

Communication Paper

**Gene Therapy Discussion Group Meeting
Portland, Oregon, June 3-5, 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 second draft of an ICH Considerations on Oncolytic Viruses and agreed to complete preparation of this document in parallel with the proposed ICH Considerations on Viral / Vector Shedding.

ICH Considerations on Viral / Vector Shedding

The GTDG discussed the first draft of an ICH Considerations on Viral / Vector Shedding and agreed to complete preparation of this document in parallel with the proposed ICH Considerations on Oncolytic Viruses.

Future activities

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

- ICH Considerations on Oncolytic Viruses
- 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 November 2008.