Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

The 28th GHWP Annual Meeting & GHWP Technical Committee Meeting Agenda
Kuala Lumpur Convention Centre (KLCC), Kuala Lumpur, Malaysia
9-12 Decemeber 2024

Day 1 Agenda: 9 December 2024	
TIME	
Morning	Welcome DAY 1
	Keynote Speech
	GHWP Capacity Building Initatives
	Regulatory Excellence
	Introduction to Regulatory Excellence - What is Regulatory Excellence - Defining and Assessing Regulatory Excellence
	How To Regulate With Excellence- Achieving Regulatory Excellence
	Excel Regulatory Excellence in the MedTech industry
	Reg. Excellence Perspective of WHO (e.g.GBT)
	PANEL Sharing best practise of Regulatory Excellence - Regulators and Industry perspectives
	Global Regulatory Framework
	GHWP Playbook for Implentation of Medical Device Regulatory Frameworks and support from GHWP to establish a regulatory framework
	WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF)
	IMDRF Regulatory Framework
	Sharing best practices of implementing a national regulatory framework
	PANEL - What does an ideal regulatory framework look like?
	LUNCH
Afternoon	**Regulatory Skills and Talent Pipeline**
	Insights to GHWP Regulatory Competency Framework and Curriculum for Industry and Regulators
	Regulatory Excellence Ecosystem Industry : sharing best practise to actively support growth and development of regulatory professionals
	Regulatory Excellence Ecosystem Regulators : sharing best practise to actively support growth and development of regulators

	Experience sharing on enforcing regulatory requirements to ensure continuous compliance
	Conversations That Matter - Interactions with Health Authorities
	PANEL - Working in regulatory affairs - Sharing tips and experiences (beginners and mature regulatory personal of Industry and Authorities)
	Clinical Evidence & RWE
	How to demonstrate Clincial Evidence
	Unifying Clinical Evaluation Requirements: Exploring ISO 18969
	Post Market Clinical Studies-Post-market surveillance activities in mitigating potential and actual risk
	Acceptance of clincial oversea data for Clincial Evidence versus Local Testing
	The importance of Data Standardization in Clinical Trials
	Evaluating the Quality of Real-World Evidence Used to Support Regulatory Decision-Making for Medical Devices
	Best practise on Real World Evidence Usability in Device Applications
	Panel on Challenges and Opportunities on Clinical Evidence using RWE
	Summary Day 1
	Adjourn
END OF DAY 1	

Day 2 Agenda: 10 December 2024	
TIME	
Morning	Welcome DAY 2
	Cybersecurity and Robotics
	Cybersecurity Update or Raising the Bar on Cybersecurity: Understanding New Regulations and How IEC 81001-5-1 Can Help Navigate
	Cybersecurity Landscape in Asia Pacific
	Cybersecurity: Integrating Medical Device Cybersecurity in the Quality Management System
	Consideration for innovative robotic assisted Surgical Devices
	PANEL or Fire side chat
	Labeling and UDI
	Key trends on ditial labeling
	Update from the MEA region on Electronic Instructions for Use (EIFU)
	Hospital, Patient, HCP perspective on e-labeling
	Regulatory perspective on elabeling
	E label Devolopment in Europe
	Industry perspective on UDI - Opportunities and challenges
	The role of UDI in whole product life cycle management

	PANEL - Benefits, opportunities and approaches on e-lableing
	LUNCH
Afternoon	**QMS and Audits**
	Briefing of ISO/TC 210 progress on ISO13485
	Overview of QMS implementation in GHWP member economies
	Case sharing of QMS implementation in China
	What is MDSAP l Medical Device Single Audit Program?
	"Industry Perspective on MDSAP"
	Good Distribution Practices for Medical Device GDPMD
	Panel
	PMS (Vigilance, Surveillance)
	IMDRF Coding: Complaints, Vigilance, Trend Analysis, and the Benefits of Codifying Your Post Market Surveillance System
	Reporting and investigating adverse events and complaints of medical devices or Safety alerts and field safety corrective action (FSCA) for medical devices.
	Impact of digital health technologies on post-market surveillance
	Post market Data Collection and Analysis and how this information contribute to the improvement of safety & performance of a medical device. And also highlighting on the advanced analytics and artificial intelligence (AI) in monitoring device performance.
	Fit for purpose change management - GHWP Guideline (draft) - Change Management - Industry Perspective
	PCCP -Predetermined change control plan- strategy with case studies for medical devices
	PANEL - PMS
	Convergence and Reliance
	Impact of regulatory reliance on expanding global access to essential medical devices
	Good Reliance Practise
	Regulatory convergence & reliance in Africa - sharing good practise
	Regulatory convergence & reliance in Asia - sharing good practise - on behalf of APACmed
	Regulatory convergence & reliance in ME - sharing good practise - MEA- Mecomed
	Sharing reliance strategy of a country
	Panel Convergence and Reliance
	Summary Day 2
	Adjourn
END OF DAY 2	

Day 3 Agenda: 11 December 2024	
	28th GHWP Technical Committee (GHWP TC) Meeting
TIME	
Morning	GHWP TC & WG Leaders Meeting with TC Advisors (Closed-Door Meeting)
Afternoon	Opening Meeting
	Opening Speech
	Roll call Adoption of Agenda
	Adoption of 26th GHWP TC Meeting Minutes
	Working Group Updates:
	Work Group 1 (WG1) - Pre-Market Submission and CSDT
	Work Group 2 (WG2) - Pre-market: IVDD
	Work Group 3 (WG3) - Pre-market: Software as a Medical Device
	Work Group 4 (WG4) - Post-Market
	Work Group 5 (WG5) - Clinical Evidence for Performance and Safety
	Work Group 7 (WG7) - Quality Management System: Operation & Implementation
	Work Group 8 (WG8) - Standards
	Work Group 9 (WG9) - UDI & Nomenclature
	Special Task Group (STG) - Common Evaluation Reliance Practice (CERP)
	TC Advisors Summary Report
	Closing Remarks for Day 3
	Adjourn
END OF DAY 3	
	Gala Dinner

Day 4 Agenda: 12 December 2024	
TIME	**28th GHWP Annual Meeting (Main Meeting)**
Morning	Announcement by MC
	Opening Ceremony - Welcome Video - Welcome Addresses - Opening Address - Group Photo
	Main Meeting - Roll Call - Adoption of the Agenda - Adoption of the 27th GHWP Annual Meeting Minutes
	GHWP Status Reports: a) GHWP Overall Status Report b) GHWPTC Status Report

	IMDRF Updates
	International Organizations & Harmonization Efforts a) WHO b) African Medical Devices Forum (AMDF)
	GHWP Liaison Member Updates
	Country/Region Updates
Afternoon	Country/Region Updates (Cont')
	Resolution and Endorsement 1. Election / Endorsement of WG8 Chair 2. Endorsement of Guidance Documents from Working Groups (WG) 3. Endorsement of New Members, followed by short speeches
	Presentation of Certificates of Appointment to the Members of GHWP Strategic Advisory Board (SAB)
	Presentation of Souvenirs to Company Sponsors
	Announcement of the next GHWP Annual Meeting Host & Short Speech
	Closing Remarks
	Adjourn
END OF DAY 4	