



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

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

Authoring Group: Working Group 1, Pre-Market: General MD

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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

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

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

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

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

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

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

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

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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:

104

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

105

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

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

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

- 112 • if the labelling, packaging and IFU of the medical device to be
113 supplied or placed on the member economy's market is **identical** to
114 that approved by each reference agency, a declaration that the
115 labelling, packaging and IFU of the medical device for to be supplied or
116 placed on the member economy's market is **identical** to that approved
117 by each reference agency is to be provided.
- 118 • if the labelling, packaging and IFU of the medical device to be
119 supplied or placed on the member economy's market is **not identical**
120 to that approved by each reference agency, the differences between
121 the reference agency's labelling, packaging and IFU and each reference
122 agency's approved labeling, packaging and IFU is to be described.
123 The reason for the differences must also be provided.

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

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

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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

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For reported field safety corrective actions (FSCAs):

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted

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

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- 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).

148 **4. ELEMENTS OF THE COMMON SUBMISSION DOSSIER TEMPLATE**

149 **4.1. Relevant Essential Principles and Methods Used to Demonstrate**
150 **Conformity**

151 **4.1.1 Essential Principles and Evidence of Conformity**

152 **Common Submission Dossier Template Requirements**

153 **4. Elements of the Common Submission Dossier Template**

154 **4.1 Relevant Essential Principles and Method Used to Demonstrate**
155 **Conformity**

156 The CSDT should identify the Essential Principles of Safety and Performance
157 of Medical Devices that are applicable to the device. The CSDT should
158 identify the general method used to demonstrate conformity to each
159 applicable Essential Principle. The methods that may be used include
160 compliance with recognized or other standards, state of the art or internal
161 industry methods, comparisons to other similar marketed devices, etc.

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

164 **4.1.1 Essential Principles and Evidence of Conformity**

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

168 For example, a completed Essential Principles conformity checklist can be
169 used to demonstrate that a recognized test standard was used as part of
170 the method to demonstrate conformity to one Essential Principle. As such,
171 CSDT would then include a declaration of conformity to the standard, or
172 other certification permitted by the Regulatory Authority, and a summary of
173 the test data, if the standard does not include performance requirements.
174 When the manufacturer uses international or other standards to demonstrate
175 conformity with the Essential Principles, the CSDT should identify the full title
176 of the standard, identifying numbers, date of the standard, and the

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

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

183 **Guidance:**

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

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

192 (a) Applicable to the medical device?

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

198 (b) Method of conformity

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

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

208 (c) Identity of specific documents

209 (i) this column should contain the reference to the actual technical
210 documentation that demonstrates compliance to the EP, i.e. the
211 certificates, test reports, study reports or other documents that resulted
212 from the method used to demonstrate compliance, and its location within
213 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;

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

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

249 (g) An explanation of any novel features.

250 **4.2.2. Intended use**

251 **4.2.3. Indications**

252 **4.2.4. Instructions of use**

253 **4.2.5. Contraindications**

254 **4.2.6. Warnings**

255 **4.2.7. Precautions**

256 **4.2.8. Potential adverse effects**

257 **Common Submission Dossier Template Requirements**

258 **4.2.2 Intended use**

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

262 **4.2.3 Indications**

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

266 **4.2.4 Instructions of use**

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

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

272 **4.2.5 Contraindications**

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

278 **4.2.6 Warnings**

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

281 **4.2.7 Precautions**

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

288 **4.2.8 Potential adverse effects**

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

292 **Guidance:**

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

298 **4.2.9. Alternative therapy**

299 **Common Submission Dossier Template Requirements**

300 **4.2.9 Alternative therapy**

301 This is a description of any alternative practices or procedures for diagnosing,
302 treating, curing or mitigating the disease or condition for which the device is
303 intended.

304 **Guidance:**

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

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

313 **4.2.10. Materials**

314 **Common Submission Dossier Template Requirements**

315 **4.2.10 Materials**

316 A description of the materials of the device and their physical properties to
317 the extent necessary to demonstrate conformity with the relevant Essential
318 Principles. The information shall include complete chemical, biological and

319 physical characterization of the materials of the device.

320 **Guidance:**

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

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

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

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

334 **4.2.11. Other Relevant Specifications**

335 **Common Submission Dossier Template Requirements**

336 **4.2.11 Other Relevant Specifications**

337 The functional characteristics and technical performance specifications for
338 the device including, as relevant, accuracy, sensitivity, specificity of measuring
339 and diagnostic medical devices, reliability and other factors; and other
340 specifications including chemical, physical, electrical, mechanical, biological,
341 software, sterility, stability, storage and transport, and packaging to the
342 extent necessary to demonstrate conformity with the relevant Essential
343 Principles.

344 **Guidance:**

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

355 **4.2.12. Other Descriptive Information**

356 **Common Submission Dossier Template Requirements**

357 **4.2.12 Other Descriptive Information**

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

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

363 **Guidance:**

364 This section allows for the inclusion of other descriptive information about the
365 medical device that is not addressed in the preceding sections. For example,
366 when demonstrating compliance with the EPs for an ingested camera pill used
367 to image the gastrointestinal tracts of outpatients, manufacturers may wish to
368 describe in detail in this section the use of a patient card (drafted in the
369 local language) to be carried by the patient during the period of imaging. In
370 the event of non-excretion of the camera pill or acute stomach pain, the
371 patient card can be produced to attending physicians, thereby reducing the
372 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.

402 **Guidance:**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

453 (e) For devices that do not have expiry dates (e.g. infusion pump, digital
454 thermometer), the projected useful life of the medical device must be
455 provided. Manufacturers may refer to TS/ISO 14969 (Medical devices –
456 Quality management systems – Guidance on the application of ISO
457 13485:2003) for information on how to determine the projected useful life.

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

461 **4.3.1. Pre-clinical Studies**

462 **Common Submission Dossier Template Requirements**

463 **4.3.1 Pre-clinical Studies**

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

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

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

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

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

489 **Guidance:**

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

492 **4.3.1.1. Software Verification and Validation Studies**

493 **Common Submission Dossier Template Requirements**

494 **4.3.1.1 Software Verification and Validation Studies**

495 The correctness of a software product is another critical product characteristic
496 that cannot be fully verified in a finished product. The manufacturer and/or
497 device sponsor must provide evidence that validates the software design
498 and development process. This information should include the results of all
499 verification, validation and testing performed in- house and in a user's
500 environment prior to final release, for all of the different hardware
501 configurations identified in the labelling, as well as representative data
502 generated from both testing environments.

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

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505 **4.3.1.2. Devices Containing Biological Material**506 **Common Submission Dossier Template Requirements**507 **4.3.1.2 Devices Containing Biological Material**

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

514 **Guidance:**

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

- 517 (a) A list of all materials of animal, human, microbial and/or recombinant origin
518 used in the medical device and in the manufacturing process of the medical
519 device. This includes animal or human cells, tissues and/or derivatives,
520 rendered non-viable and cells, tissues and/or derivatives of microbial or
521 recombinant origin;
- 522 (b) Detailed information concerning the selection of sources/donors;
- 523 (c) Detailed information on the harvesting, processing, preservation, testing
524 and handling of tissues, cells and substances;
- 525 (d) Process validation results to substantiate that manufacturing procedures
526 are in place to minimize biological risks, in particular, with regard to viruses
527 and other transmissible agents;
- 528 (e) Full description of the system for record keeping to allow traceability from
529 sources to the finished medical device.

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531 **4.3.2. Clinical Evidence**

532 **Common Submission Dossier Template Requirements**

533 **4.3.2 Clinical Evidence**

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

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

541 **Guidance:**

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

548 **4.3.2.1. Use of Existing Bibliography**

549 **Common Submission Dossier Template Requirements**

550 **4.3.2.1 Use of Existing Bibliography**

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

557 Clinical evidence of effectiveness may comprise device-related investigations
 558 conducted domestically or other countries. It may be derived from relevant
 559 publications in a peer-reviewed scientific literature. The documented evidence
 560 submitted should include the objectives, methodology and results presented in
 561 context, clearly and meaningfully. The conclusions on the outcome of the
 562 clinical studies should be preceded by a discussion in context with the
 563 published literature.

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

565 **4.4. Device Labelling**

566 **Common Submission Dossier Template Requirements**

567 **4.4 Device Labelling**

568 This is the descriptive and informational product literature that accompanies
 569 the device any time while it is held for sale or shipped. This section should
 570 summarize or reference or contain the following labelling data to the extent
 571 appropriate to the complexity and risk class of the device, which is generally
 572 considered as “labelling”:

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

578 **Guidance:**

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

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

585 **4.4.1. Samples of Labels on the Device and its Packaging**

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Common Submission Dossier Template Requirements

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4.4.1 Samples of Labels on the Device and its Packaging

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This is the printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging

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or the outside container wrapper. Any pack labelling, which is not provided on the outer packaging must be easily legible through this outer packaging.

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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.

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Guidance:

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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.

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4.4.2. Instructions for Use

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Common Submission Dossier Template Requirements

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4.4.2 Instructions for Use

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The instructions for use is commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual.

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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

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

615 Where applicable, this section should include instructions for training of the
616 end-users for competent use of the device for its intended purpose, as well as
617 installation and maintenance of the device.

618 **4.5. Risk Analysis**

619 **4.5.1 Results of Risk Analysis**

620 **Common Submission Dossier Template Requirements**

621 **4.5 Risk Analysis**

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

626 **4.5.1 Results of Risk Analysis**

627 A list of possible hazards for these devices must be prepared. Indirect risks
628 from medical devices may result from device-associated hazards, such as
629 moving parts, which lead to sustained injury, or from user-related hazards,
630 such as ionizing radiation from an X-ray machine. The evaluation of these
631 risks against the claimed benefits of the device and the method(s) used to
632 reduce risk to acceptable levels must be described. The individual or
633 organization that carries out the risk analysis must be clearly identified. The
634 technique used to analyze risk must be specified, to ensure that it is
635 appropriate for the medical device and the risk involved.

636 **Guidance:**

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

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

643 **4.6. Manufacturer Information**

644 **4.6.1 Manufacturing Process**

645 **Common Submission Dossier Template Requirements**

646 **4.6 Manufacturer Information**

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

650 **4.6.1 Manufacturing Process**

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

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

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

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

672 **Guidance:**

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

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

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

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

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

697 **5. REFERENCES**

- 698 I. ACCSQ-MDPWG Guidance for Common Submission Dossier
699 Template (Version 6), Document Number: N0013, ASEAN
700 Consultative Committee for Standards and Quality Medical device
701 Product Working Group (ACCSQ-MDPWG), 16 February 2006
- 702 II. Summary Technical Documentation for Demonstrating
703 Conformity to the Essential Principles of Safety and Performance
704 of Medical devices (STED), SG1(PD)N011, Global Harmonization
705 Task Force (GHTF), 26 March 2007
- 706 III. Medical Device Guidance document: Common Submission
707 Dossier Template, MDA/GD-03, First Edition, March 2014.
- 708 IV. Draft Medical Device Guidance document: GN-17: Guidance on
709 Preparation of a Product Registration Submission for General
710 Medical Devices using the ASEAN CSDT, May 2014
- 711 V. Medical Device Guidance document: Guidance on Preparation of
712 a Product Registration Submission for General Medical Devices
713 using the ASEAN CSDT Template, Oct 2010
- 714 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: <ul style="list-style-type: none"> • 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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