Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Guidance for Preparation of a Common Submission Dossier Template Dossier for General Medical Device Product Submission

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Contents

1. INTRODUCTION

1.1. Purpose

The document is intended to provide guidance for submission of device information to the regulatory authorities; structured in the format of one common template acceptable by all AHWP member economies regulators. It is envisaged that a Common Submission Dossier Template (CSDT) will harmonize the differences in documentation formats that presently exist in different AHWP member economies jurisdictions. The adoption of this guidance document in AHWP member economies will eliminate the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different regulatory authorities.

1.2. Scope

This guidance document describes the format for an AHWP member economy harmonized common submission dossier template and provides general recommendation on the content of the formatted elements. This document does not recommend any new or additional technical documents above and beyond what should be created by the manufacturer to comply with existing requirements to demonstrate conformity to the Essential Principles [GHTF SG1/N041], and to address any country-specific requirements.

This document applies to all products that fall within the definition of a medical device (See section 1.3), except for in-vitro diagnostic medical devices.

Essentially, the CSDT contains elements of the Summary Technical Documentation (STED) [GHTFSG1/N011R17] for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices.

The format of the CSDT recommended herein is based upon the goal of both regulators and manufacturers to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Requirements for post-market vigilance or adverse event reporting are outside the scope of this document.

1.3. Definitions

Authorised Representative: means any natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under the country or jurisdiction's legislation.

Adverse Event: means either a malfunction or a deterioration in the characteristics or performance of a supplied medical device or use error, which either has caused or could have caused or contributed to death, or injury to health of patients or other people.

Field Safety Corrective Action (FSCA): A field safety corrective action is any remedial action, including preventive and corrective, taken by a manufacturer for reducing the risk of death or serious deterioration in the state of health associated with the use of the medical device. The action includes product recalls, device modification, implant alert, device precaution and user warning.

Medical Device: "medical device" shall mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:-

i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
iii. investigation, replacement, modification, or support of the anatomy or of a physiological process,
iv. supporting or sustaining life,
v. control of conception,
vi. disinfection of medical devices,
vii. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Manufacturer (or legal manufacturer or known as "product owner" in some countries): for the purposes of this guidance document, means a person who sells a medical device under his own name, or under a trade- mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for one or more of the following activities:- designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on his behalf.

Recognised Standards: A standard that is deemed by the Member Economy to offer the presumption of conformity to specific essential principles of safety and performance

2. PREPARATION OF A PRODUCT REGISTRATION SUBMISSION BASED ON THE CSDT

The authorized representative shall take note of the following pointers when preparing a CSDT dossier for submission to local regulatory Authorities. The preparation of CSDT must be made in accordance with the requirements specified in local regulation:

- The prepared CSDT dossier shall contain all sections, i.e. sections 3.0 to 4.6.1. Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading.
- Countries or jurisdictions may set the requirement for having the label of a medical device in their national languages.
- copies of labelling, certificates and reports that are referenced within the CSDT submission shall be submitted as annexes to the CSDT;
- all reports submitted as part of the CSDT should be signed-off and dated by the person issuing the report. This person should be authorised to issue such documents;
- where supporting documents such as reports or certificates are provided, every document must be submitted in full, i.e. all the pages of a document must be submitted;
- all copies of labelling, certificates, reports and other documents submitted must be legible;
- all certificates submitted must be within its validity period.

The level of detail of information to be provided under each CSDT section may depend on the classification of the device and other requirements as defined by the country or jurisdiction in the local regulation.

3. EXECUTIVE SUMMARY

Common Submission Dossier Template Requirements

3. Executive Summary

An executive summary shall be provided with the common submission dossier template, which shall include the following information:

- an overview, 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 CSDT;
- commercial marketing history;
- intended uses and indications in labelling;
- list of regulatory approval or marketing clearance obtained.
- status of any pending request for market clearance; and
- important safety/performance related information.

Guidance:

(a) If the medical device contains any **novel features**, e.g. nanotechnology, a description of the novel feature is to be provided.

(b) For **commercial marketing history**, the list of countries where the medical device is marketed and the dates of introduction into each country is to be provided for reference countries.

Country	First Launch Year

NOTE: In the event that the country's or jurisdiction's regulatory body chooses to recognise reference agencies, the below section (c) & (d) can be adopted. Reference agencies refer to approvals and clearances granted by other agencies as recognized by the member economy for the purpose of the pre-market submission.

(c) the registration status (i.e. submitted, not submitted, pending approval, rejected or withdrawn) and intended use and indications of the medical device in all reference agencies. This information is to be provided in a tabular format as given below:

Reference agency	Intended use	Indications of use	Registration status and date	Reason for rejection or withdrawal (*if applicable*)

(d) copies of certificates or approval letters from each reference agency for the medical device are to be provided as an annex to the CSDT submission.

NOTE: Should the country's or jurisdiction's regulatory body require a comparison of the proposed labelling submitted in the CSDT dossier against that approved in the reference agency, the below section (e) can be adopted.

(e) declaration on labelling, packaging and instructions for use (IFU):

- if the labelling, packaging and IFU of the medical device to be supplied or placed on the member economy's market is **identical** to that approved by each reference agency, a declaration that the labelling, packaging and IFU of the medical device for to be supplied or placed on the member economy's market is **identical** to that approved by each reference agency is to be provided.
- if the labelling, packaging and IFU of the medical device to be supplied or placed on the member economy's market is **not identical** to that approved by each reference agency, the differences between the reference agency's labelling, packaging and IFU and each reference agency's approved labeling, packaging and IFU is to be described. The reason for the differences must also be provided.

(f) For **important safety/performance related information**, the following information is to be provided:

(i) summary of reportable adverse events and field safety corrective actions (FSCAs) for the medical device since its first introduction on the global market. This is to be provided in a tabular format as given below. If there have been no adverse events or FSCAs to date, an attestation that this is the case, is to be provided.

For reported adverse events:

Description of adverse event	Frequency of occurrence (number of reports / total units sold) in the period of dd/mm/yyyy to dd/mm/yyyy

For reported field safety corrective actions (FSCAs):

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted

(ii) if the medical device contains one or more of the following, a description of the following must be provided:

- animal or human cells, tissues and/or derivatives thereof, rendered non-viable (e.g. porcine heart valves, catgut sutures, etc);
- cells, tissues and/or derivatives of microbial or recombinant origin (e.g. dermal fillers based on hyaluronic acid derived from bacterial fermentation processes);
- irradiating components, ionising (e.g. x-ray) or non-ionising (e.g. lasers, ultrasound, etc).

4. ELEMENTS OF THE COMMON SUBMISSION DOSSIER TEMPLATE

4.1. Relevant Essential Principles and Methods Used to Demonstrate Conformity

4.1.1 Essential Principles and Evidence of Conformity

Common Submission Dossier Template Requirements

4. Elements of the Common Submission Dossier Template

4.1 Relevant Essential Principles and Method Used to Demonstrate Conformity

The CSDT should identify the Essential Principles of Safety and Performance of Medical Devices that are applicable to the device. The CSDT should identify the general method used to demonstrate conformity to each applicable Essential Principle. The 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.

The CSDT should identify the specific documents related to the method used to demonstrate conformity to the Essential Principles.

4.1.1 Essential Principles and Evidence of Conformity

The evidence of conformity can be provided in tabular form with supporting documentation available for review as required. A sample of the essential principles conformity checklist is included in Annex 1.

For 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 then include a declaration of conformity to the standard, or other certification permitted by the Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements. When the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the CSDT should identify the full title of the standard, identifying numbers, date of the standard, and the

organization that created the standard. When the manufacturer uses other means, such as internal standards, the CSDT should describe the means.

Not all the essential principles will apply to all devices and it is for the manufacturer of the device to assess which are appropriate for his particular device product. In determining this, account must be taken of the intended purpose of the device.

Guidance:

The Essential Principles (EP) conformity checklist is to be prepared based on the list of EP as defined by the country or jurisdiction regulatory authority. The medical device to which the EP conformity checklist is applicable should be identified on the checklist itself.

Where applicable, the various configurations/variants of the medical device covered by the checklist are to be identified in the checklist. The columns in the recommended format for the checklist (Annex 1) should be completed as follows:

(a) Applicable to the medical device?

(i) either a 'Yes' or 'No' answer is required. If the answer is 'No' this should be briefly explained. For example: For a medical device that does not incorporate biological substances, the answer to EP 9.2 would be 'No – The medical device does not incorporate biological substances.'

(b) Method of conformity

(i) state the title and reference of the standard(s), industry or in-house test method(s), comparison study(ies) or other method used to demonstrate compliance. For standards, this should include the date of the standard and where appropriate, the clause(s) that demonstrates conformity with the relevant EP. Where a standard is referred to more than once in the checklist, the reference number and date can be repeated or standard name and year can be provided in an attachment to the EP Checklist

and EP checklist can only indicate standard organization name and number i.e. ISO 13485 or IEC 60601-1.

(c) Identity of specific documents

(i) this column should contain the reference to the actual technical documentation that demonstrates compliance to the EP, i.e. the certificates, test reports, study reports or other documents that resulted from the method used to demonstrate compliance, and its location within the technical documentation.

4.2. Device Description

4.2.1. Device description and features

Common Submission Dossier Template Requirements

4.2 Device Description

4.2.1 Device description and features

Besides a general description of the device, a more detailed description of the device attributes is necessary to explain how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging. A complete description of each functional component, material or ingredient of the device should be provided, with labelled pictorial representation of the device in the form of diagrams, photographs or drawings, as appropriate.

Guidance:

The following information shall be submitted to meet the requirements of this section:

(a) A complete description of the medical device;

(b) Principles of operation or mode of action;

(c) Risk class and applicable classification rule for the medical device according to the Member Economy's legislation;

(d) A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device. For example, patients implanted with a stent or heart valve need to be managed with appropriate medication such as warfarin, as recommended by the manufacturer;

(e) A description or complete list of the various configurations of the medical device to be registered.

(f) A complete description of the key functional elements (e.g. its parts or components, including software if appropriate), its formulation, its composition and its functionality. Where appropriate, this will include labelled pictorial representation (e.g. diagrams, photographs and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(g) An explanation of any novel 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

Common Submission Dossier Template Requirements

4.2.2 Intended use

This means 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.

4.2.3 Indications

This is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended.

4.2.4 Instructions of use

These are all necessary information from the manufacturer including the procedures, methods, frequency, duration, quantity and preparation to be

followed for safe use of the medical device. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging by other formats / forms.

4.2.5 Contraindications

This is a general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

4.2.6 Warnings

This is the specific hazard alert information that a user needs to know before using the device.

4.2.7 Precautions

This alerts the user to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid such effects.

4.2.8 Potential adverse effects

These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions.

Guidance:

Information requested for under sub-sections 4.2.2 to 4.2.8 would be typically found in the instructions for use (IFU). Therefore, the IFU can be submitted in lieu of these sections. Any of the sections 4.2.2 to 4.2.8 that are not addressed in the IFU must be addressed separately in the submission dossier. The IFU is also known as the product insert, user or operating manual.

4.2.9. Alternative therapy

Common Submission Dossier Template Requirements
4.2.9 Alternative therapy This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

Guidance:

Describe briefly the alternative practices or procedures to achieve the same intended purpose as that of the medical device. For example, for a drug eluting stent, alternative therapies will include exercise, diet, drug therapy, percutaneous coronary interventions (e.g. balloon angioplasty, atherectomy and bare metal stenting) and coronary artery bypass graft surgery. This does not include any treatment practices or procedures that are considered investigational.

Note: This information shall only be included if required by local regulation.

4.2.10. Materials

Common Submission Dossier Template Requirements
4.2.10 Materials A description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and

physical characterization of the materials of the device.

Guidance:

The following information shall be submitted to meet the requirements of this section:

(a) List of materials of the medical device making either direct (e.g. with the mucous membrane) or indirect contact (e.g., during extracorporeal circulation of body fluids) with a human body;

(b) Complete chemical, biological and physical characterisation of the materials of the medical device making either direct (e.g. mucous membrane) or indirect contact (e.g., during extracorporeal circulation of body fluids) with a human body;

(c) For medical devices intended to emit ionising radiation, information on radiation source (e.g. radioisotopes) and the material used for shielding of unintended, stray or scattered radiation from patients, users and other persons shall be provided.

4.2.11. Other Relevant Specifications

Common Submission Dossier Template Requirements
4.2.11 Other Relevant Specifications
The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.

Guidance:

The functional characteristics and technical performance specifications for the device requested in **(4.2.11)** including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles. A list of the features, dimensions and performance attributes of the medical device, its variants and accessories that would typically appear in the product specification made available to the end user, e.g. in brochures and catalogues, will satisfy the requirements of this section.

4.2.12. Other Descriptive Information

Common Submission Dossier Template Requirements

4.2.12 Other Descriptive Information

Other important descriptive characteristics not detailed above, to the extent necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished device).

NOTE: For simple, low risk devices, the above information will typically be contained in already existing sales brochures, instructions for use, etc.

Guidance:

This section allows for the inclusion of other descriptive information about the medical device that is not addressed in the preceding sections. For example, when demonstrating compliance with the EPs for an ingested camera pill used to image the gastrointestinal tracts of outpatients, manufacturers may wish to describe in detail in this section the use of a patient card (drafted in the local language) to be carried by the patient during the period of imaging. In the event of non-excretion of the camera pill or acute stomach pain, the patient card can be produced to attending physicians, thereby reducing the risk of miscommunication between patient and physician.

4.3. Summary of Design Verification and Validation Documents

Common Submission Dossier Template Requirements

4.3 Summary of Design Verification and Validation Documents

This section should summarize or reference or contain design verification and design validation data to the extent appropriate to the complexity and risk class of the device:

Such documentation should typically include:

(i) declarations/certificates of conformity to the “recognized” standards listed as applied by the manufacturer; and/or

(ii) summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.

EXAMPLE: The completed Table of Conformity to the Essential Principles that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. Section 3.0 of the CSDT would then include a declaration of conformity to the standard, or other certification permitted by the relevant Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements.

The data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the medical device:

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

Guidance:

(a) For all aspects of verification and validation described in this section and in sub-sections 4.3.1, 4.3.1.1 and 4.3.1.2, where no testing was undertaken for the medical device, a rationale for that decision must be provided. Evidence to support the rationale shall be provided.

(b) For medical devices provided sterile, the following information is to be provided in this section:

(i) detailed information of the initial sterilisation validation including bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. If initial sterilisation validation is not performed, adequate justification must be provided. For example, if reference to the sterilisation validation conducted for another medical device is made for the medical device in the application, the justification for the applicability of the previously conducted validation to the current medical device must be provided. In addition, the initial sterilisation validation report for the reference medical device must be provided;

(ii) evidence of the ongoing revalidation of the process. Typically this would consist of arrangements for, or evidence of, revalidation of the sterilisation processes;

(iii) detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed in accordance with those standards, and a summary of results;

(iv) post-sterilisation functional test on the medical device;

(v) if the sterilant is toxic or produces toxic residuals (e.g. ethylene oxide residues), test data and methods that demonstrate that post-process sterilant and/or residuals are within acceptable limits must be presented.

(c) For medical devices with a shelf life, data demonstrating that the relevant performances and characteristics of the medical device are maintained

throughout the claimed shelf life which the “expiry“ date reflects is to be provided in this section. This may include:

(i) prospective studies using accelerated ageing, validated with real time degradation correlation; or

(ii) retrospective studies using real time experience, involving e.g. testing of stored samples, review of the complaints history or published literature etc.; or

(iii) a combination of (i) and (ii).

If real time shelf life data is not available, shelf life data collected from accelerated studies can be used to support the initial shelf life claim. The rationale for the parameters selected for the accelerated studies must be provided. Shelf life data collected from accelerated studies must be supported by real time testing to confirm the initial shelf life claim. The final real time study report must be submitted upon request by local regulatory authorities.

(d) As the absence of an “expiry“ date constitutes an implicit claim of an infinite shelf life, evidence demonstrating the following shall be provided:

(i) that there are *no* safety-related performances or characteristics which are likely to deteriorate over time, or

(ii) that the *extent* of any likely deterioration does not represent an unacceptable risk, or

(iii) that the *period* over which unacceptable deterioration occurs is far beyond the likely time of the first use of the medical device e.g. 30 years.

(e) For devices that do not have expiry dates (e.g. infusion pump, digital thermometer), the projected useful life of the medical device must be provided. Manufacturers may refer to TS/ISO 14969 (Medical devices – Quality management systems – Guidance on the application of ISO 13485:2003) for information on how to determine the projected useful life.

(f) For medical devices with a measuring function where inaccuracy could have a significant adverse effect on the patient, studies demonstrating conformity with metrological requirements shall be provided.

4.3.1. Pre-clinical Studies

Common Submission Dossier Template Requirements

4.3.1 Pre-clinical Studies

Details must be provided on the pre-clinical evaluation of biological safety. As a minimum this should include identification of all component materials in contact with the patient and consideration as to the toxicological interactions of concern according to the invasiveness and duration of contact of the medical device. Evaluation should make use of pre-existing relevant data including known toxicity of the constituent materials and the known safety of similar devices composed of the same materials. Where pre-existing data are insufficient to establish safety, they must be supplemented by appropriate chemical characterisation or biological safety testing in order to provide complete information.

Physical testing must be conducted to predict the adequacy of device response to normal conditions of use and any anticipated misuse. Testing should also consider all known and possible single failure modes.

Pre-clinical animal studies used to support the probability of effectiveness in humans must be reported. These studies must be undertaken using good laboratory practices. The objectives, methodology, results, analysis and manufacture's conclusions must be presented. The study conclusion should address the device's interactions with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

All physical, chemical or biological tests must be conducted on samples from the finished, sterilized device. The report must include the objectives,

methodology, results and manufacturer's conclusions of all physical studies of the medical device and its components.

Guidance:

Data to be submitted in this section includes any pre-clinical evaluation reports, laboratory or animal studies, as appropriate for the medical device.

4.3.1.1. Software Verification and Validation Studies

Common Submission Dossier Template Requirements **4.3.1.1 Software Verification and Validation Studies** 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. This information should include the results of all verification, validation and testing performed in- house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, as well as representative data generated from both testing environments.

There is no specific guidance for this section of the CSDT.

4.3.1.2. Devices Containing Biological Material

Common Submission Dossier Template Requirements

4.3.1.2 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.

Guidance:

The following information shall be submitted to meet the requirements of this section:

(a) A list of all materials of animal, human, microbial and/or recombinant origin used in the medical device and in the manufacturing process of the medical device. This includes animal or human cells, tissues and/or derivatives, rendered non-viable and cells, tissues and/or derivatives of microbial or recombinant origin;

(b) Detailed information concerning the selection of sources/donors;

(c) Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;

(d) Process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents;

(e) Full description of the system for record keeping to allow traceability from sources to the finished medical device.

4.3.2. Clinical Evidence

Common Submission Dossier Template Requirements

4.3.2 Clinical Evidence

This section should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met.

Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar medical devices, or by clinical investigation. Clinical investigation is most likely to be needed for higher risk class medical devices, or for medical devices where there is little or no clinical experience.

Guidance:

Information required in this section is to be provided in the form of a clinical evaluation report. The format for the clinical evaluation report shall be in accordance to local regulation and guidance. This clinical evaluation report documents the assessment and analysis of clinical data to verify the clinical safety and performance of the medical device when used as intended by the manufacturer.

4.3.2.1. Use of Existing Bibliography

Common Submission Dossier Template Requirements

4.3.2.1 Use of Existing Bibliography

Copies are required of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness. These will be a subset of the bibliography of references. General bibliographic references should be medical device-specific as supplied in chronological order. Care should be taken to ensure that the references are timely and relevant to the current application.

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 documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

There is no specific guidance for this section of the CSDT.

4.4. Device Labelling

Common Submission Dossier Template Requirements

4.4 Device Labelling

This is the descriptive and informational product literature that accompanies the device any time while it is held for sale or shipped. 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”:

- Labels on the device and its packaging;
- Instructions for use;
- Physician’s manual
- Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable).

Guidance:

Apart from device labelling, the promotional material and product brochures shall be provided in this section to aid in the evaluation of the medical device.

NOTE Inclusion of promotional materials as part of the submission requirement for CSDT should not constitute approval by the Member Economy’s regulatory body of the claims contained within the promotional materials, the promotional material itself nor any future revision.

4.4.1. Samples of Labels on the Device and its Packaging

Common Submission Dossier Template Requirements

4.4.1 Samples of Labels on the Device and its Packaging

This is the 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. Any pack labelling, which is not provided on the outer packaging must be easily legible through this outer packaging.

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.

Guidance:

The labels on the medical device and its packaging are to be provided for the primary and secondary levels of packaging and shall be provided in the original colour. The labels can be provided in the form of artwork. Labels provided must be in English. Labels must be provided for all the components of a medical device system, members of a medical device family and accessories submitted for registration. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated.

4.4.2. Instructions for Use

Common Submission Dossier Template Requirements

4.4.2 Instructions for Use

The instructions for use is 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. This should include information on indications, contraindications, warnings, precautions, potential adverse

effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the medical device.

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.

4.5. Risk Analysis

4.5.1 Results of Risk Analysis

Common Submission Dossier Template Requirements

4.5 Risk Analysis

This section should summarize or reference or contain the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.

4.5.1 Results of Risk Analysis

A list of possible hazards for these devices must be prepared. Indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from user-related hazards, such as ionizing radiation from an X-ray machine. The 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. The individual or organization that carries out the risk analysis must be clearly identified. The technique used to analyze risk must be specified, to ensure that it is appropriate for the medical device and the risk involved.

Guidance:

Information required in this section is to be provided in the form of a risk management report. It is recommended that the risk management activities be conducted according to ISO 14971. A risk management report will contain

details of the risk analysis, risk evaluation, risk control conducted for the medical device. The risks and benefits associated with the use of the medical device should be described.

4.6. Manufacturer Information

4.6.1 Manufacturing Process

Common Submission Dossier Template Requirements

4.6 Manufacturer Information

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

4.6.1 Manufacturing Process

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

EXAMPLE: The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labeling, storage of the medical device. Sufficient detail must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. A brief summary of the sterilization method and processing should be included, if any.

If multiple facilities are involved in the manufacture of medical device, the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted. Firms that manufacture or process the medical device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file. The manufacturer should inform these contractors

of the need to supply detailed information on the medical device. However, it is not the intent of this section to capture information relating to the supply of sub-components (i.e. unfinished medical device) that contributes towards the manufacture of the finished medical device itself.

Guidance:

(a) Information on the manufacturing process should be provided in sufficient detail to allow a general understanding of the manufacturing processes. Detailed proprietary information on the manufacturing process is not required. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing and packaging of the finished medical device.

(b) If the manufacturing process is carried out at multiple sites, the manufacturing activities carried out at each site should be clearly identified. For example:

(i) if the manufacturing process of a product consists of a number of sub-assembly processes, the manufacturing sites where each of these sub-assembly processes are carried out must be identified, and the relationship between these processes must be shown; or

(ii) if multiple sites manufacture the same product, each of these sites must be identified.

(c) The sites (including contract manufacturers) where design and manufacturing activities are performed shall be identified. Quality Management System certificates are to be provided for the design and manufacturing sites (including contract manufacturers) as an annex to the CSDT submission. This requirement does not apply to component manufacturers (for example, contract manufacturers of PCB boards) except in cases where the components are part of a medical device system (e.g. contract manufacturers for the femoral stem and acetabular cups of a hip implant system).

5. REFERENCES

I. ACCSQ-MDPWG Guidance for Common Submission Dossier Template (Version 6), Document Number: N0013, ASEAN Consultative Committee for Standards and Quality Medical device Product Working Group (ACCSQ-MDPWG), 16 February 2006

II. Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical devices (STED), SG1(PD)N011, Global Harmonization Task Force (GHTF), 26 March 2007

III. Medical Device Guidance document: Common Submission Dossier Template, MDA/GD-03, First Edition, March 2014.

IV. Draft Medical Device Guidance document: GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT, May 2014

V. Medical Device Guidance document: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT Template, Oct 2010

VI. Taiwan Regulation for registration of Medical Device, Sept 2014

715 **ANNEX 1**

716 Example of an Essential Principles Conformity Checklist

717 *NOTE: The below table is an illustrative example. The regulations of each respective country or jurisdiction are to be referred to, for*
718 *the full list of applicable essential principles of safety and performance for the given country or jurisdiction.*

Essential Principle	Applicable to the device?	Method of Conformity	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.			
2. The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: • identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, • eliminate risks as far as reasonably practicable through inherently safe design and manufacture, • reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, • inform users of any residual risks.			

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