30th ICH Public Meeting

July 10, 2014
Nagai Kinen Hall, Shibuya-ku, Tokyo, Japan

Program

ICH Public Conference
Organized by
Japan Pharmaceutical Manufacturers Association (JPMA)
Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ)

Supported by
The Federation of Pharmaceutical Manufacturers’ Associations of JAPAN
The Pharmaceutical Manufacturers’ Association of Tokyo
Osaka Pharmaceutical Manufacturers Association
Japan Pharmaceutical Association

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Simultaneous English-Japanese Translation: Not Available
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tr>
<td>10:00-10:05</td>
<td><strong>Welcoming Address</strong></td>
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<td>Chair, ICH Project Committee, JPMA</td>
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<td>Dr. Hironobu Saito</td>
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<td>10:05-10:30</td>
<td><strong>Future of ICH</strong></td>
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<td>Dr. Hironobu Saito</td>
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<td>10:30-10:55</td>
<td><strong>Recent Developments of ICH</strong></td>
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<td>Division Director for Regulatory Coordination, Office of International Programs, MHLW (PMDA)</td>
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<td>Dr. Junko Sato</td>
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<td>10:55-11:00</td>
<td>Questions &amp; Answers</td>
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<td>11:00-11:25</td>
<td>Safety Topics</td>
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<td></td>
<td>M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk</td>
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<td>M7 expert, MHLW (PMDA)</td>
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<td>Dr. Junichi Fukuchi</td>
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<td>11:25-11:30</td>
<td>Questions &amp; Answers</td>
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<td>11:30-11:55</td>
<td>Topics for the Electronic Exchange of Information</td>
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<td>M8 EWG/IWG: Electronic Common Technical Document: eCTD</td>
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<td>M8 EWG/IWG Rapporteur, MHLW (PMDA)</td>
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<td>Mr. Taku Watanabe</td>
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<td>11:55-12:00</td>
<td>Questions &amp; Answers</td>
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<td>12:00-13:00</td>
<td>Lunch Break</td>
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<td>13:00-13:20</td>
<td>Future ICH Topics</td>
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<td>1) Overview of Future ICH Topics</td>
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<td>Director, Global Scientific and Regulatory Affairs, JPMA</td>
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<td>Dr. Kurajiro Kishi</td>
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<td>13:20-13:45</td>
<td>2) S5 (R3) informal WG: Detection of Toxicity to Reproduction for Medicinal Products &amp; Toxicity to Male Fertility</td>
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<td>S5 (R3) informal WG Topic Leader, JPMA</td>
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<td>Dr. Michio Fujiwara</td>
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<td>13:45-13:50</td>
<td>Questions &amp; Answers</td>
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<td>13:50-14:15</td>
<td>3) E6 (R2): Good Clinical Practice (GCP)</td>
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<td>E6 (R2) Topic Leader, MHLW (PMDA)</td>
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<td>Dr. Kazuhiro Matsui</td>
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<td>14:15-14:20</td>
<td>Questions &amp; Answers</td>
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<td>14:20-14:45</td>
<td>4) Informal Quality Discussion Group (IQDG)</td>
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<td>IQDG expert, MHLW (PMDA)</td>
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<td>Dr. Yoshihiro Matsuda</td>
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<td>14:45-14:50</td>
<td>Questions &amp; Answers</td>
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<td>14:50-15:10</td>
<td>Break Time</td>
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<td>15:10-15:35</td>
<td>1) Q3D: Guideline for Elemental Impurities</td>
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<td>Q3D Topic Leader, MHLW (PMDA)</td>
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<td>15:35-15:40</td>
<td>Questions &amp; Answers</td>
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<td>15:40-16:05</td>
<td>2) Q7 IWG: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients</td>
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<td>Q7 IWG Topic Leader, JPMA</td>
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<td>16:05-16:10</td>
<td>Questions &amp; Answers</td>
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<td>16:10-16:20</td>
<td>Closing Remarks</td>
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Scientific Program Committee

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Deputy Director, Evaluation and Licensing Division,  
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Pharmaceuticals and Medical Devices Agency

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Director, Global Scientific and Regulatory Affairs,  
Japan Pharmaceutical Manufacturers Association

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Ms. Sayuri Masuko  
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Japan Pharmaceutical Manufacturers Association

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