STG (U&N)

Chair: Li Jun

Co-Chair: Carol YAN

Secretary: Victoria QU

22nd AHWP Annual Meeting
Dec. 4-8, New Delhi

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Membership

Membership status

- Valid active members
  - Regulator: 8 (Saudi Arabia, Singapore, S. Korea, Thailand，China)
  - Industry: 19
  - New increased membership in our STG family: Saudi Arabia, South Korea

Continuously Attract & Recruit New Members

Invite STG Supervisor

- Industry Expert
- GS1

Our work– UDI

2017 UDI DELIVERABLES

- Teleconference within team – July.
- Training & Workshop
  - CIMDR in Aug.
  - APACMed in Sept.
- STG discussion on the Development of AHWP UDI Report and AHWP UDI rule.

Our work– UDI

UDI Implemented MKT

Understand UDI Implementation practice in US and EU.

- Visited US FDA and learn on UDI implementation
- host Expert Roundtable to better understand the new UDI requirement in EU MDR/IVDR

IMDRF

STG has participated in the in-depth discussion and information exchange in the IMDRF.

AHWP Member

Map out UDI developing status and regulations in key AHWP members.

STG Intakes input from global and regional perspective

UDI Deployment and Pilot in AHWP

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- UDI Rule under discussion
- Healthcare Institution and supply driven track and trace
- Monitor the UDI implementation

- MFDS revised its Medical Device Act on Dec 2, 2016
- MFDS set up local 'device integration data system center' to handle the UDI database

Medical Device Rule, UDI composed by DI and PI must be applicable to all licensed device from Jan. 1st, 2022

- UDI Initiative - UDI for MDs Identification & Traceability
- Create Saudi UDI Database.
- Enforce UDI to all medical Devices on several phases

Voluntary UDI guidance issued and implemented in Oct. 2015.

Status of WG Items - UDI

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WORK IN PROGRESS	
1	STG is monitoring device UDI and UDID update via different platforms/occasions, such as information exchange platform with IMDRF, US FDA and EU Commission, etc.
2	STG continuously follow members on UDI implementation status, and plans to involve in the IMDRF UDI Implementation WI.
FUTURE ACTION PLAN	
GLOBAL ATTACH	STG continuously involved in the global effort in UDI implementation under IMDRF.
	STG provide feedback to IMDRF on behalf of its members on the UDI implementation.
REGIONAL IMPLEMENTATION EFFORT	STG to lead the Mapping And Assessment On The UDI Implementation Pilots in the region and share best practices and experience learnt to the members in the next term.
	STG to develop the Draft AHWP UDI Rule for comments and feedback during the next term, which could be used to provides continuous guidance to the AHWP members on the harmonized approach of the UDI system development.
COLLABORATION WITH INTERNATIONAL ORGANIZATIONS	STG join effort with experts in international organizations, such GS1, and for technical discussion over the development of Medical Device UDI and Traceability Standard and other technical guidance to facilitate the implementation. And will share within AHWP members.

Status of WG Items -Nomenclature

2016 ACHIEVEMENTS

Post-publishing VOC done by Q3 2016

2017 NOMENCLATURE OBJECTIVES

- **STG Continue monitoring the nomenclature work in Global Organizations.**
- **Promote medical device nomenclature convergence**

ACHIEVEMENT	
1	STG Published the AHWP Nomenclature Rule in 2015.
2	STG continuously work on Medical Device Naming Catalogue and Naming Guidance, share experience learn from these initiative to STG members during 2015 – 2017.
ACTION PLAN	
1	STG will continuously involve in the harmonization work in device nomenclature for the next term.
2	STG will further understand the current status in medical device naming in members and look for piloting opportunities to promote medical device nomenclature convergence.

ASIAN HARMONIZATION WORKING PARTY

Communicate, Develop, Share, Convergence

Thank you