AHWP STG(N)

Chair: Mr. Lianchun YANG

Co-Chair: Ms. Carol YAN

Secretary: Ms. Victoria QU

No. of Active WG members:

- 8 Members from Regulatory Authorities;
- 19 members from Regulated Industry

Overview of STG(N)'s work on Nomenclature in 2012-2013

- **Overview of STG(N)'s work on Nomenclature:**
  - ✓ STG believes a uniformed and standardized device nomenclature is the base of scientific supervision of medical devices, it is important to have the implementation experience of GMDN as well as nomenclature technical framework shared within AHWP economies as essential reference.
- **Membership Expansion & Maintenance**
- **Completed:**
  - GMDN Agency Outreach
  - Workshops & Meetings
- **Work-plan in progress**

Status of Previous WG Items for Nomenclature (Completed)

No.	Previous Work Item	Status
1.	Continue participation of nomenclature work at GMDN, IMDRF and WHO, provide AHWP comments	Meet with EU DG SANCO and GMDN Agency from Sept.21st-23rd, 2013
2.	GMDN pilot program in China with start of feasibility study for share	Conducted 5 workshops & discussions in China for the feasibility analysis of GMDN application in China and drafted a report.

Work Plan in Progress for Nomenclature (On-going & New for 2014 onwards)

STG(N) will continuously involve in the harmonization work in device nomenclature , use GMDN term/code and implementation experience, further promote the establishment of a unified device nomenclature system in order to successfully set-up a device fast identification and accurate tracking system within member economies.

Overview and Next Step of STG(N)'s work on UDI in 2012-2013

- **Membership Expansion & Maintenance**
- **Completed:**
  - GS1 & EU DG SANCO Outreach
  - Workshops & Meetings
- **Work-plan in progress**

Status of Previous WG Items for UDI (Completed)

No.	Previous Work Item	Status
1.	Coordinate with IMDRF UDI experts to share in-depth UDI information among member economies	Meet with GS1 and EU DG SANCO
2.	Keep close follow and participate in IMDRF UDI working group	Discussed the suggestions and comments towards the UDI System for Medical Devices (Version 2.0) drafted by IMDRF
3.	Follow member economy UDI implementation status, and provide assistant as necessary to ensure the alignment with IMDRF global model	Conducted a workshop involving CMDSA and AdvaMed

Work Plan in Progress for UDI (On-going & New for 2014 onwards)

Further research on these first-hand information and real-life supervision experience gain from the use of UDI, guide the AHWP member economies on the harmonized approach of the UDI system.