**3rd Japan-Korea Joint Symposium on Medical Products**

**(June 18, 2018)**

· Date and time: July 3rd, 2018, 09:00 ~ 17:00

· Venue: Nihonbashi Life Science Hub Conference Room E

Medical Device session: Room 1004 [10F] at Life Science Center

· Host: Ministry of Health, Labour and Welfare (MHLW)

Pharmaceuticals and Medical Devices Agency (PMDA)

Ministry of Food and Drug Safety (MFDS)

National Institute of Food and Drug Safety Evaluation (NIFDS)

Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA)

Japan Pharmaceutical Manufacturers Association (JPMA)

Korea Medical Devices Industry Association (KMDIA)

Japan Federation of Medical Devices Association (JFMDA)

· Number of participants: 230(estimation)

· Interpreter: Japanese - Korean simultaneous interpretation

* AM: Overall Session - Pharmaceutical and Medical Device

(Venue: Nihonbashi Life Science Hub Conference Room E)

\* Master of Ceremony: MHLW: Mr. Katsuaki Ura

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| **Time** | **Agenda items** | **Remarks** |
| 09:10-09:30 | Registration | 20 min |
| 09:30-10:00 | **Opening Remarks** | |
| (1) [Japan] MHLW: Mr. Kazuhiko Mori, Councilor for Pharmaceutical Affairs,  Minister’s Secretariat, MHLW  (2) [Korea] MFDS: Dr. Won Sik Lee,  Director General, Pharmaceutical Safety Bureau  (3) [Japan] JPMA: Mr. Tadaharu Goto, Director General  (4) [Korea] KPBMA: Mr. Won-Ill Gal, Vice Chairman (as Acting Chairman)  (5) [Japan] JFMDA Mr. Masaya Watanabe Chairman  (6) [Korea] KMDIA: Mr. Kyung Kook Lee, Chairman | 30min |
| 10:00-10:20 | Photo taking | 20 min |
| 10:20  -11:20 | **Keynote Speeches** | |
| (1) Latest Trend of Pharmaceutical and Medical Device Regulation in Japan  [Japan] MHLW: Nobumasa Nakashima, Director, Division of General Affairs, Office of International Regulatory Affairs, Pharmaceutical Safety and Environmental Health Bureau  (2) Latest Trend of Pharmaceutical and Medical Device Regulation in Korea  [Korea] MFDS: Mr. Sang Bong Kim,  Director, Pharmaceutical Policy Division  (3) Q&A | 20 min  20 min  20 min |
| 11:20-13:00 | Lunch | |

* PM (1): Pharmaceutical Session

(Venue: Nihonbashi Life Science Hub Conference Room E)

\* Master of Ceremony: MHLW: Mr. Katsuaki Ura

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| **Time** | **Topic** | **Remarks** |
| ▶ Pharmaceutical Regulatory Session | | |
| 13:00-14:30 | **Part I. Regulatory promotion of Innovation (TBD)** | |
| \* Moderator: [Japan] PMDA: Naoyuki Yasuda, Office Director, Office of International Programs, |  |
| (1) Challenge of regulatory advance for Innovation | 20 min |
| [Japan] PMDA: TBD |
| (2) Introduction of multi-products guidelines for scaffold including 3D Bio printing | 20 min |
| [Korea] MFDS: Dr. Ho-Sang Jeong, Director, Cell and Gene Therapy Products Division |
| (3) What does ICH E17 imply and bring us? | 20 min |
| [Japan] JPMA : Mr. Osamu Komiyama |
| (4) Status of clinical trial approval process in Korea | 20min |
| [Korea] KPBMA: Mr. Byung-Jo Jin, Deputy Director |
| (5) Panel Discussion | 10 min |
| 14:30-14:50 | Tea/Coffee Break | 20 min |
| ▶ Pharmaceutical Industry Session | | |
| 14:50  -15:50 | **Part II. Business Trend of Development of New Drugs (including Bio-pharmaceuticals) (TBD)** | |
| \* Moderator: JPMA: Mr. Akihiro Nagaoka, Chairman of Asia Committee,  (1) Promotion of Open Innovation  [Japan] JPMA: Mr. Yoshiyuki Kawakami | 30 min |
| (2) Trend of New Drugs Development in Korea  [Korea] Dr. Soo-Hyoung Kang, Vice Chairman, Dong-A ST | 30 min |
| 15:50-16:50 | **Part III. Trend of Drug Pricing System (TBD)** | |
| \* Moderator: JPMA: Mr. Akihiko Matsubara, Managing Director  (1) Update of Drug Pricing System in Japan  [Japan] MHLW : Mr. Hiroaki Mamiya, Deputy Director, Health Policy Bureau | 30 min |
| (2) Update of Drug Pricing System in Korea  [Korea] MoHW or HIRA: TBD | 30 min |
| 16:50-17:00 | **Closing Remarks** | |
| (1) [Korea] MFDS: Dr. Won Sik Lee, Director General  (2) [Japan] PMDA: Dr. Toshiyoshi Tominaga, Associate  Executive Director (for International Programs) | 5 min  5 min |

* PM (2): Medical Device Session (Venue: Nihonbashi Life Science Center, Room1004 [10F] )

\* Master of Ceremony: TBD, JFMDA

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| **Time** | **Topic** | **Remarks** |
| ▶ Medical device Regulatory Session | | |
| 13:00-14:30 | **Part IV. Updated Regulatory Strategies for Innovative Medical Devices** | |
| \* Moderator: [Japan] PMDA;, Dr. Madoka Murakami,  Unit Chief, Office of International Programs, PMDA  (1) Promotion of next generation medical device  evaluation in Japan  [Japan] Ms. Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau  (2) Regulatory innovation for new tech-applied medical  devices in Korea  [Korea] MFDS: Mr. Myungsoo Ahn, Deputy Director,  Medical Devices Policy Division,  (3) Industry perspectives in Japan  [Japan] JFMDA: Mr. Yoshiaki Nagasawa,  Chairman of QMS Committee  (4) Patient Specific Medical Device Based on 3D Printing Technology  [Korea] KMDIA: Mr. Jun Young Lim, 3D innovation Center Manager (CGbio)  (5) Panel Discussion | 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\*. Business Trend of Medical Device Industry** | |
| \* Moderator: [Japan] f JFMDA Mr. Koji Sekiguchi,  Chairman of International Policy& Strategy Committee  (1) Industry perspective in Japan (1)  [Japan] JFMDA: Mr. Chikashi Mikami, Chairman of  UDI Committee  (2) Korea UDI Introduction with industry perspective  [Korea] KMDIA: Ms. Myoung Shim Kim, Sr,  RA Manager(Johnson&Johnson Medical Korea)  (3) Industry perspective in Japan (2)  [Japan] JFMDA: Mr. Hiroshi Furukawa  Head of Medical Device Program WG  (4) Regulation for Medical Devices Program  [Korea] KMDIA: TBD | 30 min  30 min  30 min  30 min |
| 16:50-17:00 | **Closing Remarks** | |
| (1) [Korea] MFDS: Mr. Myungsoo Ahn, Deputy Director | 5 min |
| (2) [Japan] PMDA: Ms. Mari Shirotani,  Deputy Director, Office of International Programs, PMDA | 5 min |

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