GHWP Strategic Framework towards 2026

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GHWP Global Harmonization Working Party

Towards Medical Device Harmonization

GHWP Vision & Mission

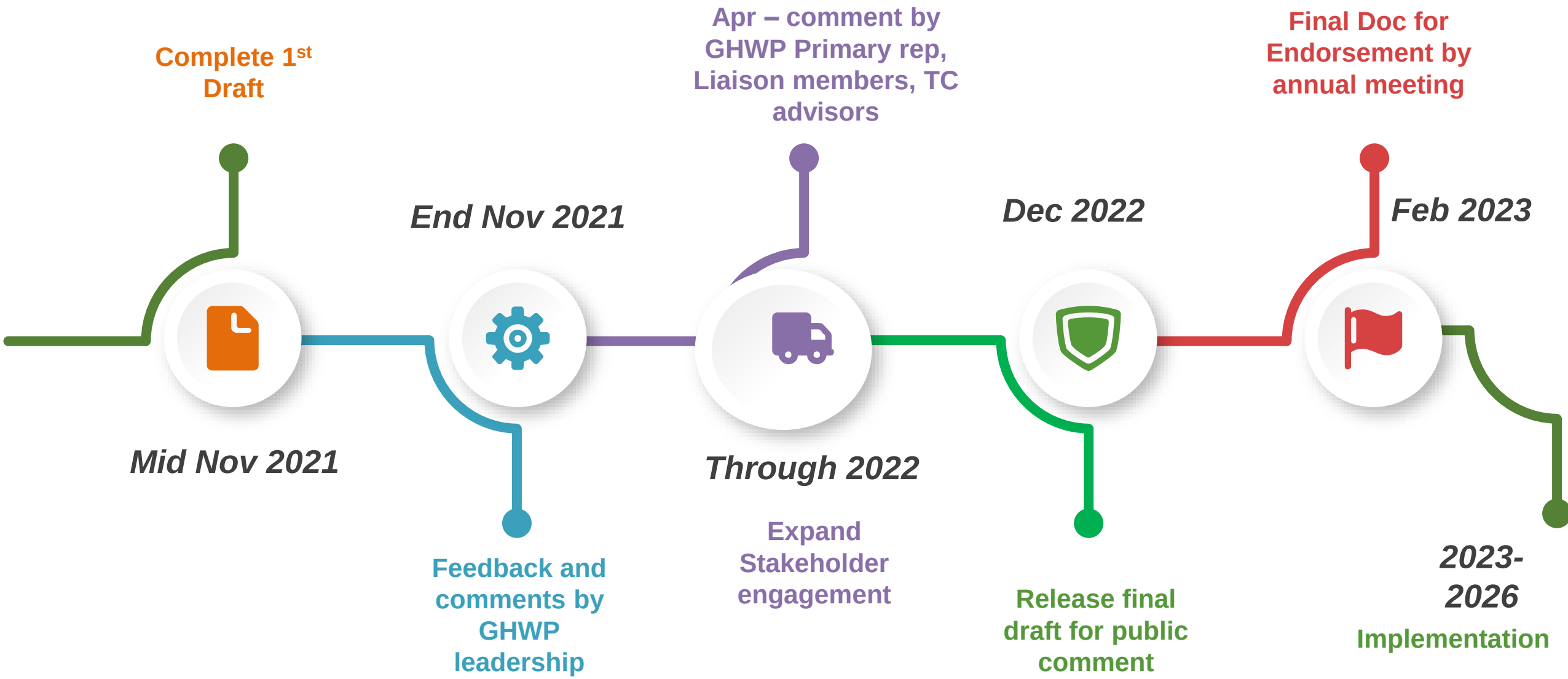
Our Vision

To achieve international harmonization of medical device regulatory framework among regulatory authorities, convergence of regulatory requirements, open and trust-based efforts between regulatory authorities and the industry across the globe.

Our Mission

- To strategically accelerate medical device regulatory convergence through promoting an agile and fit-for-purpose regulatory model for medical devices based on latest development in regulatory science.
- To lead and promote systematic capacity building for future-ready regulatory professionals in light of emerging technologies.

GHWP Strategic Framework – Milestone Plan



GHWP Strategic Objectives

MEMBERSHIP

REGULATORY CONVERGENCE

REGULATORY SCIENCE

REGULATORY RELIANCE

CAPACITY BUILDING

GLOBAL PARTNERSHIP

STRATEGIC OBJECTIVES

1. Membership

- Continues to expand membership
- Welcome any non-members to join and form alliances to expand the reach globally.

STRATEGIC OBJECTIVES

2. Regulatory Convergence

A**. Information sharing**

- Committed to organize regular annual conference (annual), TC meeting(bi-annual), Working Group meetings(quarterly) to **facilitate information and best practice sharing**.

- We will develop a global post-market exchange program and encourage participation and sharing of information amongst member.

- Initiate a post-market database at GHWP or Regional Hub level.

STRATEGIC OBJECTIVES

2. Regulatory Convergence

B. **Translating GHWP Guidance into local regulatory framework, as appropriate**

- Encourage members to constantly adopt and implement the principles in GHWP guidance documents in the local regulatory framework.

- A key performance indicator to assess regulatory convergence.

STRATEGIC OBJECTIVES

2. Regulatory Convergence

C. **Harmonized regulatory model**

- Adopt a harmonized nomenclature system for medical devices, recognize and leverage international standards, accept and recognize ISO certificates and/or MDSAP certificate for QMS certification, clinical performance evaluation and conformity testing conducted by another trusted agency.

- Encourage emerging regulatory authorities to design regulatory framework in a phased approach with reference to the AHWP Playbook.

- Encourage like-minded regulatory authorities to embark on **Memorandum of Understanding** to maximize regulatory resource efficiency. Supported by confidentiality agreement, where appropriate.

STRATEGIC OBJECTIVES

3. Regulatory Science

- Committed to prioritize knowledge sharing and capacity building to cater for needs in coping with novel technologies e.g., Software as Medical Device (SaMD), Artificial Intelligence (AI)/Machine Learning (ML), 3D printing, Cybersecurity, etc.

- Support the modernization and digital transformation of regulatory process and tools e.g., virtual audit, rolling submission, cloud submission, etc.

STRATEGIC OBJECTIVES

4. Regulatory Reliance

- Promote the regulatory models as proposed in the WHO Good Reliance Practice guidance, i.e., work-sharing, abridged pathway using reliance, regional reliance mechanism, unilateral recognition, and mutual recognition.

- Practice reliance principles throughout different stages of product life-cycle, i.e., establishment licensing, marketing authorization, quality management system audits, post market surveillance, and post-approval changes

STRATEGIC OBJECTIVES

5. Capacity Building

GHWP Academy

- **Training Hubs** that deliver face-to-face training workshops, seminars and certification courses.

- **Online training platform** that delivers:
  - Real-Time /Live workshops, Webinars, and Certification Courses.
  - Self-Directed (Learner-Paced) Learning Courses and Certification Courses
  - Interactive Learning experiences

STRATEGIC OBJECTIVES

5. Capacity Building

- Building on the competency frameworks and curriculum whitepapers for regulators and industry professionals,. Curriculum team to establish training materials and delivery programs both on-line and face-to-face

- Set up Technical Helpdesk to serve regulatory authorities and industry members .

- Establish regional focus groups for:
  - Local sharing of experiences, understanding of new & emerging technologies
  - Encourage phased introduction of regulation

STRATEGIC OBJECTIVES

6. Global Partnership

- Enhance partnerships with strategic alliances to facilitate regulatory convergence programs e.g., IMDRF, APACMed, DITTA, GS1.

- Work towards establishing formal relationship with WHO Regional Offices to carry out trainings and facilitate reliance programs.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Thank you