

Communication Paper

**Gene Therapy Discussion Group Meeting
Yokohama, June 5-8, 2006**

Status Report:

The scope of the ICH GT Discussion Group (GTDG) meeting included:

- sharing regional updates,
- discussing and further working on the draft ICH Considerations for General Principles to Address the Risk of Inadvertent Germline Integration of Gene Therapy Vectors, and
- discussing and making plans for future activities.

Representatives from the three ICH regions (including experts from regulatory authorities and industry), EFTA, and Health Canada participated.

The GTDG agreed on the following points:

ICH Considerations for General Principles to Address the Risk of Inadvertent Germline Integration of Gene Therapy Vectors

The GTDG discussed and completed draft 4 of the ICH Considerations for General Principles to Address the Risk of Inadvertent Germline Integration of Gene Therapy Vectors. Comments for incorporation into draft 5 are due in July 2006 to the U.S. rapporteur.

Future activities

The group agreed to write two additional ICH Considerations:

- ICH Considerations on oncolytic viruses based on the November 2005 workshop, and
- ICH Considerations on virus / vector shedding

ICH Guidelines may be prepared for topics for which sufficient experience has accrued in the Regions.

The GTDG recommends that the next formal meeting take place in parallel with the ICH SC EWG meeting in October 2006. The ICH GTDG made plans for a public gene therapy session in concert with ICH 7.

The next formal meeting will take place in parallel with the ICH SC EWG meeting in October 2006.