

Communication Paper

**Gene Therapy Discussion Group Meeting
St. Louis, Missouri, USA, October 25, 2009**

Status Report:

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

- sharing regional updates,
- reviewing comments received on the ICH Considerations on General Principles to Address Virus and Vector Shedding,
- discussing a proposal to write an ICH Considerations on General Principles to Address in Preparation for First-in-Human Gene Therapy Studies, and
- making plans for future activities.

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

Future activities

The GTDG agreed that productivity would be enhanced by meeting face-to-face. At the next meeting the group will exchange regional information and continue to work on ICH Considerations documents.

The GTDG wrote a draft proposal for an ICH Considerations on General Principles to Address in Preparation for First-in-Human Gene Therapy Studies and received SC approval to write this ICH Considerations.

The next formal meeting of the ICH GTDG will take place in parallel with the ICH SC and EWG meetings in June 2010.