2nd Korea-Japan Joint Symposium on Medical Products

[April 12th Draft]

- Date and time: 09:10 ~ 17:00 May 11, 2017 (Thu)

- Venue: Overall and Pharmaceutical session: Conference Room (South) 402, Coex, Seoul
  Medical Device session: Conference Room (South) 403, Coex, Seoul

- Host: Ministry of Food and Drug Safety (MFDS)
  National Institute of Food and Drug Safety Evaluation (NIFDS)
  Ministry of Health, Labour and Welfare (MHLW)
  Pharmaceuticals and Medical Devices Agency (PMDA)
  Korea Pharmaceutical Manufacturers Association (KPMA)
  Japan Pharmaceutical Manufacturers Association (JPMA)
  Korea Medical Devices Industry Association (KMDIA)
  Japan Federation of Medical Devices Association (JFMDA)

- Number of participants: 230 (estimation)

- Interpreter: Korean-Japanese simultaneous
**AM: Overall Session - Pharmaceutical and Medical Device**  
(Venue: Conference Room (South) 402, Coex)  
* Master of Ceremony: KPMA

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda items</th>
<th>Remarks</th>
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<tr>
<td>09:10 - 09:30</td>
<td>Registration</td>
<td>20 min</td>
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### Opening Remarks

- (1) [Korea] MFDS: Dr. Won Sik Lee, Director General, Pharmaceutical Safety Bureau  
  - 7 min
- (2) [Japan] PMDA: Mr. Seiichi Inoue, Executive Director  
  - 7 min
- (3) [Korea] KPMA: TBD  
  - 7 min
- (4) [Japan] JPMA: Tadaharu Goto, Director General  
  - 7 min
- (5) [Korea] KMDIA: TBD  
  - 7 min
- (6) [Japan] JFMDA: Mr. Koji Nakao, Chairman  
  - 7 min

| 10:20 - 10:40 | Photo taking                                     | 20 min  |

### Keynote Speeches

- (1) Latest Trend of Pharmaceutical and Medical Device Regulation in Korea  
  - [Korea] MFDS: Dr. Jeong Yeon Kim, Deputy Director, Pharmaceutical Policy Division, Pharmaceutical Safety Bureau  
  - 25 min
- (2) Latest Trend of Pharmaceutical and Medical Device Regulation in Japan  
  - [Japan] MHLW: Mr. Yoshihiko Sano, Deputy Director  
  - 25 min
- (3) Q&A Session                                              
  - 10 min

| 11:40 - 13:00 | Lunch                                            |         |
**PM (1): Pharmaceutical Session (Venue: Conference Room (South) 402, Coex)**  
* Master of Ceremony: KPMA

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<thead>
<tr>
<th>Time</th>
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<td>13:00 - 14:30</td>
<td><strong>Pharmaceutical Regulatory Session</strong></td>
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<td></td>
<td><strong>Part I. Pharmacovigilance</strong></td>
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<td>* Moderator: [Korea] MFDS</td>
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<td>(1) PV system in Korea</td>
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<td></td>
<td>[Korea] MFDS: Dr. Su-jung Lee, Director, Pharmaceutical Safety Evaluation Division, Pharmaceutical Safety Bureau</td>
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<td>(2) Regulations on PV in Japan</td>
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<td>[Japan] PMDA: Ms. Yuka Iida, Senior Reviewer, Office of Safety II</td>
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<td>(3) Topic</td>
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<td>[Korea] KPMA: TBD</td>
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<td>(4) Topic</td>
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<td>[Japan] JPMA: TBD</td>
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<td>(5) Panel Discussion</td>
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<td>14:30 - 14:50</td>
<td>Tea/Coffee Break</td>
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**Pharmaceutical Industry Session**

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<tr>
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<tr>
<td>14:50 - 16:50</td>
<td><strong>Part II. Trend of Japanese Bio-pharmaceuticals and Collaborative Opportunity</strong></td>
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<td>* Moderator: [Korea] KPMA</td>
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<td>(1) Recent Change of Biologicals/Biosimilars in Korea</td>
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<td>[KPMA]</td>
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<td>(2) Recent Trends of Biologicals/Biosimilars in Global and Japanese Market</td>
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<td>[JPMA] Mr. Hirotomo Akabane</td>
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<td>16:50 - 17:00</td>
<td><strong>Part III. Trend of Drug Pricing System</strong></td>
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<td>(1) Update of Drug Pricing System in Korea</td>
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<td>[KPMA]</td>
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<td>(2) Update of Drug Pricing System in Japan</td>
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<td></td>
<td>[Japan] MHLW: Mr. Hiroaki Mamiya, Deputy Director, Health Policy Bureau</td>
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<td><strong>Closing Remarks</strong></td>
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<td>16:50 - 17:00</td>
<td>(1) [Korea] MFDS: Dr. Won Sik Lee, Director General,</td>
<td>5 min</td>
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<td>Pharmaceutical Safety Bureau</td>
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<td>(2) [Japan] PMDA: Mr. Naoyuki Yasuda, Office Director</td>
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<td>▶</td>
<td>Medical device Regulatory Session</td>
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<td><strong>Part IV. QMS/GMP</strong></td>
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<td>13:30-</td>
<td>(1) Introduction of KGMP system</td>
<td>20 min</td>
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<td>14:30</td>
<td>[Korea] MFDS: Dr. Jang-Yong Choi, Deputy Director, Medical Device Safety Evaluation Division, Medical Device Safety Bureau</td>
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<td>(2) Japanese QMS system/Overview of MDSAP</td>
<td>20 min</td>
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<td>[Japan] PMDA: Mr. Junich Ohishi, QMS Inspector, Division of Medical Devices, Office of Manufacturing/Quality and Compliance</td>
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<td>(3) QMS application strategy of ISO 13485:2016</td>
<td>20 min</td>
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<td>[Korea] KMDIA: Mr. Young-Soo Seol, Executive Director, Working group member of Legal Committee</td>
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<td>(4) ISO 13485 and Japanese QMS Ordinance</td>
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<td>[Japan] JFMDA: Mr. Hideki Asai, Vice-chairman of ISO/TC 210 Japanese National Committee</td>
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<td>(5) Panel Discussion</td>
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<td>▶</td>
<td>Medical Device Industry Session</td>
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<td>*<em>Part V</em>. Business Trend of Medical Device Industry</td>
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<td>14:50-</td>
<td>(1) UDI introduction plan of Korea</td>
<td>30 min</td>
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<td>16:50</td>
<td>[Korea] KMDIA: Ms. Young Kim, CEO, Working group member of International Exchange Committee</td>
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<td>(2) UDI and Traceability (Temp.)</td>
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<td>[Japan] JFMDA: Mr. Eishi Harasawa, Executive Director</td>
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<td>(3) Regulatory requirement for medical device software in Korea</td>
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<td>[Korea] Mr. Min-Yong Choi, Head of Healthcare (BSI group Korea)</td>
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<td>(4) Software validation</td>
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[Japan] Mr. Keiichiro Ozawa (FUJIFILM Corporation)

16:50 - 17:00

Closing Remarks

(1) [Korea] MFDS: Mr. Shin Joon-su, Director, Medical Device Policy Division 5 min
(2) [Japan] MHLW: Ms. Yumiko Aoyagi, Deputy Director 5 min

* In an each time of presentation in Part V, there is Q&A time for 10 minutes.