

STG: Medical Device UDI & Nomenclature

(former STG(N)–Medical Device Nomenclature)

Chair: Mr. Lianchun YANG

Co-Chair: Ms. Carol YAN

Secretariat: Ms. Victoria QU

No. of WG members:

- 8 members from Regulatory Authorities;
- 21 members from Industry

Status of WG Items - Nomenclature

Achievement	
1.	China as key member of STG has conducted 5 workshops & expert roundtable for the feasibility analysis of GMDN application in China and drafted a report in 2013.
2.	STG Continue participation of nomenclature work at GMDN, IMDRF and WHO, provide AHWP comments from 2013-2014.
3.	China as a key member of STG has hosted various meeting/expert roundtable both by product group and in general in order to streamline the naming term and plan on selected product fields for pilot study in 2014.
4.	STG experts and experts from other regions held a 1.5 day in-depth discussion and training section on the CIMDR V – UDI & Nomenclature Forum to further share information, raise awareness and build capacity.
5.	China has issued <Supervision and Administration Measure for Medical Device (State Order 650> with requirement on product generic name. (<i>Article 26</i>)
6.	China has issued the <Medical Device Nomenclature Principle (Exposure Draft)> in August, 2014. and collect stakeholder feedback by September 2014. The Principles of this draft is based on <ISO 15225 Medical devices - Quality management - Medical device nomenclature data structure: 2010>, and also take Chinese grammar and language culture into consideration.

Status of WG Items - Nomenclature

Work in Progress	
1.	STG is monitoring device nomenclature update via different platforms/occasions, such as information exchange platform with IMDRF, US FDA and DG SANCO, etc.
2.	China as a key member of STG will continuously work on the final version of Medical Device Naming Rule, Naming Catalogue and Naming Guidance and share experience learn from these initiative to STG members.
Future Action Plan	
1.	STG will continuously involve in the harmonization work in device nomenclature.
2.	STG sees the efforts GMDN put on the medical device information exchange, and will continuously look into the use GMDN term/code and implementation experience.
3.	STG will further promote the establishment of a unified device nomenclature system to successfully set-up a device fast identification and accurate tracking system within member economies.

Status of WG Items - UDI

Achievement	
1.	China as a key member of STG has participated in the in-depth discussion and UDI information exchange as well as close follow and participate in the IMDRF UDI Working Group. Discussed and put forward suggestions/comments to the UDI System for Medical Devices drafted by IMDRF in 2013-2014.
2.	STG experts and experts from other regions held a 1.5 day in-depth discussion and training session on the CIMDR V – UDI & Nomenclature Forum to further share information, raise awareness and build capacity.
3.	China has issued <Supervision and Administration Measure for Medical Device (State Order 650> with requirement on product traceability. (<i>Article 37</i>)
4.	China as a key member of STG has pay great attend attention and focus on the development of UDI. CFDA has formed “UDI Leadership Working Group” in July as a big step forward which provide organizational support to further investigation and eventually implement device identification system in China.
5.	China as a key member of STG has further conduct information exchange and investigation by held roundtable meeting with industry, better understand the implementation of Shanghai’s Implant Registry System, as well as paid visit to GS1 China Office in August to better understand the GS1 Standard for UDI.

Status of WG Items - UDI

Work in Progress	
1.	STG is continuing UDI pilot research in China with start of feasibility study for selected product types in 2013-2014.
2.	STG is monitoring device UDI and UDID update via different platforms/occasions, such as information exchange platform with IMDRF, US FDA and DG SANCO, etc.
3..	STG continuously follow member economies on UDI implementation status, and provide support as necessary to ensure the alignment with IMDRF global model.
Future Action Plan	
1.	STG provides continuous guidance to the AHWP member economies on the harmonized approach of the UDI system.
2.	China as a key member of STG will share the China experience learned from pilot study and investigations together will research on first-hand information and real-life supervision experience gain from UDI implementation experience from US, EU and IMDRF to STG member economies to guide a harmonized approach of UDI in the region.