WorkGroup B

Discussion Report

for APEC seminar

Concluding Plenary Session

Objectives

- The importance of the GHTF guidelines to the medical device regulatory frame work 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

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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.

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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

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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.

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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.

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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

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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).

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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

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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.

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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.

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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

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Conclusion from WorkGroup B

Medical device definition and classification

GMDN

STED

Legalization documents

Essential Principles

IVD

Adverse Event

NCAR

QS and audit