GHWP/GL/WG8-SEC/P001/2024

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title:	Guidelines on Development of GHWP Documents - Part 1: Procedure for Development
Authoring Group:	Work Group 8 – Standards and GHWP Secretariat
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Working Group 8

GHWP Secretariat

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† In Memoriam of late Mrs Sabiah Binti Yaakop, for her great contributions on leading the team in preparation of this guideline.

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Foreword

This document was prepared by Global Harmonization Working Party (GHWP), Working Group 8 (Standards) together with GHWP Secretariat, and endorsed by the GHWP.

This guideline indicates the general procedures by which Global Harmonization Working Party (GHWP) Documents are developed in order to ensure that they are clear, precise and unambiguous.

This guideline is intended to ensure that any GHWP Documents produced by the committees under GHWP is presented in a uniform manner.

This guideline is subject to review and users are advised to confirm that the version used is current.

1 Scope

This guideline provides the procedure on development of GHWP documents including document, whitepaper, guidance document (GD) or guideline (GL).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Elements of a document

3.1.1
normative element
element that describes the scope of the document or sets out provisions

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.1.2
informative element
element intended to assist the understanding or use of the document or that provides contextual information about its content, background or relationship with other documents

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.1.3
mandatory element
element that has to be present in a document. EXAMPLE

The Scope is an example of a mandatory element.

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]3.1.4
conditional element
element that is present depending on the provisions of the particular document.

EXAMPLE The symbols and abbreviated terms clause are the examples of a conditional element.

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.1.5
optional element
element that the writer of a document may choose to include or not

EXAMPLE The Introduction is an example of an optional element.

[Source: ISO/IEC Directives, Part 2, 2021, 3.2.1]

3.2
GHWP Document
consensus document, whitepaper, guidance document (GD) or guideline (GL) developed by committees under GHWP for publication.

3.3 Provisions

3.3.1

provision
expression in the content of a normative document that takes the form of a statement, an instruction, a recommendation or a requirement.

NOTE. These forms of provision are distinguished by the form of wording they employ; e.g. instructions are expressed in the imperative mood, recommendations by the use of the auxiliary “should” and requirements by the use of the auxiliary “shall”.

[SOURCE: ISO/IEC Guide 2:2004, 7.1].

3.3.2
statement
expression, in the content of a document, that conveys information

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.2, modified, deleted Note 1 to entry]

3.3.3
requirement
expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled and from which no deviation is permitted if conformance with the document is to be claimed

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.3, modified, deleted Note 1 to entry]

3.3.4
recommendation
expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable without necessarily mentioning or excluding others

Note 1 to entry: In the negative form, a recommendation is the expression that a suggested possible choice or course of action is not preferred but it is not prohibited.

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.4, modified, deleted Note 1 to entry].

3.3.5
permission
expression, in the content of a document, that conveys consent or liberty (or opportunity) to do something

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.5, modified, deleted Note 1 to entry].

3.3.6
possibility

expression, in the content of a document, that conveys expected or conceivable material, physical or causal outcome

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.6, modified, deleted Note 1 to entry].

3.3.7
capability
expression, in the content of a document, that conveys the ability, fitness, or quality necessary to do or achieve a specified thing

[Source: ISO/IEC Directives, Part 2, 2021, 3.3.7, modified, deleted Note 1 to entry].

3.4
state of the art
developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience.

[SOURCE:ISO/IEC Guide 2:2004, 1.4].

4 Procedures for development of documents

In the development of GHWP documents, the following stages shall be observed.

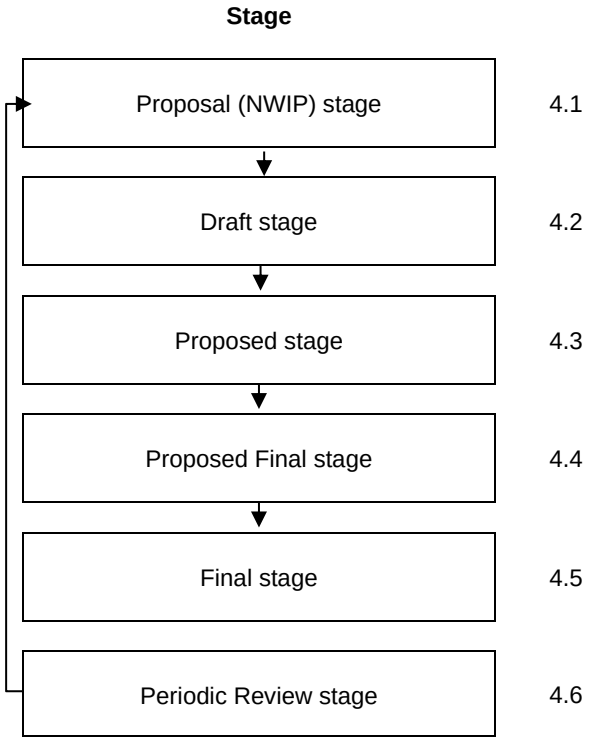

Figure 1. Procedure for development of GHWP documents

Table 1. Explanation and responsibility of each stage.

Clause	Detail	Responsibility
4.1 Proposal (NWIP) Stage	a) NWIP form shall be completed and submitted to the GHWP secretariat. See Annex F for NWIP form.	Proposer GHWP Secretariat
	b) Receipt of NWIP form should be acknowledged within three (3) working days by GHWP secretariat.	GHWP Secretariat
	c) GHWP TC Chair shall review NWIP form to ensure: - Completeness - No duplication of published GHWP document - Relevance and provide the decision to approve/ reject the proposal within 7 working days.	GHWP Secretariat GHWP TC Chair
	d) Assignment to the relevant working group(s) to initiate development of the preliminary draft shall be made within 3 working days.	GHWP Secretariat
	e) Additional information may be requested for incomplete form or insufficient information by WG chair.	WG Chair/ Proposer/ Project Leader

Clause	Detail	Responsibility
	f) The proposal is considered incomplete and should be rejected if no feedback is received within 14 days from 4.1 (e). The GHWP secretariat shall monitor and inform TC chair on the status.	GHWP Secretariat
	g) The validity of approved projects is 3 years, after which (if the project is not completed) the WG may apply for extension of time subject to approval of TC chair.	WG / GHWP TC Chair
4.2 Draft stage	a) The preliminary draft may be prepared by the proposer/ member of WG/ the Project Leader as assigned by the WG Chair.	Proposer/ member of WG/ Project Leader
	b) Deliberation of projects may be carried out in virtual or physical meetings as necessary to complete within the stipulated timeline.	WG
	c) All draft are subjected to proof reading and editing by GHWP Secretariat before releasing the draft to the next stage.	GHWP Secretariat
4.3 Proposed stage	a) Upon finalization at WG, the draft document shall be submitted to GHWP secretariat to be released for public comment within 2 weeks.	WG Chair
	b) Upon receipt of the proposed draft, GHWP Secretariat shall post it on the GHWP website, together with the GHWP commenting template (see Annex E) within 1 week. A circulation through email notification shall also be made to all member countries/regions to call for comments.	GHWP Secretariat
	c) The public comment period shall be 30 days for revised documents and 60 days for new documents. However, in any emergency situations, the public comment period may be reduced or abolished subject to GHWP TC Chair's approval.	GHWP Secretariat/ GHWP TC Chair
	d) All comments received from the public comment exercise shall be further deliberated by the WG, corresponding WG chair should prepare the response and reply to the comments proposer, and be submitted to GHWP secretariat for replying to the comments proposer within 8 weeks. If the deliberation on the comments take more than 8 weeks, then WG Chair shall apply for extension of time to the TC Chair, providing justification on the extension period.	GHWP Secretariat/ WG Chair/ GHWP TC Chair
4.4 Proposed final stage	a) PROPOSED FINAL document should be prepared and proof-read by WG Chair based on comments received, and be passed to GHWP Secretariat for further processing	WG/GHWP Secretariat
	b) The GHWP secretariat shall then circulate proposed final documents for approval by the GHWP Chair and TC Chair. The decision for approval of the draft shall be acquired in 7 working days.	GHWP Secretariat/ GHWP Chair/ GHWP TC Chair
	c) Upon approval, the proposed final documents shall be posted at the GHWP website and circulated to all member economies 4 weeks before GHWP annual meeting for endorsement purposes. However, this period may be shortened in cases where safety, health or emergency issues are involved, subject to GHWP TC Chair approval.	GHWP Secretariat/ GHWP TC Chair
4.5 Final stage	a) The proposed final document shall be listed/presented for endorsement at the GHWP annual meeting.	GHWP secretariat
	b) The final document shall be assigned with number and the document shall be published on GHWP website within 1 weeks after the endorsement at annual meeting. GHWP Document numbering shall be in the following form: • GHWP/GD/WGxxx (Technical Documents) • GHWP/GL/WGxxx (Administrative Documents)	GHWP Secretariat

Clause	Detail	Responsibility
	• GHWP/WP/WGxxx (Recommendations and Information Documents) Note: WG = GHWP WG Number (Starting from 1 to 9) or • GHWP/GD01-2:2023 Guidelines on development of GHWP GD Part 2: Structure and drafting	
	c) Announcement on the new publication shall be made immediately by GHWP Secretariat on GHWP website.	GHWP Secretariat
4.6 Periodic review stage	All GHWP documents shall be reviewed (periodic review) by TC every five (5) years to ensure the document is aligned with current developments. The TC will assign the revision of any document to a relevant WG.	GHWP Secretariat

5 Records

5.1 The following records shall be maintained by GHWP Secretariat in electronic form:

a) Completed NWIP form

b) Correspondences related to approval and inquiry processes

c) Minutes of annual meetings

d) List of projects, timelines, and progress status

e) List of approved GHWP documents with assigned document numbers

f) List of documents for periodic review and decision on their confirmation/revision

g) Copies of final drafts and published documents

6 Applicable forms

a) NWIP Form

b) Commenting Template

ANNEXES

Annex A
(normative)

New Work Item Proposal Form

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

New Document Request/ New Work Item Proposal Form

Please submit to GHWP Secretariat by email to secretariat@ghwp.info

Please choose one of the following:
☐ New Document Request
☐ New Work Item Proposal
☐ New Work Item Modification/ Extension Proposal

For GHWP and TC Leaders consideration

Proposed Project Title		
Initiator		
Purpose and Rationale (Including a reference to one or more of the goals or objectives of the GHWP)	Purpose	
	Rationale	
	Alignment with goals or objectives	
Scope	Summary of issues need to be addressed	
	Impact for regulatory convergence	
General Work Plan and Timelines		
Project Leader		
Proposed Work Group		
Work Group teams and experts if needed		
Relevant reference documents at IMDRF or GHTF and national level, ISO, as well as in international bodies		

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Annex B
(normative)

GHWP Commenting Template

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Comment Submission Form
For GHWP Proposed Document

Document Number: _____ **Document Title:** _____

Submitted by (Name): _____ **Affiliated To (Organization):** _____

Email Contact: _____ **Date:** _____ **(dd/mm/yyyy)**

No.	Page / Section / Line Number	Editorial / Technical	Comment and Rationale	Proposed Revised Text	Decision: (Fully Agreed /Partially Agreed with Justifications /Reject with justifications)	Date of Decision (dd/mm/yyyy)
1.						
2.						
3.						
4.						
5.						
6.						

Bibliography

[1] *ISO/IEC Directives, Part 1, Consolidated ISO supplement*

[2] *ISO/IEC Directives, Part 2, Principles and rules for the structure and drafting of ISO and IEC documents*