

GHTF Steering Committee *Ad hoc* Working Groups

Proposed Points to Consider

Introduction: The GHTF Steering Committee has endorsed the establishment of *ad hoc* working groups to undertake work on specific topics. This document outlines points to consider in the establishment of such working groups. It also outlines revisions to the Steering Committee policy and procedure documents adopted in Seville in May 2005 (Guiding Principles, Roles and Responsibilities, and Operating Procedures).

Aim of *ad hoc* working groups: The steering committee considers the full spectrum of possible activities or actions with regard to global harmonization in the field of medical device regulation. Some new subjects may not clearly fit into the scope or priorities of an existing GHTF Study Group. The creation of a new Study Group would in many cases not be appropriate. It could also be difficult and time consuming due to e.g. the limited resources of the parties involved. For that reason small manageable *Ad hoc* working groups should be used to support the GHTF steering committee in its task of developing advice on GHTF activities.

- *Ad hoc* WG should have limited mandates which it should be feasible to accomplish in about 18 months.
- *Ad hoc* WG could provide guidance on very specific subjects which could not be handled in an existing Study Group.
- *Ad hoc* WG could also assess the need to create a new Study Group and could also prepare the mandate for such a new Study Group.
- *Ad hoc* WG could prepare cooperation agreements and serve as the liason for GHTF partners
- *Ad hoc* WG could be used for preparation of GHTF conferences or GHTF training

1.1 GHTF Ad Hoc Working Groups

1.1.1 Creation/Termination/Renewal

Ad Hoc Groups may be formed at any time by the Steering Committee. *Ad hoc* working groups shall be appointed by the GHTF Chair with the agreement of the Steering Committee. In considering the creation of an *Ad hoc* working group the Steering Committee shall consider whether the projected mandate could fit within the terms of reference of existing Study Groups. *Ad hoc* working groups shall have narrow mandates and specific work products as developed by the Steering Committee. The projected time to complete mandates shall be short, typically 18 months maximum. The Steering Committee may also discharge an *Ad hoc* working group from further responsibility, instruct an *Ad hoc* Group to re-define its terms of reference, charge the *Ad hoc* Group with a new task, appoint a new chair, and/or renew an existing Chair's appointment.

- *Ad hoc* working groups shall be terminated upon completion of their mandate

1.1.2 Membership

The chair of an *ad hoc* working group shall be selected from among the Steering Committee members. Members of *ad hoc* working groups should be selected on the basis of their expertise in the specific subject matter and should generally be members of the Steering Committee. If necessary, members of *ad hoc* working groups may, but need not, be drawn from among Study Group members. In exceptional cases, the *ad hoc* group Chair may authorize an individual, with appropriate knowledge and expertise, to participate in an *ad hoc* Group meeting as an external observer/expert. The size and overall composition of an *ad hoc* working Group is determined by the Steering committee.

An *Ad hoc* working group shall include at least regulators from 3 different geographic regions. Membership of *ad hoc* working groups shall generally be small in numbers and shall provide a balance of regulators and industry and geographic regions.

1.2 *Ad hoc* working group Chairs

***Ad hoc* working group chairs should provide regular reports on the progress of the *ad hoc* group's work to the steering committee.**

Should an *Ad hoc* Group Chair be unable to fulfill his/her term, he/she should promptly notify the GHTF Chair who in turn will inform the Steering Committee. The GHTF Chair or his/her designee will then consult within the Steering Committee (using teleconference or e-mail as needed) and appoint a replacement, either on an interim or permanent basis.

1.3 *Ad hoc* Group Meetings

Ad hoc Groups meet as often as necessary to carry out the tasks assigned to them by the GHTF Steering Committee. *Ad hoc* groups shall generally give preference to electronic communication tools (e.g. teleconferencing or videoconferencing). If in-person meetings are considered necessary the meetings should generally take place in connection with scheduled meetings of the GHTF Steering Committee. Meetings are at the call of the individual *ad hoc* Group Chair. Meeting agendas should be circulated to all *Ad hoc* Group members at least four weeks in advance.

An activity report is to be prepared and forwarded to the GHTF Chair at least six weeks before the next meeting of the Steering Committee who will then forward it to the members of the GHTF Steering Committee.

1.4 –Management of documents

In general the process by which guidance documents developed by *ad hoc* working groups are reviewed and adopted shall be that of the GHTF Operating Procedures **GHTF/SC/N3R9:2005**, which should be adapted accordingly. Since some of the work of *ad hoc* groups will not result in a general guidance documents, the further disposition of such *ad hoc* group documents shall be decided by the Steering Committee, in accordance with the original mandate.