International Regulatory Forum of Human Cell Therapy and Gene Therapy Products
- 再生医療等製品国際フォーラム -

PROGRAM

March 16, 2016
Osaka International Convention Center
Osaka, JAPAN
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Organized by
Pharmaceuticals and Medical Devices Agency (PMDA)
The Japanese Society for Regenerative Medicine (JSRM)

With the support from
National Institute of Biomedical Innovation, Health and Nutrition (NIBIOHN)

Under the auspices of
Ministry of Health Labour and Welfare (MHLW)
Forum for Innovative Regenerative Medicine (FIRM)
Japan Pharmaceutical Manufacturers Association (JPMA)
The purpose of the symposium

This meeting will bring together an outstanding and diverse group of speakers from regulatory agencies, industry, and academia, all of whom are at the forefront of the cell therapy and gene therapy field.

We will identify regulatory points/issues to consider for specific type of products, as well as very critical points/issues for various type of products, which have to be resolved, improved, and/or developed in terms of sound scientific regulation in order to facilitate the availability of products in a rational and timely manner, and which will be valuable globally to public health.

Finally, from global point of view, we will discuss specific issues that are to be scientifically aligned internationally among the regulators, while each regulator has flexibility to decide in a case by case basis, on a risk based approach. We will explore regulatory dialogues and discussions for the future to pursue the data package under minimum consensus for global development of hCTPs.

Organizing Committee

Takao Hayakawa, Kindai Univ., Japan (Chair)
Daisuke Maeda, PMDA, Japan
Yoshiaki Maruyama, PMDA, Japan
Noriyuki Matsumoto, Japan Pharmaceutical Manufacturers Association (JPMA), Japan
Akifumi Matsuyama, NIBIOHN, Japan
Hajime Miyamoto, FIRM, Japan
Kohji Nishida, The Japanese Society for Regenerative Medicine (JSRM), Japan
Yoshinori Oie, The Japanese Society for Regenerative Medicine (JSRM), Japan
Norihisa Sakamoto, PMDA, Japan
Daisaku Sato, PMDA, Japan
Yoji Sato, National Institute of Health Sciences, Japan
Masayuki Shibasaki, FIRM, Japan
Kazuhiro Takekita, PMDA, Japan
Yuzo Toda, FIRM Chairperson, Japan
Kazuhisa Uchida, Japan Pharmaceutical Manufacturers Association (JPMA), Japan
Akihiro Umezawa, NICHD, Japan
Masayuki Yamato, Tokyo Women’s Medical Univ., Japan
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      12th Floor
   Access Information:
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General Information

Location:
Osaka International Convention Center, Osaka, Japan
5-3-51 Nakanoshima, Kita-ku, Osaka City, 530-0005 Japan
TEL: +81-6-4803-5555 (Main)
FAX: +81-6-4803-5620
http://www.gco.co.jp/en/

No Smoking:
Smoking is prohibited in all areas of the venue.

No Photos, No Audio Recording:
Photos and audio recording are prohibited.

Cellular Phones:
Using cellular phones during the sessions is prohibited.
Cellular phones must be turned off or set to silent mode during the sessions.

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Program Schedule

March 16, 2016

8:30  Registration Open

9:20  OPENING
Opening & Introduction by Chair of Congress JSRM, Japan (Co-sponsor), Kohji Nishida

9:30  Welcome Note by Executive Director, NIBIOHN, Japan (Co-sponsor), Suminori Kono

9:40  Introductory Remarks by Councilor for Pharmaceutical Safety, MHLW, Japan, Kazuhiko Mori

9:50  Session 1  Keynote Lecture
Chairs: Yuzo Toda (FIRM, Japan)
Introduction by Chair

9:55  FDA’s perspective on cellular and gene therapy regulation
Steven S. Oh (Chief, Cell Therapy Branch, OCTGT, CBER, FDA, USA)  (teleconference)

10:20  European perspective on ATMPs
Paula Salmikangas (Chair, CAT/EMA, EU)

10:45  Break

11:00  Session 2  Safety evaluation approaches for hCTPs in reference to ICH S6 and S7 guidelines
Chairs: Paula Salmikangas (CAT/EMA, EU) and Yoji Sato (NIHS, Japan)
Introduction by Chair

11:05  2.1 Process related impurity safety evaluation
Takuya Nishimura (PMDA, Japan)

11:25  2.2 Pre-clinical safety evaluation
James McBlane (MHRA, UK)

11:45  2.3 Tumorigenicity
Shin Kawamata (Institute of Biomedical Research and Innovation (IBRI), Japan)

12:05  2.4 Pre-clinical proof of concept and other pre-clinical issues
Ian Harris (Janssen Research & Development, USA)

12:25  2.5 Panel Discussion

12:45  Lunch

13:45  Session 3  Quality evaluation approaches for hCTPs in reference to ICH Q5 and Q6 guidelines
Chairs: Junichi Koga (JPMA, Japan) and Takao Hayakawa (Kindai Univ., Japan)
Introduction by Chair

13:50  3.1 Potency
Anthony Ridgway (Health Canada, Canada)

14:10  3.2 Raw materials and microbiological control
Stephen Wicks (EDQM, EU)
3.3 Specification and process validation
Yoshiaki Maruyama (PMDA, Japan)

3.4 Vector characterization of genetically-modified cell therapies
Matthias Renner (PEI, Germany)

3.5 Panel Discussion

Break

Session 4  Efficacy evaluation approaches for hCTPs
Chairs: Norihisa Sakamoto (PMDA, Japan) and Akihiro Umezawa (NICHD, Japan)
Introduction by Chair

4.1 Study design
Nobuo Kanai (Tokyo Women’s Medical Univ. Japan)

4.2 Clinical issues
Graziella Pellegrini (Università degli Studi di Modena e Reggio Emilia, Italy)

4.3 Clinical and regulatory issues in the US
Michael Werner (ARM, USA)

4.4 Panel Discussion

Session 5  International Development and Regulatory Issues
Chairs: Anthony Ridgway (Health Canada, Canada) and Daisaku Sato (PMDA, Japan)
Introduction by Chair

5.1 Endeavour to minimum consensus package
Takao Hayakawa (Kindai Univ., Japan)

5.2 Regulatory Panel
Moderator: Takao Hayakawa (Kindai Univ., Japan) and Anthony Ridgway (Health Canada, Canada)
Invited Asian regulators (incl. 10min. presentations, updates of Asian regulatory evaluation)
Jeewon Joung (MFDS, Korea)
Srinivasan Kellathur (HSA, Singapore)
Yi-Chu Lin (TFDA, Taiwan)
Daisaku Sato (PMDA, Japan)
James McBlane (MHRA, UK)
Matthias Renner (PEI, Germany)
Paula Salmikangas (CAT/EMA, EU)
Stephen Wicks (EDQM, EU)

Session 6  Summary
Daisaku Sato (PMDA, Japan)

CLOSING
Closing Remark by Chief Executive, PMDA, Japan (Co-sponsor), Tatsuya Kondo

CLOSE OF MEETING

Networking Reception