ANNEX 7

10th GHTF 2006 Conference
Asian Harmonization Working Party
Special Meeting

Update on AHWP Technical Committee Activities

Lubeck, Germany
Wednesday, 28 June 2005
1300 – 1600hrs

Alfred KWEK
Co-Chair, AHWP Technical Committee
Regulatory Scientist
Centre for Medical Device Regulation
Health Sciences Authority, Singapore

Acknowledgement

- Organizing Committee, GHTF Conference 2006
- AHWP Chair / Co-Chair (Past / Present)
- Fellow AHWP TC / WG01 members (Past / Present)
- Resource persons

Scope of Today's Presentation

- Update on the development of the pre-market Common Dossier Template (CSDT)
- Invitation to participation in Technical Committee activities

Introduction (CSDT)

Intended to:

- Be a descriptive document providing guidance for submission of device information to the regulators; and
- Be a common submission template acceptable by all Asian regulators.

Envisaged CSDT will harmonize differences in documentation formats that presently exist in different Asian jurisdictions.

Adoption in Asia will eliminate the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different regulatory authorities in Asia.

Presents least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Elements of the Common Submission Dossier Template

Item Description	Location in STED	Location in CSDT
Introduction	-	Sect 1
Scope	-	Sect 2
Executive Summary • an overview, e.g., introductory descriptive, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; • *commercial marketing history*; • intended uses and indications in labelling; • status of any pending request for market clearance; and • important safety/performance related information.	*Appendix C*	Sect 3

Elements of the Common Submission Dossier Template

Item Description	Location in STED	Location in CSDT
Relevant Essential Principles and Method Used to Demonstrate Conformity 4.1.1 Essential Principles and Evidence of Conformity	**Sect 7.1**	Sect 4.1 Sect 4.1.1

Elements of Common Submission Dossier Template

4.1.1 Essential Principles and Evidence of Conformity

The evidence of conformity can be provided in tabular form with supporting documentation available

APPENDIX A - Example of an Essential Principles Conformity Checklist

Essential Principle	Applicable to the device?	Method of Conformity[1]	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes		

Elements of the Common Submission Dossier Template

Item Description	Location in STED	Location in CSDT
Device Description	**Sect 7.2**	Sect 4.2
4.2.1 Device description & features		
4.2.2 Intended use		
4.2.3 Indications		
4.2.4 Instructions of use		
4.2.5 Contraindications		
4.2.6 Warnings		
4.2.7 Precautions		
4.2.8 Potential adverse effects		
4.2.9 Alternative therapy		
4.2.10 Materials		

Elements of the Common Submission Dossier Template

Item Description	Location in STED	Location in CSDT
Summary Documents of Design Verification & Validation 4.3 Summary of Design Verification and Validation Documents 4.3.1 Pre-clinical Studies 4.3.1.1 Software Validation Studies (if applicable) 4.3.1.2 Devices Containing Biological Material 4.3.2 Clinical Evidence 4.3.2.1 Use of Existing Bibliography	**Sect 7.3**	Sect 4.3

Elements of the Common Submission Dossier Template

Item Description	Location in STED	Location in CSDT
Labelling 4.4.1 Samples of Labels on the Device and its Packaging 4.4.2 Instructions for Use, Training Materials & Instructions for Installation and Maintenance	**Sect 7.4**	Sect 4.4
Risk Analysis 4.5.1 Results of Risk Analysis	**Sect 7.5**	Sect 4.5
Manufacturing Information 4.6.1 Manufacturing Process	**Sect 7.6**	Sect 4.6

References

SG1/N009	Labeling for Medical Devices
SG1/N015	Medical Devices Classification
SG1/N029	Information Document Concerning the Definition of the Term ‘Medical Device’.
SG1/N041	Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)
SG1/N043	Labeling for Medical Devices (including In Vitro Diagnostic Devices)
SG1/N011R17	Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

Invitation

- Currently: 18 Member Economies
- Nomination from member economies to Technical Committee

- Invitation to Resource Persons

Thank You

HSA_CMDR_Info@HSA.gov.sg
Alfred_KWEK@HSA.gov.sg

www.hsa.gov.sg

Centre for Medical Device Regulation
Health Sciences Authority
11 Biopolis Way, #11-03, Helios
Singapore 138667

Scope

- Describes the format for an AHWP harmonized common submission dossier template; and
- Provides general recommendation on the content of the formatted elements.
- No new or additional technical documents above and beyond what should be created by manufacturer to comply with existing requirements to demonstrate conformity to the Essential Principles
- All products that fall within the definition of a medical device, as defined by GHTF.
- Requirements for post-market vigilance or adverse event reporting are outside the scope.

Elements of the Common Submission Dossier Template

Summary Technical Documentation	Location in STED
Essential Principles and Evidence of Conformity	Section 7.1
Device Description	Section 7.2
Summary Documents of Design Verification & Validation	Section 7.3
Labelling	Section 7.4
Risk Analysis	Section 7.5
Manufacturing Information	Section 7.6

Elements of Common Submission Dossier Template

3.1 Relevant Essential Principles and Method Used to Demonstrate Conformity

Manufacturers to identify:

- applicable Essential Principles;
- general methods used; and
- specific documents related to the method used to demonstrate conformity to the Essential Principles.

Methods that may be used include: compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc.

Elements of Common Submission Dossier Template

3.1.1 Essential Principles and Evidence of Conformity

EXAMPLE: A completed Essential Principles conformity checklist can be used to demonstrate that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle.

As such, CSDT would include a declaration of conformity to the standard,

Not all Essential Principles will apply to all devices; manufacturer to assess appropriate EP for his device product, taking into account intended purpose.

Elements of Common Submission Dossier Template

3.2.1 Device Description & Features

General description, a more detailed description of the device attributes to explain how the device functions, basic scientific concepts that form the fundamentals for the device, component materials and accessories used in its principles of operation, and packaging.

A complete description of each functional component, with labelled pictorial representation of the device in the form of diagrams.

Elements of Common Submission Dossier Template

3.2.2 Intended use

The use for which the medical device is intended, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device.

3.2.3 Indications

3.2.4 Instructions of use

3.2.5 Contraindications

3.2.6 Warnings

3.2.7 Precautions

3.2.8 Potential adverse effects

Elements of Common Submission Dossier Template

3.2.9 Alternative therapy

Description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

3.2.10 Materials

Description of the materials of the device and their physical properties. Information shall include complete chemical, biological and physical characterization of the materials of the device.

3.2.11 Other Relevant Specifications

Elements of Common Submission Dossier Template

3.3 Summary of Design Verification and Validation Documents

- Contain design verification and design validation data to the extent appropriate to the complexity and risk class of the device
- Documentation should typically include:

a. Declarations/certificates of conformity to the “recognized” standards listed as applied by the manufacturer; and/or

b. Summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.

Elements of Common Submission Dossier Template

3.3 Summary of Design Verification and Validation Documents

- a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the device with reference to the Essential Principles;
- engineering tests;
- laboratory tests;
- biocompatibility tests;
- animal tests;
- simulated use; and
- software validation.

Elements of Common Submission Dossier Template

3.3.1.1 Process Validation Studies

Results of all applicable process validation studies

EXAMPLE: Process validation data must include sterility test data and methods, culture media, time and temperature of incubation, controls, number of samples examined and frequency of testing.

3.3.1.2 Software Validation Studies (if applicable)

The correctness of a software product is another critical product characteristic that cannot be fully verified in a finished product. The manufacturer and/or device sponsor must provide evidence that validates the software design and development process.

Elements of Common Submission Dossier Template

3.3.1.3 Devices Containing Biological Material

Results of studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents must be provided. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

Elements of Common Submission Dossier Template

3.3.2 Clinical Evidence

Indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Clinical investigation is most likely to be needed for higher risk class devices, or for devices where there is little or no clinical experience.

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3.3.2.1 Use of Existing Bibliography

Copies are required of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness.

Clinical evidence of effectiveness may comprise device-related investigations conducted domestically or other countries. It may be derived from relevant publications in a peer-reviewed scientific literature. The conclusions on the outcome of the clinical studies *should be preceded* by a discussion in context with the published literature.

Elements of Common Submission Dossier Template

3.4 Device Labelling

Descriptive and informational product literature that accompanies the device any time while it is held for sale or shipped, such as any physician's manuals, pack labeling, promotional material and product brochures etc. This section should summarize or reference or contain the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as "labelling".

Elements of Common Submission Dossier Template

3.4.1 Samples of Labels on the Device and its Packaging

Printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper.

If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.

Elements of Common Submission Dossier Template

3.4.2 Instructions for Use, Training Materials & Instructions for Installation and Maintenance

Commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. Where applicable, this section should include instructions for training of the end-users for competent use of the device for its intended purpose, as well as installation and maintenance of the device.

Elements of Common Submission Dossier Template

3.5 Risk Analysis

Summarize results of the risk analysis. Risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.

3.5.1 Results of Risk Analysis

A list of possible hazards for these devices must be prepared.

Indirect risks from such as user-related hazards, such as ionizing radiation from an X-ray machine.

Elements of Common Submission Dossier Template

3.5.1 Results of Risk Analysis (cont'd)

Evaluation of these risks against the claimed benefits of the device and the method(s) used to reduce risk to acceptable levels must be described.

Individual or organization that carries out risk analysis must be clearly identified.

The technique used to analyze risk must be specified, to ensure that it is appropriate for the device and the risks involved.

Elements of Common Submission Dossier Template

3.6 Manufacturer Information

This section should summarize documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.

3.6.1 Manufacturing Process

Manufacturing process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output.

Elements of Common Submission Dossier Template

3.6.1 Manufacturing Process (cont'd)

Sufficient detail must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. E.g. A brief summary of the sterilization method.

If multiple facilities are involved in the manufacture of device, the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted.

Does NOT intent to capture information relating to the supply of sub-components (i.e. unfinished medical device).

Country Specific Requirements

FOR DISCUSSION

1. Executive Summary

Executive summary to include at least the following information:

- Overview of the STED, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the STED;

Country Specific Requirements

FOR DISCUSSION

1. Executive Summary (cont'd)

- Commercial marketing history of the device including, for example, the countries in which the device is sold,
- Intended uses and indications in labelling,
- Status of any pending requests for market clearance, and
- Important safety or performance related information such as recalls and adverse effects encountered.