



GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

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

38
39
40
41
42
43
44
45

Acknowledgements

This GHWP document was prepared by Global Harmonization Working Party (GHWP), Working Group 8 on Standards and GHWP Secretariat. We wish to acknowledge the contributions of working group members:

Salbiah Bt Yaakop*	Medical Device Authority, Malaysia
Tony Low	Commissioning Agents International Malaysia
Muhammad Marwan Bin Anoor	Medical Device Authority, Malaysia
Abdullah Mohammed Alghuraibi	Saudi Food and Drugs Authority
Osamah Al-Barikan	Saudi Food and Drugs Authority
Sameer A. Al-Hamdan	Saudi Food and Drugs Authority
Christopher Chan	Industrial Technology Research Institute, Taiwan
Raghavan Nair Asok Kumar	Abbott Healthcare Private Limited, India
Gite Sadanand	Abbott Healthcare Private Limited, US
Zhang Yidong	Medtronic, China
Scott A. Colburn	US Food & Drug Administration
Vats Aaditya	Abbott Healthcare Private Limited, India
Bryan So	GHWP Secretariat
Elizabeth Chan	GHWP Secretariat

Note: Appreciate the valuable contributions and feedback from others that contributed to the development of this document

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

46

47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63

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
69
70
71
72
73
74
75
76
77
78
79

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]
 83
 84

85 **2 Normative references**

86 There are no normative references in this document.

87
 88 **3 Terms and definitions**

89 For the purposes of this document, the following terms and definitions apply.
 90

91 **3.1**

92 **GHWP Document**

93 consensus document developed by committees under GHWP for publication.
 94

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.
 99

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.
 104
 105

106 **4 Procedures for development of documents**

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

108
 109
 110

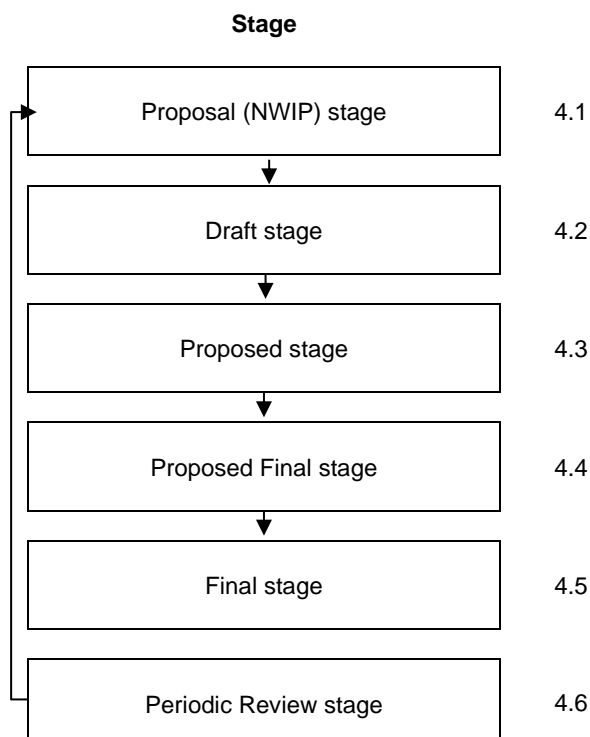


Figure 1. Procedure for development of GHWP documents**Table 1. Explanation and responsibility of each stage.**

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

123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139
140
141

- 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

142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163

ANNEXES

164
165
166
167
168
169
170
171

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

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		

172
173

174
175
176
177
178
179
180
181
182
183

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)
1.						
2.						
3.						
4.						
5.						
6.						

184
185
186

187

188

189

190

191

192

193

194

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*