



FINAL DOCUMENT

(revision of GHTF/SC/N4: 2011)

Title: Glossary and Definitions of Terms Used in GHTF Documents

Authoring Group: GHTF Steering Committee

Date: November 9th, 2012

A handwritten signature in black ink, appearing to read 'Kazunari Asanuma', written over a horizontal line.

Dr. Kazunari Asanuma, 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.

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Preface

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1.0 Introduction

The purpose of this document is to publish a list of definitions used in all GHTF Final Documents for use as a GHTF Glossary of Terms.

2.0 Rationale, Purpose and Scope

GHTF guidance documents have been written by different Study Groups and, when finalised, are published by the GHTF on its website. Many include a list of the definitions. This particular document consolidates these definitions into a single list and will improve understanding of the guidance provided in GHTF Final Documents.

3.0 References

All GHTF Final Documents.

4.0 Definitions

It should be noted that this document is intended as an information paper only and is not intended to be a definitive dictionary of each term. In some instances there may be more than one definition for a single term. Where this occurs it is recommended that the reader refer to the source documents in which they are referenced to ensure the terms are understood in the correct context. It should also be noted that some definitions are derived from international or national standards, guidance or regulations. Where such definitions are used herein, it is recommended that readers refer to the original source documents.

5.0 Existing Definitions in GHTF documents

Definitions, which appear in GHTF Final Documents, are listed in Appendix A.

When writing a new document or modifying an existing one, the relevant Study Group should review the Glossary of Terms in the Appendix and use a definition from the list whenever possible. When submitting a guidance document to the GHTF Steering Committee for endorsement, the Study Group should confirm it has made the comparison and explain the reason for incorporating an alternative to the listed definition.

Appendix A: List of Definitions

Abnormal Use: Act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer.

Note: Foreseeable misuse that is warned against in the instructions for use is considered abnormal use if all other reasonable means of risk control have been exhausted.

GHTF/SG2/N54R8:2006

Accessory: An article which, is intended specifically by its manufacturer to:

- be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device.
- or to augment or extend the capabilities of that device in fulfillment of its intended use as an IVD medical device.

and therefore should be considered an IVD medical device.

GHTF/SG1/N045:2008

Accessories: An article intended specifically by its manufacturer to be used together with a specific medical device(s), to enable the medical device to be used in accordance with its intended use. (*modified draft GHTF definition – revision SG1 N29/R16: 2005*)

GHTF/AHWG-UDI/N2R3:2011

Accessory to a medical device: An article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use.

GHTF/SG1/N071:2012/ GHTF/SG1/N77:2012

Accessory to an IVD medical device: An article intended specifically by its manufacturer to be used together with a particular IVD medical device to enable or assist that device to be used in accordance with its intended use.

Note: Some jurisdictions include ‘accessories to a medical device’ and ‘accessories to an IVD medical device’ within their definitions of ‘medical device’ or ‘IVD medical device’, respectively. Other jurisdictions do not adopt this approach but still subject an accessory to the regulatory controls (e.g. classification, conformity assessment, quality management system requirements etc.) that apply to medical devices or IVD medical devices.

GHTF/SG1/N071:2012

Active Exchange: A pro-active exchange of information involving direct notification to nominated contact addresses. This is achieved via e-mail and through the NCAR Secretariat.

Active exchange is the method of choice for high risk issues.

GHTF/SG2/N79R11:2009

Active Medical Device: Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy,

substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Standalone software is considered to be an active medical device.

GHTF/SG1/N77:2012

Active Device Intended for Diagnosis: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.

GHTF/SG1/N77:2012

Active Therapeutic Device: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

GHTF/SG1/N77:2012

Adverse Device Effect: An adverse event related to the use of an investigational medical device.

NOTE 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device

GHTF/SG5/N5:2012

Adverse Event: An “Adverse Event” is either a malfunction or a deterioration in the characteristics or performance of a sold medical device [including accessory(s) and labelling] or use error, which either has caused or could have caused or contributed to death, or serious injury to health of patients or other persons.

GHTF/SG4/N33R16:2007

Adverse Event: Any untoward medical occurrence in a subject.

Note: For the purposes of this document, this is intended to include any adverse event whether device related or not.

GHTF/SG5/N2R8:2007

Adverse Event: Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, whether or not related to the investigational medical device.

NOTE 1: This definition includes events related to the investigational medical device or the comparator.

NOTE 2: This definition includes events related to the procedures involved.

NOTE 3: For users or other persons, this is restricted to events related to investigational medical devices.

GHTF/SG5/N5:2012

Analytical Performance: The ability of an IVD medical device to detect or measure a particular analyte.

GHTF/SG1/N68:2012

GHTF/SG5/N6:2012

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).

GHTF/SG2/N38R19:2009

Audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

GHTF/SG1/N046:2008

Audit: Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

For the purpose of these guidelines, “audit” means audit of the auditee’s quality management system to determine compliance with the relevant regulatory requirements.

GHTF/SG4/N28R4:2008

Audit: Systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

GHTF/SG1/N78:2012

GHTF/SG4/N30:2010

Audit Criteria: Set of policies, procedures or requirements.

Note: Audit criteria are used as a reference against which audit evidence is compared.

GHTF/SG4/N28R4:2008 / GHTF/SG4/N30:2010

Audit Criteria: Set of policies, procedures or requirements.

GHTF/SG1/N78:2012

Auditee: Any organization whose quality systems is to be audited for compliance with relevant medical device regulatory requirements. The organization may be the manufacturer and/or their supplier(s).

GHTF/SG4/N28R4:2008

Audit Evidence: Records, statements of fact or other information, which are relevant to the audit criteria and verifiable.

Note: Audit evidence may be qualitative and/or quantitative and is used to substantiate audit observations

GHTF/SG1/N78:2012

GHTF/SG4/N28R4:2008 / GHTF/SG4/N30:2010

Audit Findings: Results of the evaluation of the collected audit evidence against audit criteria.

Note: Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement.

GHTF/SG4/N28R4:2008 / GHTF/SG4/N33R16:2007

Auditing Organisation: A body designated, on the basis of specific regulations, to carry out audits according to assigned tasks.

GHTF/SG4/N28R4:2008 / GHTF/SG4/N30:2010

Audit Language: The language(s) routinely used for the communication or exchange of information between auditee's personnel and auditors.

GHTF/SG4/N28R4:2008

Auditor: A person with relevant qualifications and competence to perform audits or specified parts of such audits and who belongs to, or is authorized by, the auditing organization.

GHTF/SG4/N28R4:2008

Audit Program: Set of one or more audits planned for a specific time frame and directed towards a specific purpose.

Note: An audit program includes all activities necessary for planning, organizing and conducting the audits.

GHTF SG4/N28R4:2008 / GHTF/SG4/N83:2010

Automatic Identification and Data Capture (AIDC): The methods for automatic identifying objects, collecting data about them, and entering the data directly into computer systems.

GHTF/AHWG-UDI/N2R3:2011

Authorized Representative: Any natural or legal person established within a country or jurisdiction who has received a mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

GHTF/SG1/N046:2008

Authorized Representative: Any natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

GHTF/SG1/N055:2009

Blinding/Masking: Procedure in which one or more parties to the clinical investigation are kept unaware of the treatment assignment(s).

NOTE: Single-blinding usually refers to the subject(s) being unaware of the treatment assignment(s). Double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, centralized assessors being unaware of the treatment assignment(s).

GHTF/SG5/N5:2012

Centralized Function: A quality management system function that is applicable to one or more sites, but is controlled from a single site (which may not necessarily be the lead site).

GHTF/SG4/N83:2010

Central Circulatory System: The major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries.

GHTF/SG1/N77:2012

Central Nervous System: The brain, meninges, and spinal cord.

GHTF/SG1/N77:2012

Cleaning: Removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.

GHTF/SG1/N77:2012

Clinical Data: Safety and/or performance information that are generated from the clinical use of a medical device.

GHTF/SG1/N68:2012

GHTF/SG5/N1R8:2007 / GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010 / GHTF/SG5/N4:2010

Clinical Evaluation: The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

GHTF/SG1/N68:2012

GHTF/SG5/N1R8:2007 / GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010 / GHTF/SG5/N4:2010

Clinical Evidence: The clinical data and the clinical evaluation report pertaining to a medical device.

GHTF/SG5/N1R8:2007 / GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010 / GHTF/SG5/N4:2010

Clinical Evidence for an IVD Medical Device: All the information that supports the scientific validity and performance for its use as intended by the manufacturer.

GHTF/SG1/N68:2012

GHTF/SG5/N6:2012

Clinical Investigation: Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device.

GHTF/SG1/N70:2011

GHTF/SG5/N1R8:2007 / GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010 / GHTF/SG5/N4:2010

Clinical Investigation Plan: Document that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation.

GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010 / GHTF/SG5/N5:2012

Clinical Investigator: The individual responsible for the conduct of a clinical investigation who takes the clinical responsibility for the well-being of the subjects involved.

GHTF/SG5/N2R8:2007

Clinical Performance: The ability of a medical device to achieve its intended purpose as claimed by the manufacturer.

GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010

Clinical Performance of an IVD Medical Device: The ability of an IVD medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with target population and intended user.

GHTF/SG1/N68:2012

GHTF/SG5/N6:2012

Clinical Performance Study: A study undertaken to establish or confirm the clinical performance of an IVD medical device.

NOTE: This term is synonymous with ‘clinical trial’ and ‘clinical study’.

GHTF/SG5/N6:2012

Clinical Performance Study Protocol: Document that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study.

GHTF/SG5/N8:2012

Clinical Safety: The absence of unacceptable clinical risks, when using the device according to the manufacturer’s Instructions for Use.

GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010

Clinical Utility of an IVD Medical Device: The usefulness of the results obtained from testing with the IVD medical device and the value of the information to the individual being tested and/or the broader population.

GHTF/SG5/N6:2012

Common Function: A quality management system function defined by a single site that is applicable to more than one site and may be controlled by multiple sites.

GHTF/SG4/N83:2010

Comparator: Medical device, therapy (e.g. active control), placebo or no treatment, used in the reference group in a clinical investigation.

GHTF/SG5/N5:2012

Compliance: Overall conformity to regulatory requirements.

GHTF/SG4/N28R4:2008

Compliance / Conformity: Fulfillment of regulatory requirements.

Note: In this document the terms “compliance” and “conformity” are used interchangeably whereas in some jurisdictions they may have distinct and different meanings.
GHTF/SG4/N33R16:2007

Concession: Permission to use or release a product that does not conform to specified requirements.
GHTF/SG3/N18:2010

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.
GHTF/SG2/N38R19:2009 / GHTF/SG2/N79R11:2009

Conformity: Fulfillment of a requirement.
GHTF/SG4/N28R4:2008

Conformity Assessment: The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices*.
GHTF/SG1/N044:2008 / GHTF/SG1:N046:2008 / GHTF/SG1/N78:2012
GHTF/SG5/N2R8:2007 / GHTF/SG5/N3:2010

Conformity Assessment Body (CAB): A body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorized to undertake specified conformity assessment activities by a Regulatory Authority that will ensure performance of the CAB is monitored and, if necessary, withdraw designation.
GHTF SG1/N044:2008 / GHTF/SG1/N046:2008

Conformity Assessment Body (CAB): A body, other than a Regulatory Authority, engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled.
GHTF/SG1/N78:2012

Contact Details: A postal address in a format that allows physical location to be established together with a telephone number and e-mail address.
GHTF/SG1/N065:2010

Correction: Action to eliminate a detected nonconformity.
Note 1: A correction can be made in conjunction with corrective action.
Note 2: Corrections can be, for example, rework or re-grade.
GHTF/SG3/N18:2010

Corrective Action: Action to eliminate the cause of a detected nonconformity or other undesirable situation
Note 1: There can be more than one cause for nonconformity.

Note 2: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Note 3: There is a distinction between correction and corrective action.

GHTF/SG3/N18:2010

Critical Supplier: A critical supplier is a supplier delivering materials, components, or services, that may influence the safety and performance of the product.

(GHTF/SG4/N33R16:2007)

Note: In the context of audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause a significant degradation in performance. This can include suppliers of services which are needed for compliance with QMS or regulatory requirements, e.g. internal audit contractors or EU Authorized Representatives.

GHTF/SG4/N84:2010

Data Sources: The processes within a Quality Management System that provide quality information that could be used to identify nonconformities, or potential nonconformities.

GHTF/SG3/N18:2010

Designating Authority (DA): Body established within government or empowered by government to designate auditing organizations, suspend or withdraw their designation or remove their suspension from designation.

GHTF/SG4/N33R16:2007

Device Deficiency: Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance.

NOTE: Device deficiencies include malfunctions, misuse or use errors and inadequate labeling

GHTF/SG5/N5:2012

Device Identifier (DI): The Device Identifier Is a unique numeric or alphanumeric code specific to a model (or version) of medical device and that is also used as the "access key" to information stored in a UDI Database.

GHTF/AHWG-UDI/N2R3:2011

Device Registry: An organized system that uses observational study methods to collect defined clinical data under normal conditions of use relating to one or more devices to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves (a) predetermined scientific, clinical or policy purpose(s). (Agency for Healthcare Research and Quality, "Registries for Evaluating Patient Outcomes: A User's Guide", modified).

Note: The term "device registry" as used here should not be confused with the concept of device registration and listing. (See GHTF SG1N065)

GHTF/SG5/N4:2010

Diagnostic sensitivity (Clinical sensitivity): Ability of an IVD medical device to identify the presence of a target marker associated with a particular disease or condition.

NOTE 1: Also defined as percent positivity in samples from subjects where the target disease or condition is known to be present.

NOTE 2: Diagnostic sensitivity is a number fraction, calculated as true positive values divided by the sum of true positive plus false negative values.

NOTE 3: The disease or condition is defined by criteria independent of the IVD medical device under consideration.

GHTF/SG5/N7:2012

Diagnostic specificity (Clinical Specificity): Ability of an IVD medical device to recognize the absence of a target marker associated with a particular disease or condition.

NOTE 1: Also defined as percent negativity in samples where the target analyte (measurand) is known to be absent.

NOTE 2: Diagnostic specificity is a number fraction, calculated as true negative values divided by the sum of true negative plus false positive values.

NOTE 3: The disease or condition is defined by criteria independent of the medical device under consideration.

GHTF/SG5/N7: 2012

Direct Part Mark (DPM): "... A technology used to produce two different surface conditions on an item. These markings can be created by laser etching, molding, peening, etc."

GHTF/AHWG-UDI/N2R3:2011

Disinfection: Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.

GHTF/SG1/N77:2012

Distributor: Any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

Notes:

1. More than one distributor may be involved in the supply chain.
2. Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

GHTF/SG1/N055:2009

Duration of use

Transient: Normally intended for continuous use for less than 60 minutes.

Short term: Normally intended for continuous use for between 60 minutes and 30 days.

Long term: Normally intended for continuous use for more than 30 days.

NOTE: continuous use means:

- a) The entire duration of use of the same device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device.

- b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

GHTF/SG1/N77:2012

Endpoint: Indicators measured or determined to assess the objectives of a clinical investigation, prospectively specified in the clinical investigation plan.

GHTF/SG5/N3:2010

Establish: Establish means define, document (in writing or electronically), and implement

Note: This definition differs from the usage of the word “establish” in ISO 13485: 2003.

GHTF/SG4/N28R4:2008 / GHTF/SG4/N30:2010

Examination: Set of operations having the object of determining the value of a property.

Note: In the IVD medical device industry and in many laboratories that use IVD medical devices, examination of an analyte in a biological sample is commonly referred to as a test, assay or analysis.

GHTF/SG1/N045:2008

Examination: Set of operations having the object of determining the value or characteristics of a property.

NOTE 1: In some disciplines (e.g., microbiology) an examination is the total activity of a number of tests, observations or measurements.

NOTE 2: Laboratory examinations that determine the value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

NOTE 3: Laboratory examinations are also called ‘assays’ or ‘tests.’

GHTF/SG5/N7:2012

Field Safety Corrective Action (FSCA): A field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. Such action should be notified via a field safety notice.

In assessing the need of the FSCA the manufacturer is advised to use the methodology described in the harmonised standard EN ISO14971.

This may include:

- return of a medical device to the manufacturer or its representative;
- device modification;
- device exchange;
- device destruction;
- advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants)

Device modifications may include:

- retrofit in accordance with the manufacturer's modification or design change;
- permanent or temporary changes to the labelling or instructions for use;
- software upgrades including those carried out by remote access;

- modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device. For example:
 - For implantable devices it is often clinically unjustifiable to explant the device. Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return.
 - For any diagnostic device (e.g. IVD, imaging equipment or devices) the retesting of affected patients, samples or the review of previous results.

advice on a change in the way the device is used (e.g. IVDS manufacturer advises revised quality control procedure -use of third party controls or more frequent calibration).

GHTF/SG2/N57R8:2006 / GHTF/SG2/N79R11:2009

Field Safety Notice: A communication sent out by a manufacturer or its representative to the device users in relation to a Field Safety Corrective Action.

GHTF/SG2/N57R8:2006

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 National Competent Authorities (NCAs).

GHTF/SG2/N38R19:2009

Harm: Physical injury or damage to the health of people or damage to property or the environment.

*GHTF/SG1/N41R9:2005 / GHTF/SG1/N045:2008 / GHTF/SG1/N68:2012 /
GHTF/SG1/N77:2012*

GHTF/SG3/N15R8:2005

Hazard: Potential source of harm.

*GHTF/SG1/N41R9:2005 / GHTF/SG1/N045:2008 / GHTF/SG1/N68:2012 /
GHTF/SG1/N77:2012*

GHTF/SG3/N15R8:2005

Human Readable Interpretation (HRI): Human Readable Interpretation is a legible interpretation of the data characters encoded in the AIDC symbol.

GHTF/AHWG-UDI/N2R3:2011

Immediate Adverse Event Report: For purposes of adverse event reporting, immediately means as soon as possible, but not later than 10 elapsed calendar days following the date of awareness of the event.

GHTF/SG2/N54R8:2006

Importer: Any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

GHTF/SG1/N055:2009

Information Supplied by the Manufacturer: Means 'Labelling'.

GHTF/SG1/N70:2011

Installation Qualification (IQ): Establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered.

GHTF/SG3/N99-10:2004 (Edition 2)

Instructions for Use: Information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.

GHTF/SG1/N70:2011

Instrument: Equipment or apparatus intended by the manufacturer to be used as an IVD medical device.

GHTF/SG1/N045:2008

Intended Purpose: The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

GHTF/SG2/N54R8:2006

Intended Use / Purpose: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

*GHTF/SG1/N045:2008 / GHTF/SG1/N68:2012 / GHTF/SG1/N70:2011 / GHTF/SG1/N77:2012
GHTF/SG5/N6:2012*

Invasive devices

Invasive device: A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

Surgically invasive device:

(a) An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

(b) A medical device which produces penetration other than through a body orifice.

Implantable device: Any device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

GHTF/SG1/N77:2012

Investigational Medical Device: Medical device being assessed for safety or performance in a clinical investigation

NOTE 1: This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes.

NOTE 2: In this standard the terms 'investigational medical device' and 'investigational device' are used interchangeably.

GHTF/SG5/N5:2012

Investigator: Individual member of the investigation site team designated and supervised by the principal investigator at an investigation site to perform critical clinical investigation-related procedures or to make important clinical investigation-related decisions.

NOTE 1: An individual member of the investigation site team can also be called 'sub-investigator' or 'co-investigator'.

GHTF/SG5/N5:2012

In Vitro Diagnostic (IVD) Medical Device: A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Note2: In some jurisdictions, certain IVD medical devices may be covered by other regulations.

GHTF/SG1/N071:2012

GHTF/SG5/N6:2012 / GHTF/SG5/N7:2012

IVD Medical Device: A device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostics, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Note: In some jurisdictions, some IVD medical devices may be covered by separate regulations.

GHTF/SG1/N045:2008

IVD Medical Device for Self-Testing: Any IVD medical device intended by the manufacturer for use by lay persons.

GHTF/SG1/N045:2008 / GHTF/SG1/N68:2012

Kits: A collection of medical products, including medical devices, and other products that are packaged together to achieve a stated intended use, being distributed as a single medical device. This includes procedural packs and convenience kits.

GHTF/AHWG-UDI/N2R3:2011

Label: Written, printed or graphic information provided upon the medical device itself.

Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

GHTF/AHWG-UDI/N2R3:2011

Label: Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

GHTF/SG1/N70:2011

Labelling: The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

GHTF/SG1/N70:2011

Lay Person: Individual that does not have formal training in a specific field or discipline.

GHTF/SG1/N045:2008 /GHTF/SG1/N68:2012 / GHTF/SG1/N70:2011 / GHTF/SG1/N77:2012

Lead Auditor: An auditor appointed to manage an audit.

GHTF/SG4/N28R4:2008

Lead Site: A site having an identified central function, by which the quality management system applied to the sites is established and subject to continuous surveillance and internal audits. The lead site can require any site to implement corrective actions when needed. Where applicable this should be set out in the formal agreement between the lead site and the other sites.

GHTF/SG4/N83:2010

Life-Cycle: All phases in the life of a medical device, from the initial conception to final decommissioning and disposal

GHTF/AHWG-GRM/N1R13:2011

Life Supporting or Life Sustaining: A device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

GHTF/SG1/N77:2012

Listing: The process whereby a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification of a medical device(s) that is or will be supplied to the market in that jurisdiction.

GHTF/SG1/N065:2010

Malfunction or Deterioration: A failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

GHTF/SG2/N54R8:2006

Manufacturer*: Any natural or legal person¹ with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Notes:

1. This ‘natural or legal person’ has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.
2. The manufacturer’s responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.
3. ‘Design and/or manufacture’, as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.
4. Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.
5. Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.
6. An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.
7. To the extent than an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

GHTF/SG1/N055:2009

* The definition of the term “manufacturer” in GHTF/SG1/N055:2009 is the preferred and default definition. It should be generally understood to apply wherever that term appears in GHTF guidance documents, unless the specific context directs otherwise. As and when GHTF guidance documents are revised in the future, consideration should be given to uniform incorporation of that definition.

¹ The term “person” that appears here includes legal entities such as a corporation, a partnership or an association.

Manufacturer: Any natural or legal person¹ with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). [GHTF SG1/N055] This includes Reprocessors and Remanufacturers that take responsibility for the device and reintroduce it into commercial distribution.

GHTF/AHWG-UDI/N2R3:2011

Manufacturer: For the purpose of this document, the term “manufacturer” must be understood to include the manufacturer, its authorized representative or any other person who is responsible for placing the device on the market.

GHTF/SG2N36R7:2003 / GHTF/SG2/N54R8:2006

Manufacturer: Any natural or legal person¹ who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies).

(GHTF/SG1/N055R6)

Note: In some internationally recognized Standards and Guidelines on auditing, specific responsibilities are assigned to the client (i.e. a person or the organization requesting or commissioning the audit). These responsibilities are assigned on the basis that the client, as the financial supporter and primary customer of the audit, has the ultimate authority regarding the audit. The ultimate authority for the audit of medical device manufacturers is the auditing organization and the term “client” is not used therefore in these guidelines.

GHTF/SG4/N28R4:2008

Manufacturer: Any natural or legal person¹ who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies). *(GHTF/SG1/N055R6)*

Note 1: This ‘natural or legal person’ has ultimate responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold.

Note 2: The manufacturer’s responsibilities are described in other GHTF guidance documents. They include a responsibility to ensure pre- and post-market regulatory requirements for a finished medical device are met. This includes adverse event reporting and notification of corrective actions.

Note 3: “Design and/or manufacture”, as referred to in the above definition, may include:

- a) specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing; and/or
- b) assembly, packaging, processing and/or labelling of one or more finished products.

¹ The term “person” that appears here includes legal entities such as a corporation, a partnership or an association.

Note 4: Any person who assembles or adapts a device(s) that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the device(s).

Note 5: Any person who changes the intended use of, or modifies, a finished medical device in a way that may affect safety or performance, without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6: To the extent that an accessory is subject to regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is deemed to be a manufacturer.

GHTF/SG3/N17:2008

Manufacturer: Any natural or legal person¹ with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). (GHTF SG1/N55:2009)

GHTF/SG3/N19:2012

Manufacturer: Any natural or legal person¹ with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). (*GHTF/SG1/N055*)

Note: the term “Virtual Manufacturer” is sometimes used for a manufacturer which subcontracts nearly all of the design, production and other activities associated with making the finished medical device on the market.

GHTF/SG4/N83:2010 / GHTF/SG4/N84:2010

Manufacturer with Multiple Sites: A manufacturer which conducts activities under the same quality management system at more than one site.

GHTF/SG4/N83:2010

Marketing: The distribution and/or use of a device in commerce (based on definition of Supplying to the Market).

GHTF/AHWG-GRM/N1R13:2011

Medical Device: Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

GHTF/SG1/N071:2012

NCAR Secretariat: The organisation which receives NCARs from reporting NCAs and distributes them to other NCAR participants in accordance with this guidance and GHTF SG2 N38 is known as the Secretariat.

GHTF/SG2/N79R11:2009

Near Patient (testing): Testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient.

GHTF/SG1/N045:2008

Nonconformity: Non-fulfillment of a requirement.

GHTF/SG3/N18:2010 / GHTF/SG3/N19:2012

Note: For explanation of the term “major nonconformity” see SG4N28

GHTF/SG4/N33R16:2007

Other terms may be used to mean the same as nonconformity ‘e.g. ‘non compliance’, ‘deficiency’).

GHTF/SG4/N28R4:2008

Objective Evidence: Data supporting the existence or verity of something

Note: Objective evidence may be obtained through observation, measurement, test, or other means.

GHTF/SG3/N17:2008

Objective Evidence: Verifiable information or records pertaining to the quality of an item or service or to the existence and implementation of a quality management system requirement, which is based on visual observation, measurement, testing, or other means.

Note: ISO 9000:2005 3.8.1 defines objective evidence as “data supporting the existence or verity of something”.

GHTF/SG4/N28R4:2008

Operational Qualification (OQ): Establishing by objective evidence process control limits and action levels which result in product that meets all predetermined requirements.

GHTF/SG3/N99-10:2004 (Edition 2)

Overall lead Auditor: The auditor who has oversight of the audit program described in this document.

GHTF/SG4/N83:2010

Own Brand/Private Labelers: An Own Brand or Private Labeler relabels a device from a 3rd party with his own name without making any further changes to the device thereby taking responsibility for it as the manufacturer.

GHTF/AHWG-UDI/N2R3:2011

Packaging Levels: Packaging levels means the various levels of device packages that contain a fixed quantity of medical devices, e.g., each, carton, case. This does not include shipping containers such as pallets.

GHTF/AHWG-UDI/N2R3:2011

Passive Exchange: The exchange of information via the use of a database, website or other means for exchange participants to view at their discretion.

GHTF/SG2/N79R11:2009

Performance Evaluation for an IVD Medical Device: Assessment and analysis of data to establish or verify the performance of an IVD medical device

GHTF/SG1/N68:2012

GHTF/SG5/N6:2012

Performance Evaluation for an IVD Medical Device: Investigation process of an IVD medical device for the purpose of establishing or verifying its performance.

GHTF/SG1/N70:2011

Performance of an IVD Medical Device: The ability of an IVD medical device to achieve its intended use as claimed by the manufacturer. The performance of an IVD medical device consists of the analytical and, where applicable, the clinical performance supporting the intended use of the IVD medical device.

GHTF/SG5/N6:2012

Performance Qualification (PQ): Establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.

GHTF/SG3/N99-10:2004 (Edition 2)

Post-market Clinical Follow-Up Study: A study carried out following marketing approval intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a device when used in accordance with its approved labelling. These may examine issues such as long-term performance, the appearance of clinical events (such as delayed hypersensitivity reactions or thrombosis), events specific to defined patient populations, or the performance of the device in a more representative population of providers and patients.
GHTF/SG5/N4:2010

Predictive value: Probability that a person with a positive IVD medical device test result has a given condition under investigation, or that a person with a negative IVD medical device test result does not have a given condition.

NOTE 1: The predictive value is determined by the diagnostic sensitivity and diagnostic specificity of the IVD medical device test procedure, and by the prevalence of the condition for which the examination is used.

NOTE 2: Prevalence means the proportion of persons with a particular disease within a given population at a given time.

NOTE 3: The positive predictive value indicates how effectively an IVD medical device separates true positive test results from false positive test results for a given attribute in a given population.

NOTE 4: The negative predictive value indicates how effectively an IVD medical device separates true negative test results from false negative test results for a given attribute in a given population.

GHTF/SG5/N7:2012

Preventive Action: Action to eliminate the cause of a potential nonconformity or other undesirable situation

Note 1: There can be more than one cause for nonconformity.

Note 2: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

GHTF/SG3/N18:2010

Principal Investigator: Qualified person responsible for the conduct of the clinical investigation at an investigation site

NOTE 1: If a clinical investigation is conducted by a team of individuals at an investigation site, the principal investigator is the person responsible for leading the team.

NOTE 2: Whether this is the responsibility of an individual or an institution responsibility can depend on national regulations.

GHTF/SG5/N5:2012

Process: Set of interrelated or interacting activities which transform inputs into outputs.

GHTF/SG4/N30:2010

Note 1: Inputs to a process are generally outputs of other processes.

Note 2: Processes in an **organization** are generally planned and carried out under controlled conditions to add value.

Note 3: A process where the **conformity** of the resulting **product** cannot be readily or economically verified is frequently referred to as a “special process”.

GHTF/SG3/N17:2008

Process Validation: Establishing by objective evidence that a process consistently produces a result or product meeting its predetermined requirements.

GHTF/SG3/N99-10:2004 (Edition 2)

Process Validation Protocol: A document stating how validation will be conducted, including test parameters, product characteristics, manufacturing equipment, and decision points on what constitutes acceptable test results.

GHTF/SG3/N99-10:2004 (Edition 2)

Product: Result of a **process**

Note 1: There are four generic product categories, as follows:

- services (e.g. transport);
- software (e.g. computer program, dictionary);
- hardware (e.g. engine mechanical part);
- processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product “automobile” consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver’s manual), and service (e.g. operating explanations given by the salesman).

Note 2: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);
- an activity performed on a customer-supplied tangible product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or **procedures**.

Hardware is generally tangible and its amount is a countable **characteristic**. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

Note 3: **Quality assurance** is mainly focused on intended product.

GHTF/SG3/N17:2008

Product Documentation: These documents are the final output for a particular product resulting from a design and development process whether or not the design and development process is regulated or under the scope of the quality management system.

Note: In different jurisdictions different terms are used.

GHTF/SG4/N30:2010

Production Identifier (PI): The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, manufacturing and/or expiration date.

GHTF/AHWG-UDI/N2R3:2011

Product Realization: The process starting with planning and proceeding through determination of customer requirements and customer communication, design and development, purchasing, production, servicing, control of monitoring and measuring devices, and including delivery of the medical device.

Note: For further definitions please refer to GHTF SC(PD)N4 Glossary document.

GHTF/AHWG-GRM/N1R13:2011

Public Information: For the purposes of this document, public information 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.

GHTF/SG2/N38R19:2009 / GHTF/SG2/N79R11:2009

Quality Management System (QMS): Management system to direct and control an organization with regard to quality.

GHTF/SG3/N19:2012

Quality Management System: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management. For the purpose of these guidelines ‘implementing quality management’ is taken to include both the establishment and maintenance of the system.

Note: ISO 9000:2005 3.2.3 defines quality management as “management system to direct and control an organization with regard to quality”.

GHTF/SG4/N28R4:2008

Radio Frequency Identification (RFID): A technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

GHTF/AHWG-UDI/N2R3:2011

Reagent: Chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as IVD medical devices.

GHTF/SG1/N045:2008

Recognised Standards: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

*GHTF/SG1/N011:2008 / GHTF SG1/N044:2008 / GHTF/SG1/N046:2008 /
GHTF/SG1/N63:2011 / GHTF/SG1/N78:2012
GHTF/SG5/N2R8:2007 / GHTF/SG5/N7:2012*

Registration: The process by which a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification and establishment location(s) of the manufacturer and other parties, responsible for supplying a medical device(s) to the market in that jurisdiction.
GHTF/SG1/N065:2010

Regulatory Audit: The audit of a quality management system to demonstrate conformity with quality management system requirements for regulatory purposes.

Note: For the purpose of these guidelines, “audit” means a regulatory audit.
GHTF/SG4/N28R4:2008 / GHTF/SG4/N30:2010 / GHTF/SG4/N33R16:2007

Regulatory Audit Report: The regulatory audit report is a document or set of documents from the regulatory audit team containing administrative data, a summary of the locations, functions or processes that were audited, audit findings and conclusions.

Note: For the purpose of these guidelines, “audit report” means a regulatory audit report.
GHTF/SG4/N33R16:2007

Regulatory Authority (RA): A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

GHTF/SG1/N044:2008 / GHTF/SG1/N046:2008 / GHTF/SG1/N78:2012

Regulatory Authority (RA): a government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

GHTF/SG1/N68:2012

Regulatory Requirements: Any part of a law, ordinance, decree, or other regulation which applies to medical device manufacturers.

Note 1: Guidelines, draft documents or the like should not be used as regulatory documents and should not be considered as such unless formally promulgated.

(GHTF/SG4/(99)28)

Note 2: For the purpose of this guidance regulatory requirements are restricted to those pertaining to the quality management system.

GHTF/SG4/N33R16:2007

Residual Risk: Risk remaining after protective measures have been taken.

GHTF/SG3/N15R8:2005

GHTF/SG4/N30:2010

Residual Risk: Risk remaining after risk control measures have been taken (e.g. known or emerging risks, or potential risks due to statistical limitations).

GHTF/SG5/N3:2010 / GHTF/SG5/N4:2010

Reusable medical device: Means a device intended for repeated use either on the same or different patients, with appropriate decontamination and other reprocessing between uses.
GHTF/SG1/N77:2012

Reusable Surgical Instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.
GHTF/SG1/N77:2012

Risk: Combination of the probability of occurrence of harm and the severity of that harm.
*GHTF/SG1/N044:2008 / GHTF/SG1/N045:2008 / GHTF/SG1/N68:2012 / GHTF/SG1/N77:2012
GHTF/SG3/N15R8:2005*

Risk Analysis: Systematic use of available information to identify hazards and to estimate the risk.
GHTF/SG3/N15R8:2005

Risk Assessment: Overall process comprising a risk analysis and a risk evaluation.
GHTF/SG3/N15R8:2005

Risk Control: Process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels.
GHTF/SG3/N15R8:2005

Risk Evaluation: Judgment, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society.
GHTF/SG3/N15R8:2005

Risk Management: Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk.
*GHTF/SG3/N15R8:2005
GHTF/SG4/N30:2010*

Risk Management: The systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.
GHTF/SG5/N3:2010

Safeguard Action: The action taken by an EU Member State to withdraw, prohibit or otherwise restrict a device from the market or from being put into service, in accordance with EU Community Law on medical devices. (e.g. Article 8 of the Medical Device Directive 93/42/EEC).
GHTF/SG2/N79R11:2009

Scientific Validity of an Analyte: The association of an analyte to a clinical condition/physiological state.

GHTF/SG5/N6:2012

Self-testing: Testing performed by lay persons.

GHTF/SG1/N045:2008

Serious Adverse Event: An adverse event that

1. led to a death;
2. led to a serious deterioration in health of a patient, user, or others that
 - a. results in a life threatening illness or injury;
 - b. results in a permanent impairment of a body structure or body function;
 - c. requires inpatient hospitalisation or prolongation of existing hospitalisation
 - d. results in medical or surgical intervention to prevent permanent impairment to body structure or a body function;
 - e. led to foetal distress, foetal death or a congenital abnormality/ birth defect.

GHTF/SG5/N2R8:2007

Serious Adverse Event: Adverse event that:

- a) led to a death;
- b) led to a serious deterioration in the health of the subject that either
 - 1) resulted in a life-threatening illness or injury, or
 - 2) resulted in a permanent impairment of a body structure or a body function, or
 - 3) required in-patient hospitalization or prolongation of existing hospitalization, or
 - 4) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function;
- c) led to foetal distress, foetal death or a congenital abnormality or birth defect.

NOTE: A planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without a serious deterioration in health is not considered to be a serious adverse event.

GHTF/SG5/N5:2012

Serious Health Threat: (adapted from GHTF/SG2/N54:2006) Any event type, which results in imminent risk to the study population of death, serious injury, or serious illness that requires prompt remedial action.

GHTF/SG5/N5:2012

Serious Public Health Threat: Any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.

GHTF/SG2/N54R8:2006 / GHTF/SG2/N79R11:2009

Single Use Device: Means the medical device is intended to be used on an individual patient during a single procedure and then disposed of. It is not intended to be reprocessed and used again.

GHTF/SG1/N70:2011

Site: A place where a manufacturer conducts activities.

GHTF/SG4/N83:2010

Specimen: The discrete portion of a body fluid or tissue or other sample associated with the body taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole.

GHTF/SG1/N68:2012

Specimen Receptacle: A device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment of specimens derived from the human body.

GHTF/SG1/N045:2008

Sponsor: Individual or organization taking responsibility and liability for the initiation or implementation of a clinical investigation.

NOTE: When an investigator initiates, implements and takes full responsibility for the clinical investigation, the investigator also assumes the role of the sponsor and is identified as the sponsor-investigator.

NOTE: *(added for the purpose of this document)* The sponsor may be the manufacturer, may be designated by the manufacturer, or may be designated by the regulatory authority.

GHTF/SG5/N5:2012

Standard: Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Note: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

Basic Standards (also known as horizontal standards): Standards indicating fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk management, clinical investigation and the quality management system for the manufacture of medical devices).

Group Standards (also known as semi-horizontal standards): Standards indicating aspects applicable to families of similar products and/or processes making reference as far as possible to basic standards (e.g., standards concerning sterile medical devices, electrically-powered medical devices, stability of IVD reagents).

Product Standards (also known as vertical standards): Standards indicating necessary safety and performance aspects of specific products and/or processes, making reference, as far as possible, to basic standards and group standards (e.g., standards for infusion pumps, for anaesthetic machines, for blood glucose meters for self testing).

GHTF/SG1/N044:2008

Sterilisation: Validated process used to render product free from viable microorganisms.

NOTE: In a sterilisation process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.
GHTF/SG1/N77:2012

Subject: Individual who participates in a clinical investigation

NOTE: A subject can be either a healthy volunteer or a patient.
GHTF/SG5/N5:2012

Summary Technical Documentation (STED): A summary of technical documentation submitted for conformity assessment purposes.
GHTF/SG1/N046:2008 / GHTF/SG1/N78:2012

Supplier: Organization or person that provides a product.
GHTF/SG4/N28R4:2008

Supplier: Organization or person that provides a product.
Example: Producer, distributor, retailer or vendor of a product, or provider of a service or information.

Note 1: A supplier can be internal or external to the organization.

Note 2: In a contractual situation a supplier is sometimes called “contractor”.

GHTF/SG3/N17:2008

Supplier: Organization or person that provides a product.
Example: Producer, distributor, retailer or vendor of a product, or provider of a service or information.

Note 1: A supplier can be internal or external to the organization.

Note 2: In a contractual situation a supplier is sometimes called “contractor or consultant”.

For the purpose of this document, the supplier refers to an organization or person outside the QMS of the manufacturer.

This document addresses suppliers outside of the QMS of the manufacturer. Suppliers within the QMS of the manufacturer are addressed in GHTF SG4/N83 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 4: Multiple Site Auditing

In the context of auditing medical device manufacturers, this definition applies regardless of the legal or financial relationship between the manufacturer and the supplier.

GHTF/SG4/N84:2010

Supply(ing) to the Market: The making available, in return for payment or free of charge, of a device, other than a device intended for clinical or performance evaluation, with a view to distribution and/or use on the market.

GHTF/SG1/N065:2010

Surgically Invasive Device: Refer to definition of “**Invasive Device**”
GHTF/SG1/N15:2006

Technical Documentation: The documented evidence, normally an output of the quality management system, that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices (SG1/N041)*.
GHTF/SG1/N046:2008

Technical Documentation: The documented evidence, normally an output of the quality management system, which demonstrates conformity of a device to the *Essential Principles of Safety and Performance of Medical Devices (SG1/N041)*.
GHTF/SG5/N7:2012

Technical Documentation / File: The documented evidence, normally an output of the quality management system that demonstrates conformity of a device to the *Essential Principles of Safety and Performance of Medical Devices*.
GHTF/SG1/N011:2008 / GHTF/SG1/N063:2011 / GHTF/SG1/N78:2012
GHTF/SG5/N2R8:2007

Training Elements: Topics within a training programme that describe the content for addressing a particular training need. The topic may contain information, regulatory requirements, policies and technical data used for learning and developing skills and competencies as listed in clause 10.2.3 (b) of the ‘Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: general requirements’.
GHTF/SG4/(00)3

Transmissible Agent: An agent capable of being transmitted to a person, as a communicable, infectious or contagious disease.
GHTF/SG1/N045:2008

Transmission: The conveyance of disease to a person.
GHTF/SG1/N045:2008

Unanticipated Serious Adverse Device Effect: A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

NOTE: An anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.

NOTE: (*added for the purpose of this document*) This includes unanticipated procedure-related serious adverse events; that is, serious adverse events occurring during the study procedure that are unrelated to any malfunction or misuse of the investigational medical device.

GHTF/SG5/N5:2012

UDI: Unique Device Identification. The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI comprises the Device Identifier and Production Identifier.

Note: The word "Unique" does not imply serialization of individual production units.

GHTF/AHWG-UDI/N2R3:2011

UDI Carrier: To convey the UDI by using Automatic Identification and Data Capture (AIDC) and, if applicable, its human readable interpretation (HRI).

GHTF/AHWG-UDI/N2R3:2011

UDI Database (UDID): The UDI Database contains identifying information and other elements associated with the specific medical device.

GHTF/AHWG-UDI/N2R3:2011

UDI System: The framework for the production of a Unique Device Identification (UDI), the application of the UDI on the label or directly on device, and the storage of the DI and additional device related information in a UDI Database.

GHTF/AHWG-UDI/N2R3:2011

Unanticipated Death or Unanticipated Serious Injury: A death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.

GHTF/SG2/N54R8:2006

Unanticipated Serious Adverse Device Effect: A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

NOTE: An anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.

NOTE: *(added for the purpose of this document)* This includes unanticipated procedure-related serious adverse events; that is, serious adverse events occurring during the study procedure that are unrelated to any malfunction or misuse of the investigational medical device.

GHTF/SG5/N5:2012

Use Error: Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator. Use error includes slips, lapses, mistakes and reasonably foreseeable misuse.

GHTF/SG1/N78:2012

GHTF/SG2/N54R8:2006

Use Error: An act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user.

NOTE 1: Use error includes slips, lapses, and mistakes.

NOTE 2: An unexpected physiological response of the subject does not in itself constitute a use error.

GHTF/SG5/N5:2012

User: The person, either professional or lay, who uses a medical device. The patient may be the user.

GHTF/SG1/N70:2011

Validation: Confirmation through provision of objective evidence that the requirements for a specific intended use or application have been fulfilled

Note 1: The term “validated” is used to designate the corresponding status.

Note 2: The use conditions for validation can be real or simulated.

GHTF/SG3/N18:2010

Verification: Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

GHTF/SG3/N99-10:2004 (Edition 2)

Verification: Confirmation through provision of objective evidence that specified requirements have been fulfilled

Note 1: The term “verified” is used to designate the corresponding status.

Note 2: Confirmation can comprise activities such as:

- performing alternative calculations,
- comparing a new design specification with a similar proven design specification, undertaking tests, performing demonstrations, and reviewing and approving documents prior to issue.

GHTF/SG3/N18:2010

Vital physiological process: A process that is necessary to sustain life, the indicators of which may include any one or more of the following:

- respiration;
- heart rate;
- cerebral function;
- blood gases;
- blood pressure;
- body temperature.

GHTF/SG1/N77:2012

XML (Extensible Markup Language): A condensed form of Standard Generalized Markup Language (SGML) that enables developers to create customized tags that offer flexibility in organizing and presenting information. XML enables data to be organized and exchanged in ways that were previously impossible or very difficult. By using customised XML schemas, specific pieces of business data can be identified and extracted from ordinary business documents.

GHTF/SG2/N87:2012

Source documents for compiled definitions

AHWG-GRM/N1R13:2011	The GHTF Regulatory Model
AHWG-UDI/N2R3:2011	Unique Device Identification (UDI) System for Medical Devices
SG1/N011:2008	Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
SG1/N044:2008	Role of Standards in the Assessment of Medical Devices.
SG1/N045:2008	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
SG1/N046:2008	Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
SG1/N055:2009	Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer
SG1/N063:2011	Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Medical Devices
SG1/N065:2010	Registration of Manufacturers and other Parties and Listing of Medical Devices
SG1/N068:2012	Essential Principles of Safety and Performance of Medical Devices
SG1/N70:2011	Label and Instructions for Use for Medical Devices
SG1/N071:2012	Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'
SG1/N77:2012	Principles of Medical Devices Classification
SG1/N78:2012	Principles of Conformity Assessment for Medical Devices
SG2/N008R4	Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
SG2/N016R5	Charge & Mission Statement
SG2/N38R19:2009	Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program
SG2/N47R4:2005	Review of Current Requirements on Postmarket Surveillance
SG2/N54R8:2006	Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
SG2/N57R8:2006	Medical Devices Post Market Surveillance: Content of Field Safety Notices
SG2/N79R11:2009	Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form
SG2/N87:2012	An XML Schema for the electronic transfer of adverse event data between manufacturers, authorised representatives and National Competent Authorities (Based on GHTF/SG2/N54: 2006)
SG3/N99-10:2004 (Edition 2)	Quality management System- Process Validation Guidance
SG3/N15R8:2005	Implementation of risk management principles and activities within a Quality Management System

SG3/N17:2008	Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers
SG3/N18:2010	Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes
SG4/(00)3	Training Requirements for Auditors
SG4/N28R4:2008	Guidance for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 1: General Requirements
SG4/N30:2010	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy
SG4/N33R16:2007	Guidance for Regulatory Auditing of Quality Management System of Medical Device Manufacturers- Part 3: Regulatory Audit Reports
SG4/N83:2010	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 4: Multiple Site Auditing
SG4/N84:2010	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 5: Audits of Manufacturer Control of Suppliers
SG5/N1R8:2007	Clinical Evidence – Key Definitions and Concepts
SG5/N2R8:2007	Clinical Evaluation
SG5/N3:2010	Clinical Investigations
SG5/N4:2010	Post-Market Clinical Follow-Up Studies
SG5/N5:2012	Reportable Events During Pre-Market Clinical Investigations
SG5/N6:2012	Clinical Evidence for IVD medical devices – Key Definitions and Concepts
SG5/N7:2012	Clinical Evidence for IVD medical devices – Scientific Validity Determination and Performance Evaluation
SG5/N8:2012	Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices

Revision history

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