

Communication Paper

**Gene Therapy Discussion Group Meeting
Chicago, October 23-26, 2006**

Status Report:

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

- sharing regional updates,
- discussing and finalizing the 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, Health Canada, and SFDA 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 finalized the ICH Considerations for General Principles to Address the Risk of Inadvertent Germline Integration of Gene Therapy Vectors.

ICH Considerations for Oncolytic Viruses

The GTDG wrote a proposal for an ICH Considerations for Oncolytic Viruses.

Future activities

The group agreed to write an additional ICH Considerations:

- ICH Considerations for Virus / Vector Shedding

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

The GTDG discussed the possibility of a public workshop in conjunction with a scientific conference to aid in drafting a guideline on virus / vector shedding.

The next formal meeting will take place in parallel with the ICH SC EWG meeting in May 2007.