

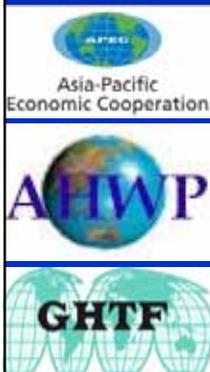
WorkGroup B

Discussion Report
for APEC seminar
Concluding Plenary Session



Objectives

- The importance of the GHTF guidelines to the medical device regulatory framework in Asia
 - ◆ SG1: Regulatory Requirements for Pre-market Review
 - ◆ SG2: Post-market Vigilance and Surveillance
 - ◆ SG3: Quality System Requirements
 - ◆ SG4: Quality System Audit Practices
- Concerns
- Acceptance and its obstacles for the implementation



SG1: Regulatory Requirements for Pre-market Review

Definition and Classification of Medical Device (N029 and N015)

Importance 1:

- Well defined where the principal action of medical device by physical means and not by pharmacological, immunological, metabolic.
- The manufacturer determines the type of classification and conformity assessment for their products following the appropriate regulatory controls.

Concerns:

- There are still some grey area products where the regulator and the industry still in question.
- Current depends on the available guidances related to combination products from EU, FDA or TGA.
- Diverse classification, all economies are not in agreement with.

Acceptance and its obstacles:

- The risk-based classification are being accepted by the member economies. However, it takes time, and economies are sensitive to giving up ownership due to regulations in respective economies.



SG1: Regulatory Requirements for Pre-market Review

Global Medical Device Nomenclature (GMDN)

Importance 2:

- Comprehensive compilation of different medical device terms and coding from the available data source.
- Common term can be useful to identify the product and for vigilance system
- Manufacturers are responsible to decide on the on nomenclature for their device.

Concerns:

- The manufacturer has difficulties in defining the right GMDN for their device products.
- Who is going to teach industry on how to use GMDN
- Fee is required to purchase/upgrade the GMDN
- Terminology is not same in all economies, laws in individual economies would have to be enacted to accept GMDN nomenclature

Acceptance and its obstacles:

- The manufacturer may need more time to familiar with this nomenclature system
- Guidance should be provided by the regulator for its implementation in the respective economies.
- Need document to convert UMDNS to GMDNS



SG1: Regulatory Requirements for Pre-market Review

Summary Technical Documentation (STED)

Importance 3:

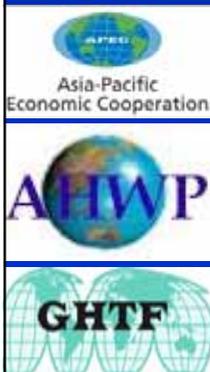
- STED for demonstrating conformity to the Essential Principles of Safety and Performance of medical device
- Harmonization the documentation of evidence of conformity to regulatory requirements and allow timely assess of new technology device to the healthcare industry.
- The number of documents are proportional to the risk of device

Concerns:

- How to determine the amount of information for STED
- Economies modify STED, and industry is customizing dossiers for economies
- Confidentiality of STED documentation for pre-market review
- Industry would like to see confidentiality clauses when providing STED documents and all other information

Acceptance and its obstacles:

- AHWP WG1 is in discussion with the Asia member economies on the Common Technical Documentation based on STED. It serves as a reference and format for pre-market submission. Individual economies may have their own national requirement (eg. languages) which may still apply.
- Some regulators needs more training on STED requirements
- Industry would like to see confidentiality clauses when providing STED documents and all other information



SG1: Regulatory Requirements for Pre-market Review

Essential Principles of Safety and Performance of Medical Devices (including IVD) (N020)

Importance 4:

- Definitely useful checklist of safety and performance requirements for manufacturer in the design and manufacturing of medical device.
- Clinical evaluation, labelling and self-administration requirements included.
- Manufacturer may use the appropriate standards (eg general, horizontal, vertical standards) to demonstrate the device meets the essential principles.

Relevant Concerns:

- National deviations from ISO would make it difficult for manufacturers to conform. Suggest harmonize National Standards with ISO.

Acceptance and its obstacles:

- The change of the current regulatory system requires planning and agreement from the policy maker. Some economies have use this guidelines as a reference and the incorporation of the IVD requirements may be relevant.



SG1: Regulatory Requirements for Pre-market Review

E-Labelling

Importance 5:

- Different languages
- Latest information update and detailed information
- Information still available when Manufacturer and/or Local representative no longer in service.

Concerns:

- Not all user easily access to on-line or PC system
- Changes in the legal environment would need to be made

Acceptance and its obstacles:

- Hospital would need a registry of relevant manuals to ensure availability when needed.
- The regulatory authority will require further discussion and probably a risk analysis on acceptance. Product basis.
- Feedback from the trainer and end user from the healthcare institution need to be sought.
- Consider pilot study within Asia.



SG1: Regulatory Requirements for Pre-market Review

Document Legalization

Importance 1:

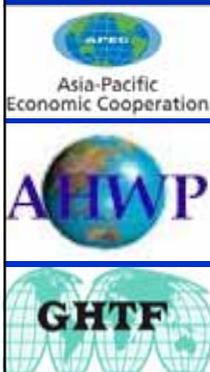
- Why is legalization of documents, such as CFG required?

Concerns:

- Is it value added?
- Extra time and long process
- Manufacturers are required to obtain notarization and consularization from the Embassy for the country of origin.

Acceptance and its obstacles:

- Regulators should accept the original CFG documents which issued by the Authority
- Industry should discuss with the regulators



SG1: Regulatory Requirements for Pre-market Review

IVD Definition and Classification included in the Medical Device (N029 and N015)

Importance 1:

- Medical device review should include IVDs
- Definition and classification should be harmonized amongst regulators

Concerns:

- IVD classification according to GHTF which is based on the individual and population may not be detailed for the regulator.

Acceptance and its obstacles:

- The classification rules in Europe are simple classification list, however it is a closed system. Therefore, we should look at the classification models in TGA and TPP (Canada).



SG2: Post-market Vigilance and Surveillance

Criteria for Adverse Event Reporting (N21)

Importance 6:

- To define the seriousness of an event to be reported to the Authority and follow-up action

Concerns:

- Initial adverse event reporting does not conclude that it is due to the defect of the product
- Not clear on Anticipated and Unanticipated event
- Unanticipated death and serious injury or serious public threat – 10 days
- Anticipated, including death and serious injury – 30 days.
- Address issue with user reporting.

Acceptance and its obstacles:

- The economies may have their own requirements due to the public safety and issues in the economies.
- All economies have different reporting requirements and need harmonization and legal changes



SG2: Post-market Vigilance and Surveillance

National Competent Authority Reporting (NCAR)

Importance 7:

- To inform other member economies on the adverse event or recall from the affected economies
- To be alerted about the post-market event and recall and follow-up action, if necessary

Concerns:

- Not clear on the information to be reported
- Manufacturers should make the decision on recalls in conjunction with regulators.

Acceptance and its obstacles:

- With the training provided by the GHTF, the member economies may consider in the participation.
- A set of requirements may need to be fulfilled by the participating regulators and these include the vigilance system which may not be implemented in most of the economies in Asia.



SG3: Quality System Requirements

Quality system

Importance 8:

- The GHTF QS model which is based in ISO13485 can be a good model for manufacturer to comply with.

Concerns:

- Not all manufacturer able to comply with the GHTF QS model
- Regulator or audit organization are not ready to change the current GMP local requirements to GHTF QS model.

Acceptance and its obstacles:

- A gap analysis should be conducted on how this GHTF QS model is appropriate to some of the countries which are still using GMP requirements.



SG4: Quality System Audit Practices

Audit report

Importance:

- Strong harmonization of the regulator audit report to be recognised by different regulators or audit organization bodies

Concerns:

- Competency of the auditor organization
- How do local manufacturers (small industry) pay for certification fees
- Site as certificate; economies still require extra docs

Acceptance and its obstacles:

- Understanding between manufacturer, regulators and audit organization bodies is importance for such harmonization
- Global Harmonization of notified bodies



Conclusion from WorkGroup B

Medical device definition and classification

GMDN

STED

Legalization documents

Essential Principles

IVD

Adverse Event

NCAR

QS and audit

