

Communication Paper

**Gene Therapy Discussion Group Meeting  
Brussels, Belgium, November 10-14, 2008**

**Status Report:**

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

- sharing regional updates,
- discussing the ICH Considerations on Oncolytic Viruses,
- discussing the ICH Considerations on Viral / Vector Shedding, 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 on Oncolytic Viruses**

The GTDG discussed the third draft of an ICH Considerations on Oncolytic Viruses and finalized the document. The ICH Considerations on Oncolytic Viruses will be posted to the ICH GTDG web page for comments. Comments should be made by April 1, 2009. Comments will be reviewed and, if relevant, the document will be revised prior to the June 2009 ICH meetings.

**ICH Considerations on Viral / Vector Shedding**

The GTDG discussed the second draft of an ICH Considerations on Viral / Vector Shedding. A third draft is in progress. The GTDG plans to complete the ICH Considerations by the end of 2009.

The GTDG plans to use the final version of ICH Considerations for Viral / Vector Shedding to write a concept paper to initiate the ICH guideline process.

**Future activities**

At the next meeting the group will exchange regional information and continue to work on the ICH Considerations document:

- ICH Considerations on Viral / Vector Shedding

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

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