

Communication Paper

**Gene Therapy Discussion Group Meeting  
Yokohama, Japan, June 8-11, 2009**

**Status Report:**

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

- sharing regional updates,
- discussing and completing the ICH Considerations for Viral / Vector Shedding,
- discussing a revision of the ICH Considerations for Oncolytic Viruses,
- discussing a proposal to write a guideline on shedding, and
- discussing and making plans for future activities.

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

The GTDG agreed on the following points:

**ICH Considerations on Oncolytic Viruses**

The GTDG discussed comments received and will complete the revision of ICH Considerations on Oncolytic Viruses by email. The revised document will be submitted to the SC post-meeting, and once approved, posted to the ICH GTDG web page.

**ICH Considerations on Viral / Vector Shedding**

The GTDG discussed and finalized an ICH Considerations on Viral / Vector Shedding. The finalized document will be posted to the ICH GTDG web page for public comment after SC approval.

**Future activities**

The group agreed that productivity would be enhanced by meeting face-to-face twice a year. At the next meeting the group would exchange regional information and continue to work on the ICH Considerations documents, with the possible topic of dosing units for different vector types.

The GTDG plans to propose the writing of an ICH Guideline on Viral / Vector Shedding. The GTDG will write a concept paper and business plan post-meeting, with the intent to submit to the SC for their approval at the time of their September teleconference.

The next formal meeting of the ICH GTDG will take place in parallel with the ICH SC EWG meeting in October 2009.