GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title:	Amendment 12 to the Global Harmonization Working Party House Rules
Authoring Group:	GHWP SECRETARIAT
Date:	12th November 2026

Copyright © 2026 by the Global Harmonization Working Party
All Rights Reserved

1. Purpose

This document proposes to make amendment to the Global Harmonization Working Party (GHWP) House Rules as detailed in section 2 below under "Proposed Amendments to the GHWP House Rules".

2. Proposed Amendments to the GHWP House Rules

1. Applications of the GHWP House Rules

A. The GHWP House Rules are guidelines to supplement the Terms of Reference of the GHWP and GHWPTC for promoting the GHWP activities. The House Rules shall be followed by all members as far as applicable.

B. Should there be any conflicts between the House Rules and the Terms of Reference, the latter shall prevail.

2. Requirements of the GHWP Chair/Vice-chairs

A. The GHWP Chair/Vice-chairs shall be strong supporters of the Goals of GHWP and could take the lead to promote these Goals to all related parties. GHWP Chair/Vice-chairs shall be actively involved in GHWP meetings, and to actively promote the implementation of GHWP guidance documents in their corresponding countries/regions.

B. The GHWP Chair/Vice-chairs shall fulfil the following requirements:

- **(a)** The GHWP Chair and two of the GHWP Vice-chairs shall come from Regulatory Authorities while the other two GHWP Vice-chairs shall come from the Industry;
- **(b)** The Chair and the Vice-chairs from Regulatory Authorities shall come from the senior management with decision making power while the Vice-chairs from the Industry shall come from the senior management of a reputable organization with good knowledge of the Industry;
- **(c)** They shall have sufficient support and resources in planning, organizing and participating in meetings and teleconferences within GHWP as well as with other international organizations;
- **(d)** They shall have been actively participating in GHWP activities and are familiar with the GHWP operations;
- **(e)** They shall have good networks with other Regulatory Authorities and the Industry; and
- **(f)** They shall be committed to promote the Goals of GHWP.

3. Nominations and Elections of the GHWP Chair/Vice-chairs

A. GHWP Primary Representatives from Regulatory Authorities could be nominated by Primary GHWP Representatives as the candidates in the GHWP Chair election and GHWP Vice-chair (Regulatory Authority) election. GHWP Primary Representatives from the Industry could be nominated as the candidates in the GHWP Vice-chair (Industry) election.

B. Candidates shall submit their nomination forms to the Secretariat before the commencement of each election as declared by the chair of the meeting or, where the election is conducted by electronic voting, by the deadline set by the Secretariat. Every nomination shall be supported by at least five Primary GHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.

C. Every Primary GHWP Representative shall support only one nomination in each election. He/she may vote for another candidate in the election.

D. In the GHWP Chair election, every Primary GHWP Representative shall vote for one candidate, at the GHWP Meeting or by electronic voting. The candidate with the highest number of votes will be elected the GHWP Chair. The chair of the meeting can cast an extra vote when there is more than one candidate having the highest number of votes.

E. Upon the completion of the GHWP Chair election, the GHWP Vice-chair (Regulatory Authority) election will be conducted in the same way as the GHWP Chair election.

F. Upon the completion of the GHWP Vice-chair (Regulatory Authority) election, the GHWP Vice-chair (Industry) election will be conducted in the same way as the GHWP Chair election.

4. Requirements of the GHWPTC Chair/Co-chairs

A. The GHWPTC Chair/Co-chairs shall be strong supporters of the Goals of GHWP and shall possess experience and expertise in medical device regulatory services. GHWPTC Chair/Co-chairs shall be actively involved in GHWP meetings, and to actively promote the implementation of GHWP guidance documents in their corresponding countries/regions.

B. The GHWPTC Chair/Co-chairs shall fulfill the following requirements:

(a) The GHWPTC Chair and two of the GHWPTC Co-chairs shall come from Regulatory Authorities while the other two GHWPTC Co-chairs shall come from the Industry;

(b) They shall have sufficient support and resources in planning, organizing and participating in meetings and teleconferences within GHWPTC as well as with other international organizations;

(c) They shall have been actively participating in GHWPTC activities and are familiar with the GHWPTC operations;

(d) They shall have good networks with other Regulatory Authorities and the Industry; and

(e) They shall be committed to execute the policies and decisions of GHWP and provide professional support to achieve the Goals of GHWP.

5. Nominations and Elections of the GHWPTC Chair/Co-chairs

A. GHWPTC Representatives from Regulatory Authorities could be nominated by Primary GHWP Representatives as the candidates in the GHWPTC Chair election and GHWPTC Co-chair (Regulatory Authority) election while GHWPTC Representatives from the Industry could be nominated as the candidates in the GHWPTC Co-chair (Industry) election.

B. Candidates shall submit their nomination forms to the Secretariat before the commencement of the election as declared by the chair of the meeting or, where the election is conducted by electronic voting, by the deadline set by the Secretariat. Every nomination shall be supported by at least five Primary GHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.

C. Every Primary GHWP Representative shall support only one nomination. He/she may vote for another candidate in the election.

D. In the GHWPTC Chair election, every Primary GHWP Representative shall vote for one candidate, at the GHWP Meeting or by electronic voting. The candidate with the highest number of votes will be elected the GHWPTC Chair. The chair of the meeting can cast an extra vote when there is more than one candidate having the highest number of votes.

E. Upon the completion of the GHWPTC Chair election, the GHWPTC Co-chair (Regulatory Authority) election will be conducted in the same way as the GHWPTC Chair election.

F. Upon the completion of the GHWPTC Co-chair (Regulatory Authority) election, the GHWPTC Co-chair (Industry) election will be conducted in the same way as the GHWPTC Chair election.

6. Responsibility of GHWP Chair/Vice-chairs and GHWPTC Chair/Co-chairs

A. GHWP Chair, GHWP Vice-chairs, GHWPTC Chair, GHWPTC Co-chairs are responsible for the implementation of the decisions endorsed in GHWP Annual Meetings, recommendation of the development strategy of the GHWP, recommendation of the schedule of the annual meetings, preparation of the annual work plan, preparation of the

proposals when necessary, review of the implementation of annual work plan, recommendation of the accession and withdrawal application by member country/region, facilitation of exchange and cooperations with other international organizations, and the review on any needs for internal restructuring in GHWP.

B. Decisions and resolutions on key issues and controversial matters should be made through voting at GHWP Meetings or by electronic voting, and the voting should be arranged only after thorough discussions. The GHWP Chair shall decide the mode of voting in accordance with paragraph 1.7 of the Terms of Reference.

7. Roles and Responsibilities of the Secretariat

A. The Secretariat is a team including the Secretary-General, Executive Secretary-General, Deputy Secretary-General and other team members providing secretariat support to the GHWP including the organization of meetings and activities, coordination with international organizations, implementation of resolutions and decisions, management of website, preparation of meeting agendas and minutes, keeping of documents and records, management of funds, updating of contact emails and promotion of activities. Its email address is secretariat@ghwp.org.

B. The Executive Secretary-General is the person in charge of the Secretariat. He/she shall assist the GHWP Chair to overlook the performance of the Secretariat Team.

C. The Deputy Secretary-General is the person in charge of the day-to-day operations of the Secretariat. He/she shall provide assistance to the GHWP Chair and Secretary-General to manage the GHWP and promote its activities.

D. Deputy Secretary-General shall provide assistance to the GHWP Chair, Secretary-General and Executive Secretary-General, to manage the GHWP and promote its activities.

8. Appointment of the Secretariat Team

A. The GHWP Chair may appoint office bearers of the Secretariat including one Secretary-General, one Executive Secretary-General and several Deputy Secretary-Generals responsible for different duties. The Secretary-General takes charge of the Secretariat and supervises the Executive Secretary- General and Deputy Secretary-Generals.

B. The GHWP Chair shall appoint the President of the GHWP Administration Services Ltd duly elected in the general meeting of the company the Deputy Secretary-General responsible for the day-to-day operations of the company. The GHWP Chair may recommend the Secretary-General or one person to join the company as Director.

9. Applications for Joining GHWP

A. The Regulatory Authority of any country or region interested in joining GHWP shall send the application form to the Secretariat.

B. The Secretariat shall inform the GHWP Chair upon the confirmation of the application.

C. The applicants will be invited to attend the next GHWP Meeting where voting on their applications will take place or voting on their applications will be taken place electronically.

D. GHWP Liaison Membership

(a) The Liaison Membership is open to the regional and international organizations who wish to join GHWP and with their goals in-line with the work of GHWP towards harmonization of medical device regulations.

(b) Any organization interested in joining GHWP as a Liaison Member shall send their request to GHWP with attention to GHWP Chair and cc GHWP Secretariat at secretariat@ghwp.org.

(c) GHWP shall evaluate and determine the suitability of the applying organization for joining GHWP as a Liaison Member.

(d) GHWP Chair shall have the rights to reject any GHWP Liaison Membership application.

(e) Once the Liaison Membership application is confirmed, an official letter of confirmation from the GHWP Chair will be send via GHWP Secretariat to the new Liaison Member.

(f) The confirmed Liaison Member shall nominate a representative and subscribe to GHWP Secretariat as the contact person.

(g) Liaison Member of GHWP shall have higher priority to co-organize activities with GHWP.

(h) The representative from Liaison Member can be an observer; however, shall not have voting rights in GHWP meetings.

(i) The full list of Liaison Members of GHWP as well as the contacts of the corresponding representatives shall be kept by the GHWP Secretariat for record.

(j) The list of Liaison Members of GHWP shall also be available at GHWP website.

10. Appointments of GHWP and GHWPTC Representatives

A. Member Regulatory Authority and member Industry of a country or region shall appoint their GHWP and GHWPTC Representatives and inform the Secretariat accordingly.

B. The GHWP and GHWPTC Representatives of a member Regulatory Authority or member industry of a country or region may be changed at any time via a notification to the Secretariat and the Chair accordingly. Such notification shall be provided by the GHWP Primary Representative from the member Regulatory Authority of the respective country or region.

C. Any disputes on representations should be referred to the Secretariat. The Secretariat shall seek comments from the Representatives from member Regulatory Authority of the respective country or region before making recommendations to the GHWP Chair for the final decision.

11. Upkeep of Members and Representatives Records

A. The Secretariat shall keep the most up-to-date records of members, representatives, office bearers, working group members and special task group members.

B. The records kept by the Secretariat shall be the only official records.

C. Members, representatives, office bearers, working group members and special task group members shall ensure that their contact email addresses being kept by the Secretariat are correct.

D. Chairs of Technical Committee, Working Groups and Special Task Groups shall inform Secretariat of any changes in memberships under their charge.

12. Hosting GHWP and GHWPTC Meetings

A. Members intend to host any GHWP and/or GHWPTC Meetings shall plan ahead before making applications. They shall inform the GHWP Chair, GHWPTC Chair and Secretariat of their intention as early as possible. If there is more than one applicant, the decision shall be made in the GHWP Meeting or by electronic voting through voting by Primary GHWP Representatives and the one with the highest number of votes will be selected. The chair of the meeting can cast an extra vote when there is more than one applicant having the highest number of votes. GHWP Meetings are normally held on yearly basis while the GHWPTC Meetings are held on need basis.

B. In the planning of a Meeting, the host member shall ensure that the event will be self-financed while sponsorships may be sought if needed. There shall be a contingency plan for the settlement of deficits that may arise.

C. The host member shall prepare a financial statement for posting on the GHWP website after the completion of the event. The surplus should be contributed to the GHWP Reserve.

13. Management of the GHWP Account and Reserve

A. The Executive Secretary-General is responsible to supervise the GHWP account

including that of the GHWP Administration Services Ltd. The Secretariat shall prepare annual financial statements and post them on the website.

B. The Secretariat shall prepare financial budgets for approval in the GHWP Meetings on annual basis. The ceiling of the overall budget shall not be exceeded unless the supplementary budget is approved as stated in paragraph C below.

C. If any budgets are needed without the approval in an GHWP Meeting or a supplementary budget is needed, an ad hoc Budget Committee shall be formed to vet and approve the request. The request shall be made to the Secretariat who shall seek the consent from the Chair to form the Budget Committee. The Committee shall be chaired by the GHWP Chair or his/her delegate. All the GHWP and GHWPTC Representatives interested shall be invited through the Secretariat to join as Committee Members.

14. Management of the GHWP Website

A. The Secretariat is responsible to develop, operate and maintain the website.

B. The Secretary-General and/or the Executive Secretary-General shall have the authority to decide whether any specific document/information should be posted or not. If there are any disputes, the Secretary-General shall consult the Chair for the final decision.

C. Logos of sponsors may be put on GHWP website whilst the money from the sponsorship shall be credited to the GHWP account.

15. Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat

A. Chairs of committees, working groups, special task groups and the Secretariat could initiate the preparation of documents for discussions, approvals and resolutions/endorsements.

B. Documents shall be labeled “DRAFT” when they are prepared for discussion within their group members.

C. Documents shall be labeled “PROPOSED” if they are prepared for the discussion in the GHWP and/or GHWPTC Meetings.

D. Documents prepared for resolutions/endorsements and/or approvals shall be labeled “PROPOSED FINAL”.

E. Documents accepted, approved, and/or prepared for already passed resolutions/endorsements shall be labeled “FINAL”.

F. “FINAL” documents should be forwarded to the Secretariat and posted on the website unless considered inappropriate.

16. Proposing Issues For Discussion in GHWP Meetings

A. Important policies and/or ways forward that may affect many members shall be brought up for approval as Issues For Discussion in GHWP Meetings. Resolutions shall be initiated for disputable issues.

B. Chairs of committees, working groups, special task groups, the Secretariat, GHWP Representatives and GHWPTC Representatives could initiate Issues For Discussion that shall reach the Secretariat at least one week before the GHWP Meeting. The Secretariat shall add them to the meeting agendas and post the related documents, if any, on the website.

C. Consensus views shall be sought in the GHWP Meeting to agree on the policies and/or ways forward regarding the Issues for Discussion. If no consensus could be reached, the Chair may appoint the GHWPTC, the Secretariat or any GHWP/GHWPTC Representative to form a committee, working group or special task group to study the issues and make recommendations for resolving in the GHWP Meetings.

D. If the Issues for Discussion are of urgent nature, the Chair may initiate a voting that will be passed by a simple majority.

17. Proposing Resolutions in GHWP Meetings

A. Resolutions shall be initiated for disputable issues after discussions so as to seek majority views from all GHWP members. Resolutions are only GHWP policies and/or recommendations that shall not be binding on members.

B. Chairs of committees, working groups, special task groups, the Secretariat, GHWP Representatives and GHWPTC Representatives could propose resolutions that shall reach the Secretariat at least one week before the GHWP Meeting. The Secretariat shall post the proposed resolutions and related documents, if any, on the website and add them to the meeting agendas.

C. All proposed resolutions shall be discussed and voted in the GHWP Meeting or by electronic voting. A simple majority is needed to pass the resolution.

D. If the matter is under the purview of GHWPTC, the resolution shall be resolved in the GHWPTC Meeting before passing it to the GHWP Meeting for discussion and voting.

18. Advisor to GHWPTC

A. GHWPTC shall appoint expert(s) from GHWP member Regulatory Authorities or member Industries of countries or regions, or other international or regional organizations as advisor(s) on a need basis, for the purpose of seeking his/her/their technical/professional advice towards meeting the goals of GHWP.

B. The role of TC Advisors is to bring their knowledge and experience to support the activities of the GHWP. This is accomplished via such activities as providing objective advice, gauging future trends for new strategic positioning, advocating for the GHWP's harmonization work with the increase in its visibility globally, as well as providing input on the scope of work through comments and recommendations, providing support to TC's and WG's activities covering guidelines development, for the decision making by GHWP TC and WG leaders on WG work items. TC Advisors operate and provide input under the direction of the TC Chair.

C. Chairs and Co-chairs of GHWPTC, WGs and STGs shall propose the criteria for Advisor to GHWPTC. The proposed criteria as well as any changes of the criteria shall be updated to GHWP Secretariat.

D. Chairs and Co-chairs of GHWPTC, WGs and STGs shall nominate expert(s) to GHWP Secretariat. Secretariat shall review the suitability of the nominated expert(s) and submit the recommendations to GHWPTC Chair. Nominated experts who satisfy the criteria shall be considered being appointed to the GHWPTC Advisory Panel. GHWPTC Chair shall submit the name of candidate(s) and advice to GHWP Chair for final confirmation. With the confirmation of GHWP Chair, GHWPTC Chair shall appoint the confirmed candidate(s) to GHWPTC Advisory Panel as Advisor(s) to GHWPTC. The number of Advisors in the panel shall not exceed ten (10).

E. The GHWPTC Advisory Panel is independent to WGs and STGs, but shall be available to all WGs and STGs. The scope of expertise shall meet the needs of GHWPTC, WGs and STGs.

F. The term of office of Advisor(s) to GHWPTC commences from the date of appointment. All Advisors to GHWPTC, regardless of when they are appointed during the term of a given GHWPTC Chair, shall retire altogether at the same time with that GHWPTC Chair. The reappointment of Advisor(s) to GHWPTC shall be made by the new GHWPTC Chair.

G. Appointment to the GHWPTC Advisory Panel is on a voluntary basis. All GHWPTC Advisory Panel members shall receive no compensation from GHWP, GHWPTC and GHWP Administration Services Ltd.

H. Apart from this panel of Advisors, WGs and STGs Chairs and Co-chairs may nominate individual experts as advisor(s) to their corresponding WGs or STGs on a need basis. With the final confirmation of GHWPTC Chair, the WG or STG Chair shall appoint the individual experts, with a maximum number of two (2), to his/her WG or STG. Advisor(s) to WGs and STGs will not be appointed to the Advisory Panel to GHWPTC.

I. The term of office of Advisor(s) to WGs and STGs commences from the date of

appointment. All Advisors to WGs and STGs, regardless of when they are appointed during the term of a given WG or STG Chair, shall retire altogether at the same time with that WG or STG Chair. The reappointment of Advisor(s) to WGs and STGs shall be made by the new WG and STG Chairs.

J. Advisor(s) to GHWPTC as well as Advisor(s) to WGs and STGs shall be updated to GHWP Secretariat for record.

K. An Advisor to GHWPTC, or to a WG or STG, may withdraw from the appointment, temporarily or permanently, by written notice to the Chair who appointed him/her, with a copy to the GHWP Secretariat.

L. The GHWPTC Chair may suspend or terminate the appointment of an Advisor to GHWPTC, or, after consulting the Chair of the WG or STG concerned, of an Advisor to a WG or STG, on the grounds of misconduct, conflict of interest or sustained non-participation. The GHWPTC Chair shall inform the GHWP Secretariat of any withdrawal, suspension or termination, and the Secretariat shall update its record accordingly.

19. Roles and Responsibilities of Technical Committee

A. Role and Responsibility of GHWPTC Chair

- **i.** The GHWPTC Chair shall conduct the decision-making on the overall WG work plan.
- **ii.** The GHWPTC Chair shall designate a TC secretary who can dedicate his/her time and effort for GHWPTC, especially for WI and Guidance document management.
- **iii.** The GHWPTC Chair shall conduct the final approval on WG members and WG advisors.
- **iv.** The GHWPTC Chair shall designate TC advisors.
- **v.** The GHWPTC Chair shall assign tasks to TC advisors.
- **vi.** The GHWPTC Chair shall make the overall confirmation of TC workshop program.
- **vii.** The GHWPTC Chair shall sign communication letter with international partners, e.g. ISO, etc., for technical related subjects.
- **viii.** The GHWPTC Chair shall conduct the overall approval on GHWPTC and WG member's nomination for representing GHWP in international organization, e.g. ISO, etc.
- **ix.** The GHWPTC Chair shall make the overall confirmation of speaker on behalf of GHWP or GHWPTC

B. Role and Responsibility of GHWPTC Co-chairs (Regulatory Authority)

- **i.** The GHWPTC Co-chairs shall conduct the overall coordination of program of GHWPTC workshop.
- **ii.** The GHWPTC Co-chairs shall be the contact person for important international organizations, e.g. WHO, APEC, PAHO, etc.
- **iii.** The GHWPTC 1st Co-chair shall take over GHWPTC Chair's responsibilities in case of absence, and the GHWPTC 2nd Co-chair shall take over GHWPTC Chair's responsibilities in case of the absence of both GHWPTC Chair and GHWPTC 1st Co-chair.
- **iv.** The GHWPTC Co-chairs shall recommend GHWPTC WG member's nomination for representing GHWP in international organizations.
- **v.** The GHWPTC Co-chairs shall recommend speaker on behalf of GHWP or GHWPTC.

C. Role and Responsibility of GHWPTC Co-chairs (Industry)

- **i.** The GHWPTC Co-chairs shall be the contact person for Industry Liaison Members, i.e. APACMed, DITTA and GSI.
- **ii.** The GHWPTC Co-chairs shall conduct the overall coordination of Joint-workshop program of GHWPTC workshop with Liaison Members.
- **iii.** The GHWPTC Co-chairs shall recommend GHWPTC WG member nomination for

representing GHWP in international organizations.

iv. The GHWPTC Co-chairs shall recommend speaker on behalf of GHWP or GHWPTC.

D. Role and Responsibility of WG Chairs and Co-chairs

i. The WG Chairs and Co-chairs shall conduct the management of WG members and updates.

ii. The WG Chairs and Co-chairs shall designate member with the confirmation by GHWPTC Chair.

iii. The WG Chairs and Co-chairs shall make progress report to GHWPTC Chair every 3 months.

iv. The WG Chairs and Co-Chairs shall setup prior or post side-meeting to GHWP Meeting to avoid any influences on GHWP main meetings.

E. Additional Role and Responsibility of GHWPTC Advisors

i. The GHWPTC Advisors shall designate a leader of GHWPTC Advisors

ii. The GHWPTC Advisors shall report assignment to GHWPTC Chair.

20. GHWPTC WGs and STG Membership

A. Only members of GHWP member Country or Region can be accepted as WGs or STG members.

B. In case of absence of WG chair, GHWPTC Chair can assign one of the WGs or STG regulatory members with the most expertise along with GHWPTC Co-chairs agreement.

C. Any person who is not from the member regulatory authority or member industry of a country or region can participate in WGs or STG as an observer or can become a WG advisor on a case-by-case basis with an approval of TC Chair.

D. All WGs and STG members need to be confirmed by TC Chair.

21. Capacity Building Committee

A. GHWP Chair, GHWP Vice-Chairs, GHWPTC Chair and GHWPTC Co-Chairs *shall establish a Capacity Building Committee (the "Committee") as a standing operating committee to deliver the capacity building mission and goal of GHWP set out in the Terms of Reference, including the training syllabus, training workshops, in-country training and the related certification.*

B. The Committee shall be led by a Committee Director and a Committee Deputy Director appointed by the GHWP Chair. Appointments to the Committee are not subject to election. All appointees shall retire together with the GHWP Chair in office at the time of their appointment and are eligible for re-appointment by the incoming GHWP Chair.

C. The Committee shall operate under Operating Procedures approved by the GHWP Chair, which set out its structure, reporting line, functions and working methods and shall be consistent with the Terms of Reference and these House Rules.

---------- End ----------