:40-10:20  | 40          | PQLI SAM&GMP API 2                      | PQLI GPG Update and Application at the Plant   | John Lepore/Roger Nosal  | Merck/Pfizer   |   |  |
|                        | 10:20-10:30   | 10          | Break                                   |  |  |  |   |  |
|                        | 10:30-12:00   | 90          | PQLI SAM&GMP API 3                      | QbD Applied in the Industries  | Kenji Hamaura  | DAIICHI SANKYO CO., LTD.   | Yoshihito Ikeda                               | Seikagaku Co.                              |
|                        |   |             | PQLI SAM&GMP API 4                      | QbD Applied in the Industries  | John Lepore  | Merck  |   |  |
|                        |   |             | PQLI SAM&GMP API 5                      | Case Study of ICH Q11 Step2 Applied to Small Molecule API  | Yoshitaka Nishida  | Sumitomo Chemical Co., Ltd.  |   |  |
|                        | 12:00-12:45   | 45          | Lunch                                   |  |  |  |   |  |
|                        | PM  | 12:45-13:35 | 50                                      | PQLI SAM&GMP API 6   | Sakuramil Mock: An Outcome of MHLW Sponsored Science Research Study Group for Implementing Q11 | Haruhiro Okuda   | NIHS  | Yoshiaki Kato                              |
| 13:35-14:30            |   | 55          | PQLI SAM&GMP API 7                      | EFPIA'S Mock S2 Project for Small Molecule Drug Substance Update on EMA consultations              | Frank Montgomery   | Astra Zeneca/SBRS  |   |  |
| 14:30-14:45            |   | 15          | Break                                   |  |  |  |   |  |
| 14:45-15:30            |   | 45          | PQLI SAM&GMP API 8                      | The current state of QbD applications in Japan   | Yoshihiro Matsuda  | PMDA   | Yoshiaki Kato                                 | Teijin Pharma                              |
| 15:30-16:30            |   | 60          | Panel discussion                        | Challenges in Implementing Enhanced Approach   | John Lepore, Roger Nosal, Haruhiro Okuda, Frank Montgomery, Yoshihiro Matsuda, Kenji Hamaura   | Merck, Pfizer, NIHS, Astra Zeneca/SBRS, PMDA, DAIICHI SANKYO           | Tsutom Kojima, Takayuki Owaki, Ayako Nakajima | Ono Pharmaceutical, Eisai, Nissan Chemical |
| AM                     | <b>9:00-16:30 Workshop 2-1, 2-2: Containment COP</b>                                      |             |   |  | MC: Morihiko Takeda  | Pharma Solutions Co Ltd  |   |  |
|                        | <b>Containment Technologies &amp; Risk Based Manufacturing for Highly Potent Products</b> |             |   |  |  |  |   |  |
|                        | 9:00-10:00  | 60          | Containment 1                           | Risk-MaPP Past, Present and Future   | Stephanie Wilkins  | President of PharmaConsult US, Inc., / Chairman of Risk MaPP Task Team | Jun Ooyama                                    | KIKUSUI SEISAKUSHO                         |
|                        | 10:00-11:00   | 60          | Containment 2                           | Trends in Containment  | Julian Wilkins   | VP PharmaConsult US inc.   | Masahiro Oda                                  | Nihon Pall                                 |
|                        | 11:00-11:15   | 15          | Break                                   |  |  |  |   |  |
|                        | 11:15-12:15   | 60          | Containment 3                           | Example of Risk Assessment by FMEA (from viewpoints of Cross-contamination and industrial hygiene) | Hisao Takahashi  | ISPE Japan Containment COP   | Takahide Hashizume                            | HATA IRON WORKS                            |
|                        | 12:15-13:00   | 45          | Lunch                                   |  |  |  |   |  |

|   |   |   |  |  |  |  |   |                            |
|---|---|---|--|--|--|--|---|----------------------------|
| PM  | 13:00-14:45   | 105   | Containment 4  | Handling potent compounds: Integrating the risk-based approaches of industrial hygiene and GMP(Introducing highly potent API/QSD/Parenteral manufacturing)                           | Andreas Flueckiger   | Chief Occupational Health Officer, F. Hoffmann-La Roche Ltd. Basel           | Daisuke Hirasawa                              | CHUGAI PHARMACEUTICAL      |
|   | 14:45-14:55   | 10  | Break  |  |  |  |   |                            |
|   | 14:55-15:10   | 15  | Containment 5  | Introduction of the Local ISPE COP Containment in Germany/Austria /Switzerland and the current status of the Containment Manual  | Richard Denk   | Leader of D/A/CH Containment C   | Morihiro Takeda                               | Pharma Solutions           |
|   | 15:10-15:50   | 40  | Containment 6  | Introduction of Containment Technologies applied to API Facilities   | Richard Denk   | the Head of the Pharma and Sales Department from Hecht                       | Yuji Yamaura                                  | ASAHI KASEI FINECHEM       |
|   | 15:50-16:30   | 40  | Containment 7  | Introduction of containment technologies in tableting  | Ingo Stammnitz   | KORSCH, Director Asia-Pacific  | Hiroaki Matsumoto                             | ASAHI KASEI FINECHEM       |
| <b>9:00-16:00 Workshop 3-1,3-2: MM COP</b>  |   |   |  |  | MC: Kiyoshi Yoshida  | GlaxoSmithKline  |   |                            |
| <b>For the Patients - The approach for the improvement in products quality and the stable products supply</b> |   |   |  |  |  |  |   |                            |
| AM  | 9:00 - 9:20   | 20  | MM 1   | Introduction   | Hideaki Hirukawa   | MSD  |   |                            |
|   | 9:20 - 10:30  | 70  | MM 2   | Analytical approach for Human Error  | Makoto Takeda  | NIPPON SHINYAKU CO.,LTD.   | Makoto Takao                                  | MSD                        |
|   |   |   |  | Keynote lecture : Interview method   | Makoto Takao   | MSD  |   |                            |
|   |   |   |  | Case Study 1 : Simplified case   | Satoshi Murata   | TAIHO PHARMACEUTICAL CO.,LTD.  |   |                            |
|   | 10:30 - 10:45   | 15  | Break  |  |  |  |   |                            |
| 10:45 - 12:00   | 75  | MM 3  | Work : manner of utilization for m-SHEL chart  | Satoru Murase,Kyoko Toshinai, Hideaki Ogihara  | Ajinomoto Pharmaceutical, Bushu PharmaceuticalsLtd.,MKS Japan Inc. | Makoto Takao   | MSD   |                            |
|   |   |   | Case Study 2 : Complicated case  | Goichi Yokoyama  | sanofi-aventis K.K   |  |   |                            |
|   |   |   | Conclusion   | Hideaki Hirukawa   | MSD  |  |   |                            |
| PM  | 12:00 - 13:00   | 60  | Lunch  |  |  |  |   |                            |
|   | 13:00 - 13:45   | 45  | MM 4   | From suffering a disaster to recovery by the Higashi-Nihon Great Earthquake - Practice of a pharmaceutical facility.   | Shinji Oshiguchi, Yasutada Shirakura                               | Ajinomoto Pharmaceutical, Kanae  | Makoto Takao                                  | MSD                        |
|   | 13:45 - 14:25   | 40  | MM 5   | Simulation - The ideal image of a pharmaceutical facilities' BCP (Part 1)  | Masato Kato, Shingo Sugimoto, Hideaki Ban                          | MSD, Asutellas Pharma Tech, Ajinomoto Pharmaceutical                         |   |                            |
|   | 14:25 - 14:40   | 15  | Break  |  |  |  |   |                            |
|   | 14:40 - 15:20   | 40  | MM 6   | Simulation - The ideal image of a pharmaceutical facilities' BCP (Part 2)  | Misato Takei, Hitoshi Nakahara, Miho Nakamura, Shoji Miyake        | TERUMO, Taiyo Pharmaceutical Industry, Taiho Pharmaceutical, Novartis Pharma | Makoto Takao                                  | MSD                        |
| 15:20 - 16:00   | 40  | MM 7  | The information sharing for the accident prevention technology.- As the experience of the Higashi-Nihon Great Earthquake | Hiddenori Okamoto, Taizo Hiraga  | Kajima, Chuo Setsubi Engineering                                   |  |   |                            |
| AM  | <b>9:00-12:00 Workshop 4: BIO COP</b>                             |   |  |  |  | MC: Sei Murakami   | Hitachi Plant Technologies                    |                            |
|   | <b>QbD Application in Biopharmaceuticals</b>                      |   |  |  |  |  |   |                            |
|   | 9:00-10:00  | 60  | BIO 1  | The CHO Cell Genome Analysis-Impact on Biologics Production  | Takeshi Omasa  | Tokushima University   | Sei Murakami                                  | Hitachi Plant Technologies |
|   | 10:00-11:00   | 60  | BIO 2  | Drug Development to Manufacturing - alignment of Big Parma to Biotechnology in a study of the Roche and Genentech relationship How Therapies get from Concept into Commercialization | Kelly Keen   | Genentech  |   |                            |
| 11:00-12:00   | 60  | BIO 3   | Introduction of A-MAB  | Motoyoshi Okamura  | Pharmatelier Inc.  |  |   |                            |
| PM  | 12:00-13:00   | 60  | Lunch  |  |  |  |   |                            |
|   | <b>13:00-16:00 Workshop 6: EM</b>                                 |   |  |  |  | MC:Chizuru Inoue   | MAEDA CORPORATION                             |                            |
|   | <b>Construction Project Management Follow Up Report</b>           |   |  |  |  |  |   |                            |
|   | 13:00 - 13:50   | 50  | EM 1   | Learn from IchemE Form of Contract "Reimbursable contracts" and How to Reflect Its to the Domestic Pharmaceutical Construction Project   | Katsushi Ito   | KAJIMA CORPORATION   | —   | —                          |
|   | 13:50 - 14:30   | 40  | EM 2   | Project Deliverable List for Drug Products Facilities and Introduction of Typical Example of Deliverables  | Osamu Matsumoto  | CHIYODA CORPORATION  | —   | —                          |
|   |   |   | EM 2 Attachments 1 2 3   |  |  |  |   |                            |
|   |   |   | EM 2 Attachments 4 5 6   |  |  |  |   |                            |
|   | 14:30 - 14:50   | 20  | Break  |  |  |  |   |                            |
| 14:50 - 15:20   | 30  | EM 3  | Comparison Study Report of UR and URS  | Takashi Hoshino  | TAKEDA PHARMACEUTICAL  | —  | —   |                            |
|   |   | EM 3 Attachment 1                                   |  |  |  |  |   |                            |
| 15:20 - 16:00   | 40  | EM 4  | Introduction of Drug Products Facility's UR Example  | Kazuyuki Ohta  | TAKENAKA CORPORATION   | —  | —   |                            |
|   |   | EM 4 Attachment 1                                   |  |  |  |  |   |                            |
| AM  | <b>10:00-11:30 Workshop 5: Panel Discussion</b>                   |   |  |  | Norikazu Eiki  | Bayer Yakuhiin   |   |                            |
|   | <b>PIC/S and Regulatory matters</b>                               |   |  |  |  |  |   |                            |
| 10:00-11:30   | 90  | Brief remarks by each Panelist and Panel Discussion |  | Helena Baiao, Shingo Sakurai, Hirotada Nagai, Takao Kiyohara, Takashi Nagashima, Bryan Wright,   | PIC/S, PMDA, MHLW ,PMDA . PMDA , ISPE EU Regulatory Advisor        | Facilitator: Robert W. Tribe   | Asia-Pacific Regulatory Affairs Adviser, ISPE |                            |
| PM  | 12:00-13:00   | 60  | Lunch  |  |  |  |   |                            |
|   | <b>13:00-16:30 Workshop 7 :IP</b>                                 |   |  |  |  | MC:Kaoru Oda   |   |                            |
|   | <b>Optimization of clinical supply / storage and distribution</b> |   |  |  |  |  |   |                            |
|   | 13:00-13:10   | 10  | IP 1   | IP-COP Introduction  | Kaoru Oda  | Novartis Pharma K.K.   |   |                            |
|   | 13:10-14:00   | 50  | IP 2   | IP COP Booklet Label Task Team Booklet Label Strategy - an update  | Esther Sadler-Williams   | Catalent Pharma Solutions  | Tony Collins                                  | Pfizer Japan Inc.          |
|   | 14:00-14:40   | 40  | IP 3   | Blindness, Warehousing and Distribution ; Path Forwards Excellence   | Chie Igush / Kazuaki Abe   | Pfizer Japan Inc./World Courier  | Hirofumi Suzuki                               | Bayer Yakuhiin Ltd.        |
|   | 14:40-15:00   | 20  | Break  |  |  |  |   |                            |
| 15:00 - 15:40   | 40  | IP 4  | What is Required of a Clinical GMP Warehouse System? - Transition, Moving Forward to the Future                          | Robert Kamphuis  | Fisher Clinical Services Japan K.K                                 | Shuji Hongo  | Astellas Pharma Inc.                          |                            |
| 15:40-16:30   | 50  | IP 5  | Around the World in 80 ways? A Contractors View of How to Ensure a Lean and Efficient Clinical Distribution Supply Chain | Esther Sadler-Williams   | Catalent Pharma Solutions  | Yuki Hayashi   | Astellas Pharma Inc.                          |                            |