



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Asian Harmonization Working Party STG

Work Plan

20 Dec 2008

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Nomenclature is one of the most Fundamental and Critical Task

- Welcome more participation to nomenclature STG:
Please contact:
Yanliang@smda.gov.gov.cn;
Ltao@medcn.jnj.com,
- Email group and communication: by the end of
Dec. 2008
- Quarterly telecom and ad-hoc face to face
meeting for particular issue, starting from January,
2009

Nomenclature is one of the most Fundamental and Critical Tasks

1. Understand: status, gap and urgency
2. Study: international base practice
3. Decide: future direction for AHWP
4. Implement: get alignment and implementation

AHWP STG Work Items

1. Understand current status, needs and gap: questionnaire and survey: end of Q2, 2009
 - Share current relevant materials
2. Study international best practice, current available nomenclature system, like GMDN, UMDN, and etc. thru:
 - Follow up and participate GHTF
 - Communicate with international expert from industry, competent authority, and others, like WHO
 - Research on difference of current pros and cons
 - Share information and study result
 - Clear nomenclature tendency Q3-Q4 2009d

AHWP STG Work Items

3. Decide future direction based on all the research and learning: by the end of 2009

- Hopefully we can reach a result on the AHWP meeting

4. Implement:

- Discuss with relevant agency on governance and structure
- Assessment
- Get alignment among AHWP member economics
- Translation and fees
- 2010 and onwards

AHWP STG Work Items

Recommendations:

- Nomenclature is very important for post market surveillance, and closely related to UDI
- Suggest SGT to study and follow up UDI at the same time, by 2009

Thanks