

Conference Team :What are required to deliver combination products to medical front

14-Sep-21

| 1 日目   | Title   | Time        | Lecturer  | 座長 |
|--|---|-------------|---|----|
| Opening  | Opening remarks   | 9:00-9:10   | Mr. Eiji Watanabe   |    |
| <b>Session A: Latest regulatory status</b>                         |   |             |   |    |
| A-1  | Invited Lecture: Japanese medical device regulations as seen from pre-filled syringes   | 9:10-9:50   | Mr. Katsunori Ishiguro (JAAME)                              |    |
| A-2  | (Tentative) Update- Regulations in Biosimilar Combination Drug Development-Focusing on US FDA Cases                                     | 9:50-10:30  | Dr. Alison BASCOU (BECTON DICKINSON)                        |    |
| <b>Exhibition break</b>  |   | 11:30-11:20 |   |    |
| <b>Session B: Aseptic operation &amp; sterilization technology</b> |   |             |   |    |
| B-1  | Qualification of X-ray Sterilization for Single-Use Bioprocess Equipment: A Coordinated Industry Approach to Ensure Business Continuity | 11:20-12:00 | Dr. James Hathcock (Pall Biotech)                           |    |
| <b>Lunch &amp; Exhibition</b>                                      |   | 12:00-13:00 |   |    |
| B-2  | How to Manage the ring of concern of Rapid Transfer Systems.  | 13:00-13:40 | Mr. Thierry GIRARD (ABC TRANSFER)                           |    |
| B-3  | PERFORMANCE OF NEW 5th GENERATION PFS   | 13:40-14:20 | Mr. Rajeev Kabbur (Brevetti Angela)                         |    |
| <b>Exhibition break</b>  |   | 14:20-15:10 |   |    |
| <b>Session C: Freeze-drying technology and its applications</b>    |   |             |   |    |
| C-1  | Latest developments in the field of pharmaceutical freeze drying  | 15:10-15:50 | Dr. Benjamin Ledermann(GEA Lyophil)                         |    |
| C-2  | "Development of a drug product in a dual chamber 2 system: things to consider and lessons learnt"                                       | 15:50-16:30 | Dr. Markus Neumeier (Vetter Pharma-Fertigung GmbH & Co. KG) |    |
| <b>D: What's New in Europe</b>                                     |   |             |   |    |
| D  | Voice From EU   | 16:30-17:30 | Dr.Georg Roesslong (PDA Europe)                             |    |

15-Sep-21

| 2 日目   | 内容   | 時間          | 演者   |  |
|--|--|-------------|--|--|
| <b>Session E: What's New in the United States</b>                          |  |             |  |  |
| E  | Voice From US : Recent Trend of Injectable Combination Product Development In US   | 9:00-9:50   | Dr. Amy Wang(Alexion US)                               |  |
| <b>Session F: Physical test for combination products</b>                   |  |             |  |  |
| F-1  | Reliable test results guarantee high quality of Primary Packaging and Devices  | 9:50-10:30  | Erik Berndt, Peter Schmidt ( ZwickRoell)               |  |
| <b>Exhibition break</b>  |  | 10:30-11:20 |  |  |
| <b>Session G: Dosage design</b>  |  |             |  |  |
| G-1  | Integrated capabilities from Design to final Device Assembly: early considerations for an emergency use auto-injector                | 11:20-12:00 | Paolo Golfetto (Stevano)                               |  |
| <b>Lunch &amp; Exhibition</b>  |  | 12:00-13:00 |  |  |
| G-2  | Bringing a high Volume PFS Immunoglobulin Drug Successfully to the Market  | 13:00-13:40 | Frank Bamberg(CSL Behring) & Tom van Ginneken (SCHOTT) |  |
| G-1  | Key points in the development of combination products through intradermal injection device (Immucise®) and future development trends | 13:40-14:20 | Dr. Yoichiro Iwase(Terumo)                             |  |
| <b>Exhibition break</b>  |  | 14:20-15:10 |  |  |
| <b>Session H: Container integrity in ultra cold environments</b>           |  |             |  |  |
| H-1  | Container closure integrity of syringes stored and shipped at ultra cold temperatures  | 15:10-15:50 | Dr. James Veale (Lighthouse)                           |  |
| <b>Session I: From development to market response in antibody medicine</b> |  |             |  |  |
| I-1  | Development of injection device for antibody drug  | 15:50-16:30 | Mr. Yoshiya Minakami ( Chugai pharmaceutical )         |  |
| <b>Session J:Panel discussion</b>  |  |             |  |  |
| J  | Panel discussion (answers to pre-questions and discussions)  | 16:30-17:30 |  |  |