



# PMDA Updates

August, 2011

## News

### 1. Japan assumes GHTF Chairmanship effective July 1st, 2011 : July 1

Global Harmonization Task Force (GHTF) aims at achieving greater uniformity between national medical device regulatory systems. As per the GHTF procedural rules, the GHTF Chairmanship is transferred to Japan from Australia effective July 1, 2011. PMDA, in cooperation with MHLW, also fulfills the responsibility as the Task Force's secretariat. As Chair of GHTF, MHLW/PMDA manages progress of Study Groups and leads discussion among the participating nation in cooperation with MHLW until the end of 2012. It starts preparation for the steering committee meetings (telephone conferences and face-to-face meetings) during its chairmanship in order to foster the meaningful discussion.

GHTF official website : Transition of GHTF Chairmanship

<http://www.gh tf.org/newsroom/news-transition.html>

PMDA's related website : <http://www.pmda.go.jp/kokusai/gh tf/index.html>

### 2. PMDA has started Scientific Advice Service on Drug Development Strategy : July 1

PMDA launched its new scientific advice service mainly for academia and research institutions on July 1, 2011. The Agency has established "Pharmaceutical Affairs Consultation Group on R&D Strategy", staffed with newly employed experts with sufficient experience in clinical development and pharmaceutical affairs in drug companies. The service provides applicants with expert advice on designing necessary clinical/non-clinical studies conducted from the final phase of choosing candidate compounds to the early phase studies including POC study. Technical experts with sufficient experience in drug development and pharmaceutical affairs were newly employed as advisors. PMDA is holding two explanatory meetings on the service in Osaka (Aug.29) and Tokyo (Aug.31). The participants can consult with the advisors at the meetings. For more information, please click the link below.

<http://www.pmda.go.jp/operations/shonin/info/consult/yakujiisenryaku.html>

(available only in Japanese).



Pharmaceuticals and Medical Devices Agency, Japan

### 3. PMDA held 1st GMP Inspectors Meeting toward PIC/S\* Accession : July 13

GMP inspectors from the prefectural governments participated in the first meeting of what is tentatively called "Coordination Party," organized by PMDA to prepare for Japan's participation in PIC/S. The Mechanism will strengthen partnership among domestic inspectorates (47 prefectural governments and PMDA) by measures such as standardizing their quality systems and giving continuous trainings for GMP inspectors.

\*PIC/S (Pharmaceutical Inspection Co-operation Scheme) is an international organization whose purpose is to lead the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal products. At present, 39 GMP Inspectorates in 37 nations are affiliated with it. Some Asian countries are reportedly preparing for participation.

### 4. Medical and Welfare Subcommittee of the Evaluation Committee on Independent Administrative Institutions: July 22

PMDA reported its business results for FY 2010 to Medical and Welfare Subcommittee of the Evaluation Committee on Independent Administrative Institutions. In its self-assessment submitted to the Subcommittee, PMDA graded its performance as "S", the highest score in the one-to five scale, in terms of the following three aspects of functioning; "quick operations and establishment of its operating system, "cost-trimming", and "financial planning". The rest 15 assessment items, including publicity on its relief system and provision of safety information, were graded "A", the second highest. The final assessment will be delivered by the Committee in August 2011.

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## Safety Information

Pharmaceuticals and Medical Devices Safety Information

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[http://www.pmda.go.jp/english/service/precautions\\_2011.html](http://www.pmda.go.jp/english/service/precautions_2011.html)

- ◆ Revision of package inserts of subcutaneous port and catheter
  - ◆ Information on Important ADRs and AEs
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## Events

### 1. Conferences/meetings PMDA hosts/ co-hosts

Date	Title	Location
October 31	China – Japan – Korea Director-General Meeting	Tokyo
November 1-2	APEC Multi-Regional Clinical Trial Tokyo Workshop	Tokyo

### 2. Major conferences/meetings PMDA participates in

Date	Title	Location
September 13–15	APEC Regulatory Harmonization Steering Committee	San Francisco
October 23–28	2011 Summit of Heads of Medicines Regulatory Agencies	Sydney