



GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

GHWP WG 9 UDI & Nomenclature Update

26th GHWP Annual Meeting, Riyadh

February, 2023

Jun LI, WG9 Chair

The Goal and Objective of WG 9

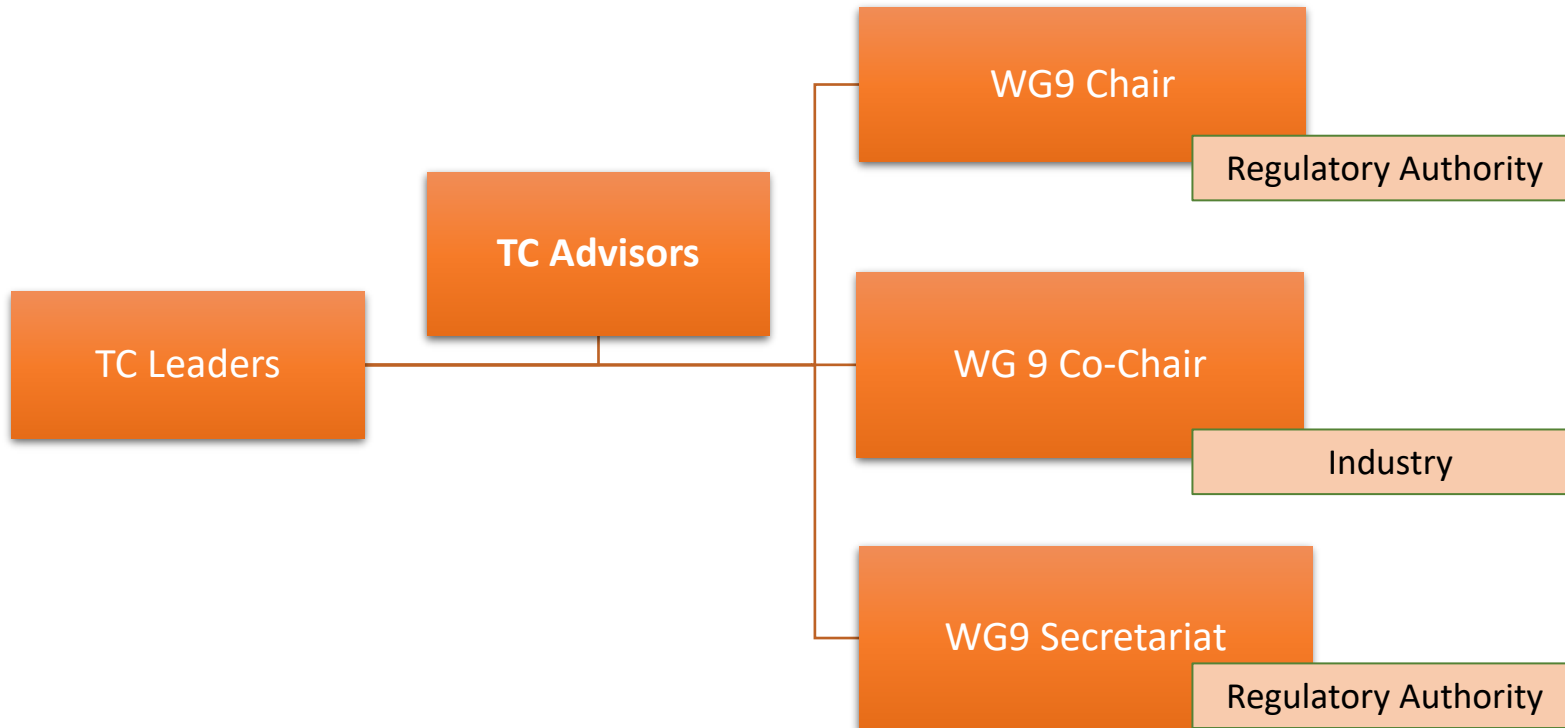


WG 9

UDI &
Nomenclature

- Establishment of a **communication platform** between the regulatory agencies and industry
- Promote a coordinative and **harmonized approach to UDI and nomenclature** during the development and implementation of related regulations and policies;
- Urge **global convergence of medical device UDI and nomenclature regulations** on behalf of the GHWP members and actively participate in the coordination of international harmonization initiatives.

WG 9 – WG Structure



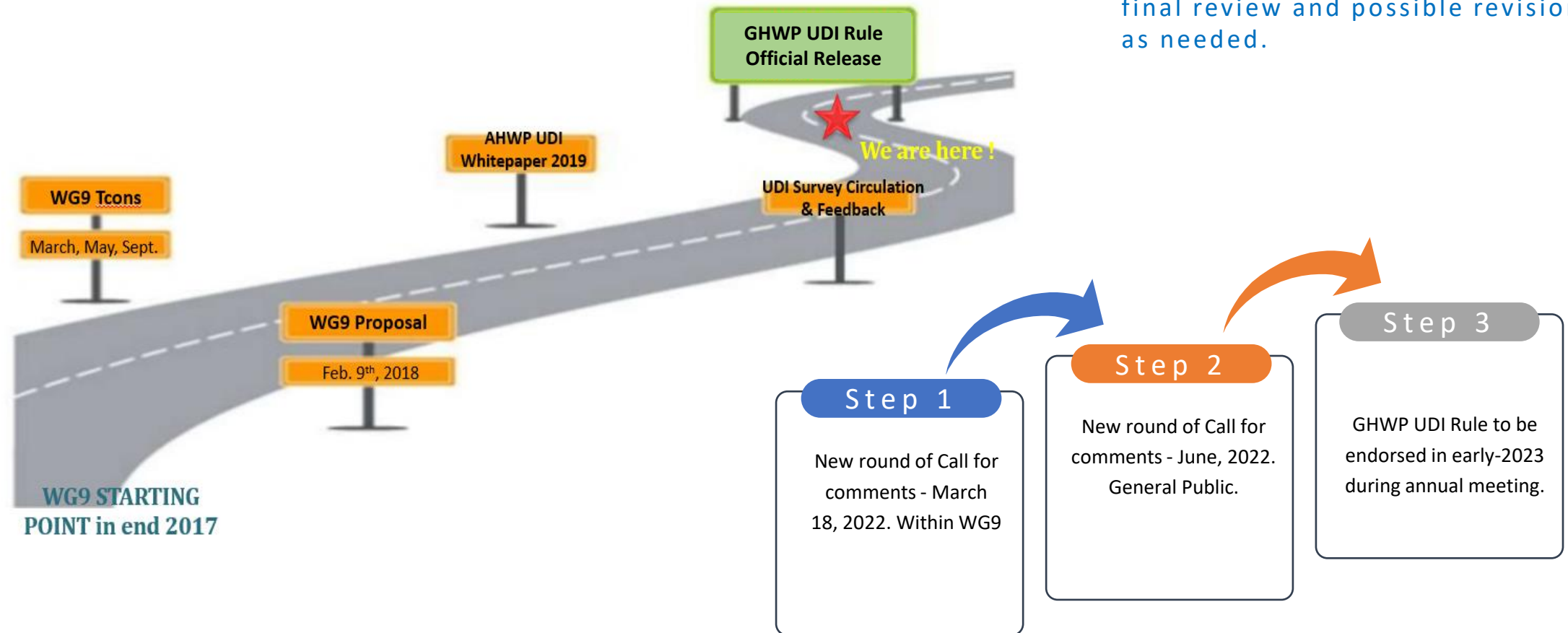
☐ Active members

- Regulator: 7
Saudi Arabia, Singapore, Thailand, China, Chinese Taipei, Kuwait, USA, *(and more to come, including Malaysia...)*
- Industry: 16

New Member

- US FDA representative officially joined WG9 in 2022
- INDIRA RAO KONDURI serves as the Deputy Director for the Division of Surveillance Support (DSS), in the Office of Regulatory Programs (ORP), and Office of Product Evaluation & Quality (OPEQ) in CDRH. She is leading the UDI program implementation efforts in OPEQ.

GHWP UDI Road Map & Timeline



- With UDI development in 2020 and 2021, the UDI rule is under final review and possible revision as needed.

Content of the UDI rule

Table of Content

Chapter I: General Provisions	2
Chapter II: UDI	3
Chapter III: UDI Carrier	4
Chapter IV: UDID	5
Chapter V: Supplementary Provisions.....	5
References	6
Abbreviations	6

General Provisions

Purpose and Scope

UDI is a system

responsibilities

UDI

DI+PI

New UDI trigger and UoU DI

Issuing Agency

UDI Carrier

AIDC+HRI

On device package levels

Open to carrier technology

UDI Database

DI and related data

Global harmonized data element

Data submission requirements

Supplementary Provisions

Encourage to use UDI

Risk-based implement strategy



A wide scope of implementation and an effective application is the vitality of the UDI system.
International Languages, General-Purpose Languages, and Specific Languages

Status of Nomenclature



Work in progress	
1.	WG has continuously involve in the harmonization work in device nomenclature by monitoring the naming work in WHO and GMDN change.
2.	WG will further understand the current status of medical device naming in members and look for piloting opportunities to gradually establish a unified device nomenclature system, by having the nomenclature system in place, and realize the device's fast identification and accurate tracking purpose.

Next steps for WG9

- ◆ Election for New chair and co-chair of WG 9
- ◆ Actively recruit new members and identify WG Advisors
- ◆ Actively support Capacity Building
- ◆ Actively promote the implementation of the GHWP UDI rule and naming rule
- ◆ Actively participate in the coordination of international harmonization initiatives on UDI and Naming



**COMMUNICATE,
DEVELOP
SHARE
CONVERGENCE**



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