FINAL DOCUMENT

Title: Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program

Authoring Group: GHTF Study Group 2

Endorsed by: The Global Harmonization Task Force

Date: **July, 2009**

Roland Rotter, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Table of Contents

Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Introduction

The purpose of a linked system incorporating adverse event reporting, and vigilance and post-market surveillance components is to improve the protection of the health and safety of patients, users and others by reducing the likelihood of repeated similar adverse events. This occurs through the dissemination of information that could be used to prevent the repetition of the adverse events or to alleviate the consequences of such repetition *(see SG2 N16, N54).*

Following the receipt of an adverse event report submitted by the manufacturer or their authorized representative, National Competent Authorities (NCA) determine the necessity/urgency of disseminating this information to member NCAs via the National Competent Authority Report (NCAR) exchange program. Important guidance on the NCAR exchange program can be found in the document entitled, "Guidance on how to Handle Information Concerning Vigilance Reporting Related to Medical Devices" *(SG2 N8).* The criteria for deciding how to disseminate information internationally, as well as the recommended procedure for this dissemination, are in the document entitled "Competent Authority Reporting Criteria*" (SG2 N79).*

1.0 Scope

In the NCAR exchange program founded by GHTF SG2, NCAs exchange two types of information: Information that may be considered highly sensitive and/or confidential; and selected public (non-confidential) information. Two levels of participation in the NCAR exchange are available: Full Participant and Associate Participant.

This document sets out the prerequisites and commitments required from an organisation before they can participate in the NCAR exchange program founded by GHTF SG2.

2.0 References

The latest revisions of GHTF SG2 N8, GHTF SG2 N54, GHTF SG2 N79 and ISO 14971

3.0 Definitions

Associate Participant: An organisation that participates in the NCAR program that receives only public information (see definition of public information) from other NCAR participants. Associate participants may contribute NCARs that contain either public or confidential information, but are not compelled to do so. An associate participant may not necessarily be a National Competent Authority (NCA).

Confidential Information: Information that due to its nature may be prejudicial to one or more persons, or that may be deemed as such by regional confidentiality acts and regulations, and that,

for this reason, has been marked by the information provider as being confidential or not for general release.

Full Participant: An organisation that participates in the NCAR program that receives both public and confidential information from other NCAR participants. Full participation is open only to NCAs.

Public Information: For the purposes of this document, information that is regarded to be non-confidential. This information may not necessarily be widely or easily available. For example, information contained in recall notifications, safety alerts, hazard alerts, product notifications and other product advisories is considered to be public information

4.0 General Principles

Participants in the NCAR program will be receiving information regarding hazards associated with the use of medical devices. It is important that recipients of NCAR reports and other adverse event information are familiar with the concept of risk management, which considers more than hazard alone, to determine whether remedial action is necessary. For this reason, an understanding of risk management principles (such as described in ISO 14971) is important for full participants and highly desirable for associate participants.

Because of the highly confidential and/or sensitive nature of some of the information being transferred, NCAs wishing to participate fully in the NCAR exchange program, **including founding members,** must meet several prerequisites and make several commitments to the other participants.

Prospective full participants to the NCAR exchange program must make an application to the GHTF Steering Committee. In the application process, the prospective full participants must demonstrate to the GHTF that they fulfill the prerequisites and make the necessary commitments before they join the exchange program. Only NCAs are eligible to apply to join the NCAR exchange program as full participants.

The prerequisites and commitments required of organisations that wish only to share public information with other NCAR program participants are much less stringent. Membership on this basis is open not only to NCAs, but also to any public, not-for-profit organisation that can demonstrate that, using the NCAR information, the organisation can make a significant contribution to the protection of public health. Such organisations must still provide a single contact point and become acquainted with document exchange procedures (GHTF SG2 N79).

NCAR exchange participants may need to manage collectively the administrative burden of the program, by cost recovery, for example, or rotation of the administrative tasks involved.

5.0 The Application Process

The application process is shown in Figure 1 and is described fully in this Section. After an application to the Steering Committee (SC) of the GHTF is made, the Steering Committee will forward the application to the SG2 Chair. After consultation of the applicant and of the SG2 members, the Chair will identify a suitable trainer, make contact with the organization the trainer belongs to and that will help the applicant with the organization of the training. GHTF SG2 will develop the list of suitable trainers and amend it periodically. Trainers must be NCAs already participating in the exchange program, preferably from the same geographical region as the applicant.

The applicant must then seek the agreement of their chosen NCA to provide the training. The agreement between the trainer and the applicant may include a provision for the recovery of costs associated with the provision of training, materials, accommodation, travel or any other reasonable costs associated with training the applicant.

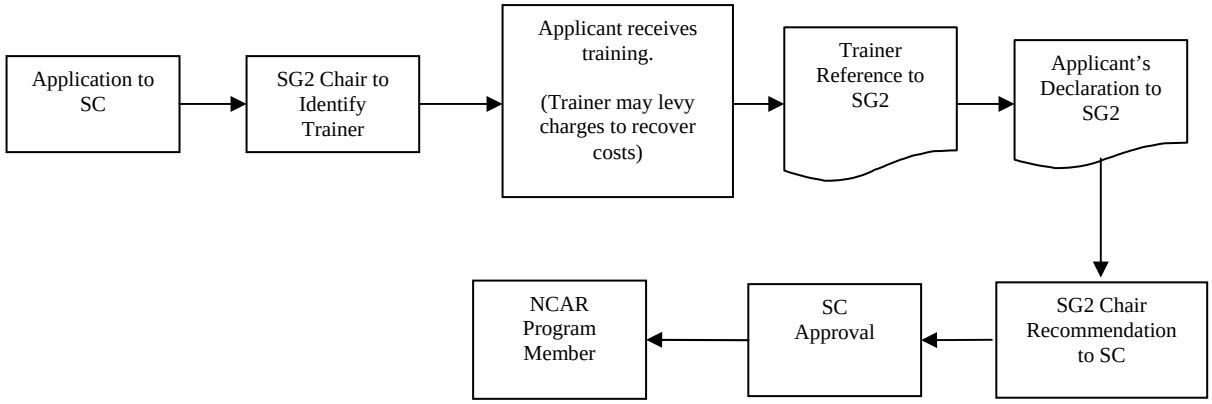

Figure 1: Application process to join the NCAR exchange program

The trainer will provide guidance on and support the implementation of GHTF documents, but especially the NCAR process documents and other GHTF SG2 documents. The amount and level of training depends on the level of participation (full or associate) the applicant seeks. When satisfied that the applicant fulfils the necessary prerequisites, the trainer will provide a reference to the GHTF SG2 Chair on behalf of the applicant. In addition, the applicant must make a declaration that they have read and understood the documents and procedures of the NCAR exchange program *(GHTF N8, N79)* and that they agree to abide by those documents and procedures.

The SG2 Chair will review the trainer's reference and the applicant's declaration. When satisfied that the conditions are met to allow the applicant to join the NCAR Exchange Programme, he/she will forward the two documents to the Steering Committee with a recommendation to consider favourably the application.

When the Steering Committee, having considered the SG2 Chair recommendation, the supportive documents and other relevant GHTF policies, is of the opinion that all necessary requirements are met, it will approve the application and inform the applicant accordingly

6.0 Prerequisites and Commitments

6.1 Associate Participants

Pre-requisites

1. Training: For organizations wishing to participate as Associates and exchange only public information, the training may be limited to document exchange procedures (GHTF SG2 79). Trainers may need to recover the costs associated with the provision of training and advice.

Commitments

2. Release of Forms & Single Contact Point: Associate Participants in the exchange program agree that NCARs will be submitted only via the form entitled "Global Medical Devices NCAR Report" *(Section 5 of GHTF SG2 N79).* In order to avoid confusion and duplicate reporting, Associate Participants must provide a single contact name and e-mail address where NCARs will be sent and must provide updates to maintain accuracy.
3. Re-distribution of NCARs: Associate Participants agree that NCARs received through the NCAR program will not be re-distributed to anyone else without the prior consent of the author of the original report. This ensures that the integrity of the original information is maintained, and that the intent of the author of the original report is respected.
4. Maintenance of Competency and Training: Associate Participants must ensure that everyone who receives NCARs is trained to do so and is aware of the commitments made to the other NCAR exchange program members. Moreover, this knowledge must be refreshed on a regular basis[1].

6.2 Full Participants

Pre-requisites

1. Existence of a National Adverse Event Reporting Program: Participation in the NCAR Exchange Programme requires that an active national reporting program be in place. NCARs are derived from information received by the NCA, either from mandatory manufacturer or medical device user reports of adverse events, identified during postmarket surveillance activities such as testing and audits, or from voluntary reports submitted by medical device users or the public. NCAs would not be able to fully participate in the NCAR exchange program unless they receive reports from within their own jurisdiction. Thus, participation in the NCAR exchange program requires that an active national reporting program be in place.

[1] The NCAR Secretariat will facilitate this by providing approved training materials and newsletter style flyers.

2. Training: Full participants in the NCAR exchange program will be receiving sensitive and/or highly technical information which must be interpreted correctly within the context of other GHTF SG2 guidance and other principles. The NCAs wishing to participate fully in the NCAR program must undertake training that will familiarise them with all GHTF SG2 documents and principles as well as risk assessment or health hazard analysis principles (eg ISO 14971), especially:

    - NCAR Report Form and Criteria *(GHTF SG2 N79)*
    - Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices (GHTF SG2 N8)
    - Global Guidance on Adverse Event Reporting (GHTF SG2 N54)
    - ISO 14971: 2000 – Risk Management

    Trainers may need to recover the costs associated with the provision of training and advice.

3. Must be a NCA: Since Full Participants are likely to receive highly sensitive or commercial – in-confidence information from time to time, full participation is open only to NCAs.

Commitments

4. Release of forms & single contact point: NCAs participating in the exchange program agree that NCARs will be submitted to members only via the form entitled "National Competent Authority Report" *(Section 5 of GHTF SG2 N79).* In order to avoid confusion and duplicate reporting, Full Participants must provide a single contact name and e-mail address where NCARs will be sent and must provide updates to maintain accuracy. Participants must ensure that everyone who sends or receives NCARs is trained to do so and is aware of the commitments made to the other NCAR exchange program members.

5. Re-distribution of NCARs: Participants agree that NCARs received through the NCAR exchange program will not be re-distributed to Competent Authorities who are not NCAR participants. The NCARs marked confidential may not be distributed to healthcare facilities or manufacturers in the country of the recipients, without the prior consent of the author of the original report. This ensures that the integrity of the original information is maintained, and that the intent of the author of the original report is respected.

6. Maintenance of Competency and Training: Participants must ensure that everyone who sends or receives NCARs is trained to do so and is aware of the commitments made to the other NCAR exchange program members. Moreover, this knowledge must refreshed on a regular basis[2].

[2] The NCAR Secretariat will facilitate this by providing approved training materials and newsletter style flyers.

7. Confidentiality: When so marked, information exchanged on this form must be considered strictly confidential and may not be released without the permission of the issuing NCA, except in cases of urgent public health need *(see GHTF SG2 N8 for guidance).* In that case, the NCA would notify the issuing NCA of the action being taken and of the reason for it. Information exchanged under other circumstances can be handled as suggested in SG2 N8. Confidentiality is best ensured through using procedures described in documents GHTF SG2 N8 and GHTF SG2 N79.

   The integrity of the NCAR exchange program remains a global priority. Prospective and active members must provide the GHTF with information concerning the status of relevant legal obligations such as Mutual Recognition Agreements, to which their country is, or is likely to become, a signatory. Such obligations can impact the NCAR exchange program.

8. Commitment to participate fully: Participants agree to act in accordance with the procedures of the NCAR exchange program. These procedures are set down in GHTF SG2 documents N8 and N79. Furthermore, countries participating in the NCAR exchange program agree to participate ***fully*** in all aspects of the exchange program, including the exchange of NCARs in accordance with GHTF SG2 N8 and N79, the review of reports sent to them by other member NCAs, the provision of comments on NCARs, and so on. If necessary, the GHTF may undertake a review of the membership of NCAs not adhering correctly to the NCAR exchange program.

7.0 Summary of Requirements for Participation in the NCAR Exchange Program

Table 1 describes briefly the prerequisites and commitments that apply to the two types of Participants in the NCAR Exchange Program. Guidance reference sections are provided in brackets (…).

Participant Level	Associate		Full	
Type of Information Sought by Participant	Public		Public & Confidential	
Prerequisites				
Possible Administration Charge	Yes	(4.0)	Yes	(4.0)
Working Reporting System	No	-	Yes	(5.2.1)
Training	Yes #	(5.1.1)	Yes *	(5.2.2)
Must be NCA	No	-	Yes	(5.2.3)
A commitment to:				
Use of NCAR form/Single Contact Point	Yes	(5.1.2)	Yes	(5.2.4)
No Re-distribution	Yes	(5.1.3)	Yes	(5.2.5)
Maintenance of Competency and Training	Yes	(5.1.4)	Yes	(5.2.6)
Confidentiality	No	-	Yes	(5.2.7)
Full Participation	No	-	Yes	(5.2.8)

Training regarding GHTF N79 only. * Full Training