



GHWP

# Global Harmonization Working Party

Towards Medical Device Harmonization

## PROPOSED FINAL DOCUMENT

**Title:** Guideline on development of GHWP Documents - Part 1: Procedure for development

**Authoring Group:** Work Group 8 – Standards and GHWP Secretariat

**Date:** Nov 2024

*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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**Contents**

**Page**

*Contents* ..... 1

*Foreword*..... 3

1 *Scope* ..... 4

2 *Normative references*..... 4

3 *Terms and definitions*..... 4

4 *Procedures for development of documents*..... 4

5 *Records* ..... 6

6 *Applicable forms* ..... 7

**ANNEXES**..... 8

*Annex A* ..... 9

*Annex B*..... 10

**Bibliography** ..... 11

64  
65  
66  
67  
68  
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**Foreword**

This document specifies the procedure for the development of GHWP consensus documents. This procedure is mandatory for all GHWP consensus documents.

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

Any statements or references from external sources are used under appropriate citations as specified in the normative references and bibliography.

This document is subject to review. Authors of GHWP consensus documents need to confirm that the version used is current.

80 **1 Scope**

81 This document specifies the procedure for the development of GHWP consensus documents.

82 Note – this document should be read along with Part 2 of the GHWP Consensus Document [Reference]  
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85 **2 Normative references**

86 There are no normative references in this document.

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 88 **3 Terms and definitions**

89 For the purposes of this document, the following terms and definitions apply.  
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91 **3.1**

92 **GHWP Document**

93 consensus document developed by committees under GHWP for publication.  
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95 **3.2**

96 **Project Leader (PL)**

97 Project Leader is responsible for the development of the project, will normally convene and chair  
 98 any related working group meetings, and reports to the Chair of the WG.  
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100 **3.3**

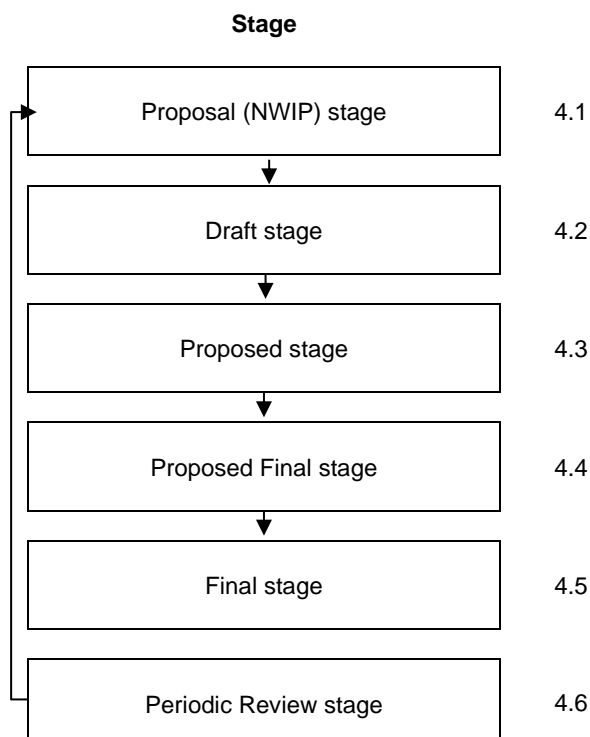
101 **Initiator**

102 Any individual or entity that initiates, contributes or advocates for the development of GHWP  
 103 document, contributing to the achievement of the vision and mission of GHWP.  
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106 **4 Procedures for development of documents**

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

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**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) New Work Item Proposal (NWIP) form shall be completed and submitted to the GHWP secretariat. See Annex A for NWIP form.	Initiator GHWP Secretariat
	b) Receipt of NWIP form should be acknowledged within three (3) working days by GHWP secretariat.	GHWP Secretariat
	c) NWIP shall be reviewed NWIP form by GHWP TC Secretariat and subject to TC approval to ensure:  - Completeness - No duplication of published GHWP document, other international standards or guidance documents - Relevance  and provide the decision to approve/ reject the proposal within 14 days.  Additional information may be requested for incomplete form or insufficient information by GHWP TC Secretariat	GHWP TC Secretariat  GHWP member countries/regions
	d) NWIP shall be circulated to all member economies and GHWP member economies shall review the NWIP form and submit comments within 4 weeks	GHWP Secretariat
	e) comments received shall forwarded to proposer within 7 days from comment deadline and initiator shall review the comments and submit the revised NWIP in 2 weeks.	GHWP Secretariat  Initiator
	g) the revised NWIP shall be posted at the GHWP website and circulated to all member economies.	GHWP Secretariat
	h) approval of the NWIP shall be discussed and voted in the GHWP meeting by electronic voting.	GHWP Secretariat
	i) The GHWP secretariat shall monitor and inform TC on the status.	GHWP Secretariat GHWP TC Secretariat
	j) Assignment to the relevant working group(s) to initiate development of the preliminary draft shall be made within 7 working days.	GHWP Secretariat
	k) The proposal is considered incomplete and should be rejected if no feedback is received within 14 working days from 4.1 (e). The GHWP secretariat shall monitor and inform TC chair on the status.	GHWP Secretariat
l) 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 document may be prepared by the initiator/ member of WG/ the Project Leader as assigned by the WG Chair.	Initiator/ 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) Once the draft document is finalized by WG, it shall be submitted to the GHWP TC Secretariat for proofreading and editing within 14 working days before releasing the draft document to the next stage.	GHWP TC 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 GHWP secretariat

Clause	Detail	Responsibility
	<p>b) Upon receipt of the proposed draft document, GHWP Secretariat shall post it on the GHWP website ((in Word and PDF formats), together with the GHWP commenting template (in Word format, see Annex B) within 1 week.</p> <p>A circulation through email notification shall also be made to GHWP Primary and Secondary Representatives, GHWP Leaderships, SAB Members, WG/STG Chairs and Co-Chairs, TC Advisors, Liaison Members, and Official Observers, as applicable</p>	GHWP Secretariat
	<p>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.</p>	GHWP Secretariat/ GHWP TC Chair
	<p>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 initiator, and be submitted to GHWP secretariat for replying to the comments initiator.</p> <p>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.</p>	GHWP Secretariat/ WG Chair/ GHWP TC Chair
4.4 Proposed final stage	<p>a) PROPOSED FINAL document should be prepared by WG Chair based on comments received, proofread by GHWP TC Secretariat, and then passed to GHWP Secretariat for further processing.</p>	WG Chair/GHWP Secretariat/ GHWP TC Secretariat
	<p>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 proposed final document shall be acquired in 14 days.</p>	GHWP Secretariat/ GHWP Chair/ GHWP TC Chair
	<p>c) Upon approval, the proposed final documents shall be posted at the GHWP website and circulated to all member countries/ regions 21 working days before GHWP annual meeting for final review and endorsement purposes. However, this period may be shortened in cases where safety, health or emergency issues are involved, subject to GHWP TC Chair approval.</p>	GHWP Secretariat/ GHWP TC Chair
4.5 Final stage	<p>a) The proposed final document shall be listed/presented for endorsement at the GHWP annual meeting.</p>	GHWP secretariat
	<p>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.</p> <p>GHWP Document numbering shall be in the following form:</p> <p><i>"GHWP/(Sequence No.)/XXXX(Year)"</i></p> <p>EXAMPLE</p> <p>If there are joint working groups (WG 1, WG 2, and WG 3) and the first work item endorsed during the 28th GHWP Annual Meeting (2024), it will be designated as GHWP/WG-1-2-3/01/2024.</p>	GHWP Secretariat
	<p>c) Announcement on the new publication shall be made immediately by GHWP Secretariat on GHWP website.</p>	GHWP Secretariat
4.6 Periodic review stage	<p>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.</p>	GHWP Secretariat

## 5 Records

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

- a) Completed NWIP form

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- 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



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**ANNEXES**

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**Annex A**  
(normative)

**New Work Item Proposal (NWIP) Form**

Note: Please visit the GHWP website and navigate to Documents > Forms.



**New Document Request/ New Work Item Proposal Form**

Please submit to GHWP Secretariat by email to [secretariat@ghwp.info](mailto: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**

Note: Please visit the GHWP website and navigate to Documents > Forms.



**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)
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5.						
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191 [1] *ISO/IEC Directives, Part 1, Consolidated ISO supplement*

192 [2] *ISO/IEC Directives, Part 2, Principles and rules for the structure and drafting of ISO*  
193 *and IEC documents*

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## **Bibliography**