**4th Korea-Japan Joint Symposium on Medical Products**

· Date and time: 16 July, 2019, 09:10 ~ 17:00

· Venue: COEX(Seoul, Korea) Room 402(South 4F)

Medical Device session: COEX Room 403(South 4F)

· Host: Ministry of Food and Drug Safety (MFDS)

· Number of participants: 200 *(estimation)*

· Interpreter: Korean - Japanese simultaneous

* AM: Overall Session - Pharmaceutical and Medical Device

(Venue: COEX(Seoul, Korea) Room 402(South 4F))

\* Master of Ceremony: KPBMA

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| **Time** | **Agenda items** | **Remarks** |
| 09:10-09:30 | Registration | 20 min |
| 09:30-10:00 | **Opening Remarks** | |
| (1) [Korea] Youngok Kim, Director General, MFDS  (2) [Japan] Takao Yamori, Executive Director, PMDA  (3) [Korea] Heemok Won, Chairman, KPBMA  (4) [Japan] Akira Kawahara, Senior Managing Director,JPMA  (5) [Korea] Minhang Heo, Chairman of International Affairs Committee, KMDIA  (6) [Japan] Kenichi Matsumoto, Chairman, JFMDA | 5 min  5 min  5 min  5 min  5 min  5 min |
| 10:00-10:20 | Photo taking | 20 min |
| 10:20-11:30 | **Keynote Speeches**  **(Latest Trend of Pharmaceutical and Medical Device Regulation)** | |
| (1) Latest Trend of Pharmaceutical and Medical Device Regulation in Korea  [Korea] MFDS TBD  (2) Latest Trend of Pharmaceutical and Medical Device Regulation in Japan  [Japan] Junko Sato, Office Director, PMDA  (3) Q&A | 30 min  30 min  10 min |
| 11:30-13:00 | Lunch | |

* PM (1): Pharmaceutical Session

(Venue: COEX(Seoul, Korea) Room 402(South 4F))

\* Master of Ceremony: KPBMA

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| **Time** | **Topic** | **Remarks** |
| ▶ Pharmaceutical Regulatory Session | | |
| 13:00-14:30 | **Part I. Improvement of Clinical Trial System (TBD)** | |
| \* Moderator: KPBMA TBA |  |
| (1) Regulatory Improvement of Clinical Trials in Korea | 20 min |
| [Korea] Jeongmi Kim, Director, MFDS |
| (2) Regulatory Improvement of Clinical Trials in Japan | 20 min |
| [Japan] Yuki Ando, Senior Scientist for Biostatistics,  PMDA |
| (3) Clinical Trials Today and Future in Korea | 20 min |
| [Korea] Donghyun Chee, KoNECT |
| (4) Further consideration beyond ICH E17 | 20min |
| [Japan] Osamu Komiyama, JPMA |
| (5) Q&A | 10 min |
| 14:30-14:50 | Tea/Coffee Break | 20 min |
| ▶ Pharmaceutical Industry Session | | |
| 14:50  -15:30 | **Part II. Business Trend of Regenerative Medicine (TBD)** | |
| \* Moderator: HongJu Lee, Director, Int’l Affairs Team, KPBMA  (1) Product Development status and Industry Promotion on Regenerative Medicine in Korea  [Korea] Bryan Choi, Professor, Inha University College of Medicine | 20 min |
| (2) Product Development status and Industry Promotion on Regenerative Medicine in Japan  [Japan] Fusako Nishigaki, Forum for Innovative Regenerative Medicine (FIRM) | 20 min |
| 15:30-16:50 | **Part III. Trend of Drug Pricing System (TBD)** | |
| \* Moderator: HongJu Lee, Director, Int’l Affairs Team, KPBMA  (1) Update of Drug Pricing System in Korea  [Korea] Yongjin Song, Deputy Director, Division of Pharmaceutical Benefits. MoHW | 40 min |
| (2) Update of Drug Pricing System in Japan  [Japan] Takafumi Yumoto, Section Chief, Health Policy Bureau, MHLW | 40 min |
| 16:50-17:00 | **Closing Remarks** | |
| (1) [Japan] Naoyuki Yasuda, Director, MHLW  (2) [Korea] Youngok Kim, Director General, MFDS | 5 min  5 min |

\* Q&A will be held in every session if time allows.

* PM (2): Medical Device Session

(Venue: COEX(Seoul, Korea) Room 403(South 4F))

\* Master of Ceremony: Heung-bok Na, Executive Director, KMDIA

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| **Time** | **Topic** | **Remarks** |
| ▶ Medical Device Regulatory Session | | |
| 13:00-14:30 | **Part IV. Regulation of Innovative and IVD Medical Devices** | |
| (1) Current Regulatory Changes and Pre-market Review Process for In-Vitro Diagnostic Devices  [KOREA] Ryu, Seung-Rel, Deputy Director of In Vitro Diagnostic Devices Division  (2) Regulatory Trends toward clinical implementation of  innovative technology: the cutting edge of in vitro diagnostics  [Japan] PMDA : Naoyuki Yabana, Director  (3) The impact of new IVD introduction on medical device industry  [Korea]KMDIA **:** Yi-jun Kim, Member of IVD Committee  (4) Guidance document for approval application for in vitro  diagnostics and its usefulness  [Japan] JFMDA : Atsuko Kawada, Member of JACRI  (5) Q&A | 20 min  20 min  20 min  20 min  10 min |
| 14:30-14:50 | Tea/Coffee Break | 20 min |
| ▶ Medical Device Industry Session | | |
| 14:50-16:50 | **Part V. Regulation for substantial equivalence approval of medical device** | |
| (1) Substantial equivalence to predicate devices  [Korea] KMDIA : Young-soo Seol, Vice-chair of Legal  Committee  (2) Substantial equivalence evaluation (TBD)  [Japan] JFMDA : Shiho Tanaka, Chair of Regulatory  System Committee  (3) Requirements of acceptable clinical data  [Korea] KMDIA : Hyeong-joo Kim, Vice-chair of  International Affairs Committee  (4) Clinical evidence (TBD)  [Japan] JFMDA : Noriko Yasuda, Member of Clinical  Evaluation Committee | 30 min  30 min  30 min  30 min |
| 16:50-17:00 | **Closing Remarks** | |
| (1) [Japan] Mari Shirotani, Division Director, PMDA | 5 min |
| (2) [Korea] Jinee Jung, Director of Medical Devices Policy  Division, MFDS | 5 min |

\* Q&A will be held in every session if time allows.