IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

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PREFACE

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of global medical device regulators from around the world. The document has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum. It is also worth noting that it is the intent of IMDRF is to continue to monitor use of this structure and work to continually improve the documents.

INTRODUCTION

The Regulated Product Submission (RPS) proposal was endorsed as a New Work Item (NWI) by IMDRF at its inaugural meeting in Singapore (March 2012). The proposal, as endorsed, included the objective of establishing a comprehensive harmonized structure for premarket medical device submissions.

This document provides an internationally harmonized, modular, format for use when filing medical device submissions to regulatory authorities for market authorization. This document is comprehensive in scope in that it defines the location of both common (IMDRF) and regional content for all submission types. As a consequence, not all headings are required for all submission types and/or IMDRF jurisdictions.

This ToC document has been developed with consideration of public comments and experience gained from the pilot testing of the draft ToC version.

The ToC documents are intended to work together with a separate document created for each participating jurisdiction – a classification matrix. The classification matrix defines whether for the given submissions type a heading is required, not required, optional, conditionally required, etc. The classification matrices are the published under the authority of participating authorities and are not products of IMDRF, please consult regional regulator websites for further information.

The release of the first version of the final ToC document makes available harmonized formats for use in filing IVD medical device submissions for market authorization.

IMDRF will monitor the use of these structures and work to continually improve the documents at appropriate intervals based on sufficient use and experience. Comments or questions associated with these documents will be accepted in the prescribed format (Feedback form – excel spreadsheet) and can be submitted to imdrf.toc@gmail.com with the following subject line: IMDRF IVD ToC MA Feedback.

SCOPE

This document was developed for in-vitro diagnostics medical device (IVD) market authorization submissions. Market authorization submissions for combination products are out of scope; refer to each specific regulator for guidance regarding combination products. Submissions to request approval to conduct clinical trials are not within the scope of this document.

The document is intended to provide guidance for industry with flexibility to adapt to the variety of products and future products.

PURPOSE

To create a comprehensive submission structure that can be used as a harmonized international electronic submission format while minimizing regional divergences and indicating where regional variation exists. This document is intended to provide guidance regarding the location of submission elements. This document is intended to work together with a separate document created for each participating jurisdiction – a classification matrix.

This document is not intended to introduce any new regulatory requirements; however, by virtue of being more transparent, it may appear to be introducing new requirements.

CLASSIFICATION MATRICES

As this document is comprehensive in nature, not all headings are required for all submission types and/or jurisdictions. This document is intended to work together with a separate document created for each participating jurisdiction – a classification matrix. The classification matrix defines whether for the given submissions type a heading is required, not required, optional, conditionally required, etc. The classification matrices are to be made available on regional regulators websites.

DEFINITIONS

FULL REPORT - Typically includes a complete, detailed description of the objective of the assessment, the methods and procedures including when applicable why a regional or harmonized/recognized standard/guidance has or has not been complied with, study endpoint(s), pre-defined pass/fail criteria, deviations, results, discussion and conclusions, and may include data. Complete, detailed support of method selection, worst case justification, study endpoint selection, and pass/fail criteria should be included.

SUMMARY - A summary should include a brief synopsis of the (1) purpose, (2) methods, (3) acceptance criteria, (4) results and (5) discussion and conclusions. Outliers and deviations should be reported with the results. Results should be stated quantitatively with appropriate statistical context where applicable (e.g. value ± SD, confidence intervals, etc.).
The summary should specifically address:

1. Why the characteristic being evaluated is of interest;

2. Why the particular methods are being used to evaluate the characteristic, if applicable including why a regional or harmonized/recognized standard/guidance has or has not been complied with;
3. How the stated acceptance and sample size are scientifically supported;
4. What device was tested and how it relates to the devices that will be marketed;
5. Why the tested components are representative of the range of devices that will be marketed;
6. Whether the summary has been previously submitted and reviewed by the regulator, including identification of the device and the reference number for the submission; and
7. The extent to which the duties and functions of a study (e.g. testing, monitoring, etc) have been conducted by an external organization (e.g. contract research organisation or individual contractor)

HEADING CLASS - Headings are classified as either **IMDRF; IMDRF, RF; or Regional**.

Heading classification is provided in this document to provide an indication of the relevance of any given heading to a particular jurisdiction. The classification matrices provide further requirement classification by jurisdiction and submission type and should be used as the final reference for information of this type.

IMDRF headings are used by most regulators and are therefore considered an IMDRF heading. Content of IMDRF heading contain common elements and may contain regional elements in addition to the common elements.

- **Regional Focus (IMDRF, RF) –** content needs to be considered with the specific region in mind and will likely need to be adapted for that region (e.g. regional approval numbers or regulatory history, regional variation in approved or requested intended use/indications for use)

- In cases where not all regulators use the heading, the applicable jurisdictions are listed following the heading classification **(e.g. IMDRF (USFDA, HC, JP)).**

Regional headings are those that contain no common elements. In this case the heading name is consistent amongst IMDRF members, but the content will be specific and different for each region. Headings are also classified as Regional if they are required by only one jurisdiction.

SUBMISSION – A regulatory submission can be any type of information related to a medical device regulatory process. This includes but is not limited to a request for approval/authorization to market a device, any communications relating to the original submission, and any request for modification to an existing approval. The submission types that will be accepted in the format described in this document will be dictated by regional policy.

NUMBERING OF HEADINGS

Numbering should remain consistent regardless of whether the heading is required or not. For example, if Heading 1.02 is not required for the submission type or jurisdiction, but Headings 1.01 and 1.03 are, then the numbering would remain 1.01 followed by 1.03.

QUALITY MANAGEMENT SYSTEM CHAPTERS (6A & 6B)

Chapter 6A & B of the ToC is written in terms of the quality management system language employed in ISO 13485. **Chapter 6A** is where the company places the standard operating procedures (SOPs) the company utilizes to implement its overall high level quality management system. **Chapter 6B** is where the company places the documents and records the company utilizes to implement the quality management system SOPs described in Chapter 6A.

LANGUAGE REQUIREMENTS

Each jurisdiction has its own language requirements. Regional guidance should be sought to ensure that content is provided in a language that is acceptable for the jurisdiction to which the submission will be submitted. Any translated material submitted should be verified for accuracy.

OTHER GENERAL NOTES

This outline of documentation is to support a smooth documentation process. It remains the applicant's responsibility to ensure all regulatory requirements are met, and that clear and transparent evidence of conformity to these requirements are provided.

Regional regulatory guidance will vary between the IMDRF member regulators and can be found in a variety of locations including the individual regulator's laws, directives, regulations, guidance documents, etc. When any requirements are conflicting between this document and regional documents (e.g. the regional laws, directives, regulations, guidance documents), the regional requirement will take precedence.

For the USFDA and ANVISA, regional regulatory guidance include the categories (1) special controls in a device specific regulation, (2) device-specific guidance document, (3) special controls guidance, (4) special controls guideline, and/or (5) statutory or regulatory criteria.

When submitting to the USFDA please refer to the current version of the following MDUFA IV guidance documents to ensure the content for each heading and the overall electronic format of the submission is sufficient to be accepted for review by the USFDA. For example:

1. Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff
2. Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff
3. eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff

For the EU, the latest EN ISO version and related Annex Z should be taken as reference to verify the correct presumption of conformity with the essential requirement of Medical Devices Directives.

Note: WHO participates as an Official Observer in the IMDRF and its working groups. Recommendations from WHO are based on the experience of Prequalification Team – Diagnostics Assessment, taking the needs of WHO Member States without strong regulatory systems into account.

ACRONYMS

ANVISA	National Health Surveillance Agency – Brazil
CAPA	Corrective Action and Preventive Action
EU	European Union
GMDN	Global Medical Device Nomenclature
HC	Health Canada
HSA	Health Sciences Authority – Singapore
IMDRF	International Medical Device Regulators Forum
JP	Japan
MDUFA	Medical Device User Fee Amendments
NB	Notified Body
NMPA	National Medical Products Administration – China
PMDA	Pharmaceuticals and Medical Devices Agency – Japan
RF	Regional Focus
TGA	Therapeutic Goods Administration – Australia
ToC	Table of Contents
USFDA	United States Food and Drug Administration
WHO PQ	World Health Organization Prequalification Team – Diagnostics Assessment

HIERARCHY PRESENTATION

The following is a hierarchical presentation of the submission structure. More detailed guidance regarding where elements belong is provided following this table.

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3.06.02.08.01	[Study description, study identifier, date of initiation]
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3.06.05.01.01	[Study description, study identifier, date of initiation, date of completion]
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3.06.05.02.01.01	Summary
3.06.05.02.01.02	Full Report
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3.06.05.3.01.03	Statistical Data
3.07	Analytical Performance and Other Evidence Bibliography
3.08	Other Evidence
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4.02.03.01	[Study description, protocol #, date of initiation, date of completion]
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4.02.03.01.02	Clinical Study Report
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6B.08	Purchasing information
6B.09	Production and service controls information
6B.10	Control of monitoring and measuring devices information
6B.11	QMS measurement, analysis and improvement information
6B.12	Other Device Specific Quality Management System Information

CHAPTER 1 – REGIONAL ADMINISTRATIVE

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
1.01	IMDRF, RF	1	Cover Letter	a) The cover letter should state applicant or sponsor name and/or their authorized representative/s, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals. b) If applicable and accepted by the regulator, it should include information pertaining to any Master Files referenced by the submission. c) If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the regulator to view or access the device (when the regulator requests a sample). d) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated. e) If the submission is in response to a request for information from the regulator this should be stated and the date of that letter should be included as well as any reference number(s). f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided. NOTE: The cover letter should not contain any detailed scientific information.	**NMPA** Attached documents should be signed or sealed by applicants and/or authorized representatives. **USFDA PMA and 510(k)** a) mailing address, b) official correspondent(s), c) phone/fax number(s), d) email address(s e) cover letter shall be signed by applicant and an authorized rep (if the applicant does not reside or have a place of business in US) – 21 CFR 814.20(a) **(PMA Only)** f) Device class and panel or classification regulation or statement that the device has not been classified with rationale for that conclusion **(510(k) only)** **TGA** The covering letter of application needs to be prepared on company letterhead and to also include; a) Submission ID that is generated electronically when completing the application form in eBusiness b) Contact details of the person authorised to liaise with TGA during the evaluation process c) Signed by the authorised person for the company
1.02	IMDRF	1	Submission Table of Contents	a) Includes at least level 1 & 2 headings for the entire submission b) Specifies the page number for each item referred to in the table. **NOTE:** Refer to the Pagination Section of this document for information about submission pagination.	
1.03	IMDRF	1	List of Terms/Acronyms	Terms or acronyms used in the submission that require definition, should be defined here.	
1.04	Regional (ANVISA, NMPA, EU, HC, HSA, JP, TGA, USFDA, WHO PQ)	1	Application Form/Administrative Information		**ANVISA** ANVISA´s "Manufacturer or Importer Form" (form available at www.anvisa.gov.br), containing general information related to the application. **NMPA** Application form shall be filled out and submitted on line (http://125.35.24.156/) **EU** Notified Bodies (NBs) will each have their own application form and company information form, including details on the submission type (new, renew, changes), administrative data of the manufacturer, overview of subcontractors and their QMS certification documentation, underlying CE certificates in case of Own Brand labelling, general information of the product, including sterilisation method where applicable, nature of selected starting materials (e.g. drugs, animal tissue), applicable directive and classification. Consult relevant NB N.B. Under EU legislation, the Own Brand Labeller is to be considered as the legal manufacturer and bears the regulatory responsibility of a manufacturer including the need to dispose of the entire

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
				technical documentation (see the EU Guideline on OBL: http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/interpretative_fiche_obl_en.pdf) **HC** Health Canada application forms should be included here. **JP** PMDA's "Application form" – from http://www.pmda.go.jp/ **TGA** Application forms to include administrative data of the applicant, application scope (including applicable conformity assessment procedure and type of application (new, change or recertification)), current certification details, manufacturer details, critical supplier details and device details including classification. Refer to www.tga.gov.au for the most up to date information. **USFDA PMA and 510(k)** CDRH Coversheet Form 3514 **WHO PQ** WHO PQ applications refer to: http://www.who.int/diagnostics_laboratory/evaluations/Application/en/
1.05	IMDRF, RF (ANVISA, NMPA, EU, HC, HSA, TGA, USFDA)	Listing of Device(s)	A table listing each variant/model/configuration/component/accessory that is the subject of the submission and the following information for each: a) the identifier (e.g. bar code, catalogue, model or part number, UDI) b) a statement of its name/description (e.g. Trade name, size, intended use) **NOTE:** i. A model/variant/configuration/component/accessory of a device has common specifications, performance and composition, within limits set by the applicant. ii. Typically each item listed should be available for sale. For example, if everything is sold as part of a kit, then this list would only include the kit. You do not need to list all components that may be sold within a kit/set, unless the component is available for sale independently of the kit. iii. This is classified as RF in recognition that identification numbers may vary from jurisdiction to jurisdiction.	**ANVISA** The grouping (family and systems) of medical devices shall be in compliance with ANVISA´s requirements which specify the conditions to establish family or system of medical devices. **EU** The listing should include the relevant Global Medical Device Nomenclature (GMDN) Code and Term **Russia NOTE:** Any model/variant/configuration of device(s) listed should be limited (covered) by a single Global Medical Device Nomenclature (GMDN) Code and Term. The components within a kit/set can have their own GMDN Codes/Terms. **TGA** For all classes of devices the applicant needs to include: a) The Global Medical Device Nomenclature (GMDN) Code and Term b) The classification and the applicable classification rule For Class 4 IVDs (other than Class 4 Immunohaematology reagents) this table should also identify the following: a) Unique Product Identifiers; and b) any variants (see Regulation 1.6 of the Therapeutic Goods (Medical Devices) Regulations **HSA** The list of devices to be included in an application is to be submitted in an excel sheet format and inclusion of devices should be based on grouping criteria specified in GN-12 guidance document. The excel format "Annex 2 for GN17 and GN18 List of Configurations" is available online at www.hsa.gov.sg

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
1.06	Regional (ANVISA, NMPA, EU, HC, HSA, TGA, WHO PQ)	Quality Management System, Full Quality System or other Regulatory Certificates		**ANVISA** Good Manufacturing Practice Certificate (GMPC) issued by ANVISA, covering the scope of products. NOTES: a) Device registration or amendment request to change/include manufacturer of Class III or IV devices requires a valid GMP Certificate issued by ANVISA. However, submission review may be initiated prior to GMP certification. In these cases, the document proving that the application for the GMP Certification has been submitted to ANVISA should be presented, identifying the manufacturer name, the address of the site to be certified and the identification number of the GMP Cert application to ANVISA. The registration or amendment will only be approved after the GMP certificate has been issued. b) Device registration renewal submissions of Class III or IV devices, also requires a valid GMP Certificate issued by ANVISA. The document proving that the GMP Certification was requested from ANVISA will be accepted if the GMP Certificate has not yet been issued. However, if the final result of the GMP certification process leads to a refusal, the device registration will be canceled. **NMPA** a) Domestic applicant shall provide: i. Copies of business license and organization code certificate. ii. When applying for registration of domestic medical devices according to Special Procedure of Approval and Evaluation for Innovative Medical Devices, applicant shall provide a notice of application for reviewing "Special procedure of approval and evaluation for innovative medical devices", and if the sample products are produced by entrusted manufacturers, manufacturing license of the entrusted manufacturer and consignment agreement shall be provided. The scope of manufacturing license shall cover the category of the submitted products. **EU** EN ISO 13485 certificate in case it is issued by another Notified Body or registrar. CE full quality system certificates (QMS and annex IV.3 IVDD) covering the scope of products when issued by another Notified Body. **HC** This subsection includes a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies CAN/CSA ISO 13485, Medical devices - Quality management systems - Requirements for regulatory purposes. Health Canada will only accept quality system certificates that have been issued by special third party auditing organizations recognized by the Minister in accordance with Section 32.1 of the *Medical Devices Regulations*. **TGA** Copies of any current TGA or other regulatory authority certification referenced within the submission or required for the submission type. The reference certificates requirements will vary based on the submission type, refer to TGA guidance for these requirements. **WHO PQ** Copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies ISO 13485, Medical devices - Quality

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
				management systems - ISO 13485 certificates that are provided must state the scope of products it covers. **HSA** ISO 13485 certificates are to be provided for manufacturing and sterilisation sites of finished devices. For sites without ISO 13485 certification, comparable audit reports for the actual site e.g. US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 can be submitted.
1.07	Regional (ANVISA, NMPA, HSA)	Free Sale Certificate/ Certificate of Marketing authorization		**ANVISA** Provide the document/certificate issued by the Regulatory Authority where the medical device is marketable, attesting that the device is marketable, without any restriction at their jurisdiction. Alternatively, provide a copy of the Inspection Report issued by ANVISA. **NMPA** a) Imported Medical Device applicant shall provide: i. Supporting documents of marketing authorization or certificate of the product issued by authority of the country (or region) where the applicant's headquarter or manufacturing site is located, and the authorization/qualification documents of the enterprise ii. If the product is not managed as a medical device by authority of the country (or region) where the Imported medical device applicant is located, applicant shall provide relevant supporting documents, quantification certificate of manufacturer issued by authority of the country (or region) where the registration office or manufacturing site is located(for registration). b) Applications for extension renewal and change registration shall include: i. Copies of the original registration certificate of medical device and its appendices, and copies of all documents on the change of registration of medical device in China (for). ii. For Imported Medical Device, the relevant documents if the new market clearance issued by the medical device authority of the country (or region) where the overseas applicant's registration office or manufacturing site is located is required for change items; or description if the change items need not to be approved by the medical device authority of the country (or region) where the overseas applicant's registration office or manufacturing site is located. **HSA** Where available, approval letters or certificates of marketing authorisation from our reference regulatory agencies (Health Canada, Japan MHLW, US FDA, TGA, and EU NB) can be submitted.
1.08	Regional (HSA)	Expedited Review Documentation		**HSA** For applications with approvals from HSA's reference regulatory agencies and applying for faster evaluation routes, following information is required: a) Declaration of no safety issues globally (refer to GN-15 for the template) b) Proof of marketing history in the independent reference regulatory agency's jurisdictions i.e. Invoice with date, proof of sale or a declaration on marketing history (refer to GN-15 for the declaration template) Refer to GN-15 available at www.hsa.gov.sg for more information
1.09	Regional (ANVISA, EU, HC, USFDA, WHO PQ)	User Fees		**ANVISA** Receipt of the User Fee payment. Information about User Fee available at: http://portal.anvisa.gov.br/taxas1 **EU**

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
				Signed quote and agreement for dossier review /audits **HC** Health Canada user fee forms should be included here. **USFDA PMA and 510(k)** FDA User Fee Form (https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref=) **WHO PQ** Attestation of fee payment.
1.10	IMDRF, RF	Pre-Submission Correspondence and Previous Regulator Interactions	a) During the product lifecycle, pre-submission correspondence, including teleconferences or meetings, may be held between the regulator and the applicant. Further, the specific subject device may have been subject to previous regulatory submissions to the regulator. The contents should be limited to the subject device as similar devices are addressed in other areas of the submission. If applicable, the following elements should be provided: i. List prior submissions or pre-submissions where regulator feedback was provided ii. For previous regulatory submission, include identification of applicable submission reference number. iii. For any pre-submission activities that have not previously been assigned any tracking/reference number, include the information package that is submitted prior to pre-submission meetings, the meeting agenda, any presentation slides, final meeting minutes, responses to any action items arising from the meetings, and any email correspondence related to specific aspects of the application. iv. Issues identified by the regulator in prior submissions (i.e., clinical study applications, withdrawn/deleted/denied marketing submission) for the subject device v. Issues identified and advice provided by the regulator in pre-submission interactions between the regulator and the applicant/sponsor. vi. Explain how and where the prior advice was addressed within the submission **OR** a) Affirmatively state there has been no prior submissions and/or pre-submission interactions for the specific device that is the subject of the current submission. **NOTE** The scope of this section is limited to the particular regulator to which the submission is being submitted (i.e. Health Canada does not need pre-submission information relating to interactions with ANVISA).	**NMPA** Provide documents when applicable. For example, innovative medical device communication record **EU** a) A statement is required that the product to be reviewed is not under application with another Notified Body, and has not previously been refused or cancelled by another notified body. b) For "borderline products", where applicable, any rationale, supportive documentation and key documentation on communication with an EU Competent Authority and/or COM services, relating to the qualification/classification decision on such product. c) In case of transfer from another Notified Body, that status, including any open Non-conformity, and the associated dossier review reports, the latest audit report and for QMS transfer all audit reports from the existing certification cycle, will need to be submitted along with a letter of access from the new notified body to contact the old notified body to confirm any open issue. This will allow a specific date of transfer of application and CE marking.
1.11	Regional (TGA, USFDA, WHO PQ)	Acceptance for Review Checklist		**USFDA PMA** Complete the checklist and provide section and pages numbers indicating where every item on the check is addressed in the submission. See Appendix A of the ***Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance*** **USFDA 510(k)**

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					Complete the checklist by answering the preliminary questions and providing the pages numbers indicating the locations of each item on the check is addressed in the submission See the Acceptance Checklist for Traditional 510(k)s in ***Refuse to Accept Policy for 510(k)s : Guidance for Industry and Food and Drug Administration Staff*** **TGA** Includes the Supporting data checklists **WHO PQ** WHO requests submission of a Product Dossier Checklist to be completed by the manufacturer which provides dossier sections and page numbers indicating where every item on the checklist is addressed in the submission. Refer http://www.who.int/diagnostics_laboratory/evaluations/140701_pqdx_049_dossier_checklist_v2.pdf?ua=1 NOTE: This provides the reviewer with a quick guide to where evidence for one requirement may be found throughout the dossier.
1.12	Regional (ANVISA, HC, EU, TGA, USFDA)	1	Statements/Certifications/Declarations of Conformity	NO CONTENT AT THIS LEVEL	NO CONTENT AT THIS LEVEL
1.12.01	Regional (USFDA)	2	Performance and Voluntary Standard		**USFDA** **Note to RPS Team:** USFDA wants this information displayed here in the admin section but will request it in Chapter 3 where standards information other IMDRF members request (List of Standards)
1.12.02	Regional (USFDA)	2	Environmental Assessment		**USFDA PMA** a) If claiming categorical exclusion, information to justify the exclusion **OR** b) Provide the environmental assessment (only required for devices that present new environmental concerns
1.12.03	Regional (USFDA)	2	Clinical Trial Certifications		**USFDA PMA and 510(k)** a) Certification of Compliance with Requirements of ClinicalTrials.gov (Form FDA 3674) b) Financial Certification or Disclosure Statement (Form FDA 3454 and Form FDA 3455)
1.12.04	Regional (USFDA)	2	Indications for Use Statement with Rx and/or OTC designation Enclosure		**USFDA 510(k)** A suggested format for enclosure can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080276.htm
1.12.05	Regional (ANVISA, NMPA, HC, TGA, USFDA, WHO PQ)	2	Truthful and Accurate Statement		**ANVISA** a) A declaration (per text below), dated and signed by the legal representative and technical manager of the company: "We declare that the information provided at this submission are truthful and accurate, and can be proven by documental evidence. We also declare that: i. The device will be marketed observing all requirements established by the Brazilian Legislation; ii. The labelling (e.g. labels, instructions of use, promotional material) of the device complies with the Brazilian regulatory requirements, and will be maintained up to date during all the period that it will be available on the Brazilian market;

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				iii. The device and accessories that accompany the device were designed and are manufactured attending the Essential Requirements of Safety and Efficacy and the Good Manufacturing Practices established by ANVISA; iv. All the reasonably foreseeable risks were identified and promptly mitigated. The residual risk is acceptable in relation to the benefits obtained by the use of the devices; v. The devices delivered to the market will be continuously monitored in order to identify new risks that have not been already addressed, according to the Risk Management Plan established by the manufacturer. The company is aware that if the Brazilian regulatory requirements were not fulfilled, administrative sanctions established on federal law (Lei nº 6437/1977) shall be applied. The legal representative and technical manager of the company are aware that they are answerable to the court by any infraction indicated on art. 273 – Decreto Lei nº 2848/1940 (Criminal Code – Chapter III: Crime against Public Health)." **NMPA** The self-assurance declaration of the authenticity of submitted data (the ones of domestic products shal be issued by applicants and the ones of imported products shall be issued respectively by applications and agents.) **HC** Attestation that statements in the application are true and that the information provided in this application and in any attached documentation is accurate and complete. Consult current Health Canada guidance for specific language. **TGA Conformity Assessment - Manufacturer's statutory declaration** a) A statutory declaration is a written statement allowing a person to declare something to be true. The declaration is signed in the presence of a witness. Giving false or misleading information as part of a statutory declaration is a criminal offence under the Criminal Code. http://www.tga.gov.au/industry/manuf-statutory-declarations.htm#forms Statements of undertaking by the manufacturer as required by conformity assessment procedures set in the Therapeutic Goods (Medical Devices) Regulations 2002 **USFDA 510(k)** a) Truthful and Accurate statement per 21 CFR 807.97(k). Text: *I certify that, in my capacity as (the position held in company) of (company name), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.* **NOTE:** Signed by a responsible person of the firm (not a consultant) **WHO PQ** a) A signed Manufacturer Declaration WHO Document PQDx_049 "Product Dossier Checklist" attesting that all the information provided in this product dossier is current and correct. b) A letter attesting that the content of the electronic version is an exact duplicate of the printed copy.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
1.12.06	IMDRF (NMPA, EU, HSA, JP, TGA)	2	Declaration of Conformity	As part of the conformity assessment procedures, the manufacturer of a medical device is required to make a Declaration of Conformity that declares that the device complies with: a) the applicable provisions of the Essential Principles/Requirements b) the classification rules c) an appropriate conformity assessment procedure	**NMPA** A declaration that : a) The products conforms to the requirements of Administrative Measures on the Registration of IVD Reagents and relevant laws and regulations; b) the product classification conforms to the requirements of Administrative Measures on the Registration of IVD Reagents and Categorized Subdirectories of IVD Reagents; **JP** Declaration and/or certificate that the relevant product is manufactured to conform to the essential principles and/or the quality management system. **NOTE:** The applicant is advised to prepare the declaration of conformity according to ISO 17050-1 "Conformity Assessment - Supplier's Declaration of Conformity - Part 1: General Requirement." **TGA** The wording of the Declaration of Conformity will depend on the conformity assessment procedure chosen by the manufacturer. Templates for each of the four possible types of Declarations of Conformity under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 are available at <http://www.tga.gov.au>. **HSA** There is an online declaration of conformity to safety, quality and efficacy requirements that every applicant submits on our MEDICS online system at the point of submission of the application. In addition, the Singapore Declaration of Conformity – refer to GN-11 available at www.hsa.gov.sg, is to be submitted. Alternatively, the Declaration of Conformity for the devices with marketing authorisation from reference regulatory agencies (e.g. EC DoC) can be submitted.
1.13	IMDRF	1	Letters of Reference for Master Files	Letter from any Master File owner granting access to the information in the master file. The letter should specify the scope of access granted.	
1.14	Regional (ANVISA, NMPA, HSA)	1	Letter of Authorization		**ANVISA** Letter issued by the manufacturer allowing the importer to submit the application to ANVISA on his behalf, and to market his product on the Brazilian market. **NMPA** a) Evidence of power of attorney of the foreign applicant for designating agent in China. b) Copies of the letter of commitment and business license or copy of organization registration certificate of agent. **HSA** Letter of Authorisation of Registrant by the Product Owner for all the products to be registered, using the latest template as per GN-15 Letter of Authorisation template – available at www.hsa.gov.sg **HSA NOTE:** Registrant refers to a Singapore-based company that is registered with the Accounting and Corporate Regulatory Authority (ACRA) of Singapore and Product owner refers to the legal manufacturer of the device.
1.15	IMDRF	1	Other Regional Administrative Information	Heading for other administrative information that may be important to the submission but that does not fit in any of the other headings of this chapter.	

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			NOTE: To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.	

CHAPTER 2 – SUBMISSION CONTEXT

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
2.01	IMDRF	1	Chapter Table of Contents	a) Includes all headings and sub-headings for the chapter. b) Specifies the page number for each item referred to in the table.	
2.02	IMDRF, RF	1	General Summary of Submission	a) Statement of the device type (e.g. Tacrolimus test system, blood specimen collection device, calibrator) and name (e.g. trade name, proprietary name), its general purpose, and a high-level summary of key supporting evidence (i.e. studies that are unique to the risks of this device type). b) Summary of submission, including i. The type of submission (e.g. new, amendment, change of existing application, renewal); ii. if amendment/supplement, the reason of the amendment/supplement; iii. if a change to existing approval, description of the change requested (e.g., changes in design, performance, indications, changes to manufacturing processes, manufacturing facilities, suppliers); iv. any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission).	**ANVISA:** If renewal, amendment or change, identification of the registration/notification number issued by ANVISA for the device, family, system or set of devices and the number of the original application must be informed. **NMPA** a) If product registration, the applicant shall describe the management category, criteria for determining the classification code b) If registration extension, the applicant shall provide the statement that no changes are made to the product. **EU** If renewal, amendment or change, identification of product (family) currently Marketed under CE mark and related certificate of IVDD annex. **HC** If amendment or new submission based on currently licenced device(s), the Canadian Medical Device Licence Number(s) and application numbers should be provided along with the description of the change requested. **TGA** If recertification or change to a conformity assessment certificate, identification of the affected TGA certificate numbers must be detailed. **USFDA 510(k)** Executive Summary **HSA** Executive summary as per GN-18 available at www.hsa.gov.sg
2.03	Regional (USFDA)	1	Summary and Certifications for Premarket Submissions		**USFDA PMA** a) Summary of the Content of the Whole PMA per 21 CFR 814.20(b)(3) **USFDA 510(k)** a) 510(k) Summary contains all elements per 21 CFR 807.92 **OR** b) 510(k) Statement contains all elements per 21 CFR 807.93
2.04	IMDRF	1	Device Description	**NO CONTENT AT THIS LEVEL**	
2.04.01	IMDRF, RF	2	Comprehensive Device Description and Principle of Operation	a) A general description of the device, including: i. The device name. ii. What does it do? iii. Who uses it and for what? (high level statement) iv. Where to use it? (places/environment where the device is intended to be used)	**ANVISA:** a) Some accessories may request independent submission at ANVISA. Especially when it is considered a medical device by itself and is not of exclusive use of the medical device to be used in combination. For this accessories shall be identified and heir registration/notification number in ANVISA provided.

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			v. General description of the principle of the assay method or instrument principles of operation. vi. Description of the components (e.g. reagents, assay controls, calibrators, cassette, etc.) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers, probes, etc.). vii. If applicable, labelled pictorial representation (diagrams, photos, drawings). viii. If system, how the components relate? ix. If applicable, identify if the device incorporates software/firmware and its role. x. If applicable, identify the instrument(s) required to perform the test. b) Product specification, including: i. Physical characteristics of relevance to the end user (dimensions, weight) ii. If applicable, technical features and operating modes iii. If applicable, operating specifications and performance characteristics (e.g. electrical power requirements, settings and associated allowable ranges/limits, units of measure, temperature and humidity limits, throughput (number of tests per hour), analytical and clinical sensitivity and specificity) iv. If applicable, a complete list of the configurations/models of the devices and a summary of the differences in specifications-(comparison table and/or pictures/diagrams with supporting text). c) Describe the different specimen types that can be used for this device (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant). d) Describe the use of controls. If applicable, a list of compatible control materials or control material specifications. e) Description of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device. f) If approved by the regulator, provide the approval number and identification for each of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device. g) If applicable, indication of biological material or derivate used in the medical device, including: origin (human, animal, recombinant or fermentation products or any other biological material) and source (e.g. blood, bone, heart, any other tissue or cells). Where a significant risk is identified, a brief summary of evaluations performed to minimize biological risks, in particular, with regard to viruses and other transmissible agents. h) If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action. i) Description of the collection and/or transport container(s) provided with the IVD medical device or a description of specifications or recommended collection and/or transport container(s). j) If applicable, a listing of assays that are compatible with the instrument. k) If applicable, a listing of compatible instruments. l) A list of any software to be used with the IVD medical device and a description of its role in the delivery of the intended purpose. m) If applicable, engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission). n)	**NMPA** Describe the preparation methods of quality control products and calibrators. **HC and USFDA** Components or accessories that can be sold separately should be identified. **JP:** Explain that the established product specifications are necessary and sufficient to ensure the efficacy, safety, and quality of the product. **USFDA PMA:** Color Additive information per item A 6.a.ii in Appendix A of the ***Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance***; 21CFR 814.20(f) **WHO PQ** a) With respect to **item a) vii.,** WHO PQ requires photographs of all kit components (packaged and individually). Not optional. b) With respect to biological safety (**item h**)), WHO PQ requires the following additional information: i. Details of the use of the biological component in the product ii. A description of steps taken for the reduction of transmission or infection risk iii. A determination of the residual risk of transmission or infection to the user of the device from these biological agents after risk reduction methods have been applied. If there are no such methods that apply to the product, state that this is the case. iv. Information on how users of the device are informed of any residual risk

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				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device.	
2.04.02	IMDRF (HC, HSA, JP)	2	Material Specifications	**HC and JP** a) Details of relevant material identifications and specifications, including critical raw materials and components should be provided. Information should include complete chemical and physical characterization of all component materials. **NOTE:** If applicable, chemicals should be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description.	**HSA** a) All components of the IVD medical device should be listed and chemically and biologically characterised, including antibodies, antigens, assay controls, substrates used to detect antigen-antibody complexes, and test reagents. Appropriate references should be cited. b) If synthetic peptides are used, the peptide sequence should be provided. c) If applicable, information is to be provided on irradiating components, non-ionizing or ionizing. d) if applicable, information to be provided on the poison or controlled substance (e.g. Buprenorphine in drug assay kit)
2.04.03	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA) WHO PQ	2	Description of Device Packaging	a) A brief description of the packaging of the devices, including the packaging configuration and materials involved. This is not intended to include shipping/transport packaging. b) Specific packaging of accessories marketed together with the IVD medical devices shall also be described.	
2.04.04	IMDRF (ANVISA, EU, HC, TGA, USFDA, WHO PQ)	2	History of Development	For any device versions/prototypes referenced in the evidence presented in the submission, a table describing the version/name, with 4 columns (Device Name and/or Version; Description of changes from previous row; motivation for the change; list of verification/validation activities, including clinical studies, conducted using this version). For any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and performance of the final IVD medical device design.	**USFDA 510(k)** It is highly recommended that the following be provided for a device that has received prior 510(k) clearance: either a description of all changes made to the device since the last 510(k) clearance. **WHO PQ** Provision of the date of design lock down. This is considered to the date that final documentation is signed off, including quality control and quality assurance specifications, and finalized method in the IFU.
2.04.05	IMDRF, RF	2	Reference and Comparison to Similar and/or Previous Generations of the Device	a) A list of the similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This should include any similar/previous generation devices that were previously reviewed and refused by the subject regulator. b) Description of why they were selected. c) A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device.	**HC** a) If the application is an amendment to a licenced device or is based on a modification of a licensed device, a description of the modifications is required (e.g., changes in design, performance, and indications). b) Comparisons can be used to support the safety and effectiveness of the device if they are made to a currently licensed device in Canada. If this method is used, ensure the Canadian Medical Device Licence Number of the comparator is stated. The comparison device does not need to be manufactured by the same manufacturer. **HSA** If applicable, comparisons can be used to support the safety and effectiveness of the subject device. For similar devices previously reviewed by HSA, provide the MEDICS online application number of the previous submission or Singapore Medical Device Register (SMDR) device registration number.
2.04.06	Regional (USFDA)	2	Substantial Equivalence Discussion		**USFDA 510(k)** a) Identify the predicate device(s) i. 510(k) number, trade name and model number

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					ii. Ensure the identified predicate device(s) is consistent throughout the submission (i.e., Substantial Equivalence discussion are the same as listed in the 510(k) summary and the same as those used in comparative performance testing). b) Include a comparison of indications for use and the technology (including features materials and principles of operation) between the predicate device(s) and subject device(s). c) Include an analysis of why any differences between the subject device(s) and the predicate device(s do not render the subject device(s) Not Substantially Equivalent, affect safety or effectiveness or raise different questions of safety and effectiveness.
2.05	IMDRF	1	Indications for Use and/or Intended Use	**NO CONTENT AT THIS LEVEL**	
2.05.01	IMDRF, RF	2	Intended Use; Intended Purpose; Intended User; Indications for Use	This section should include, **as appropriate:** a) **Intended Use:** The statement of intended use should specify what specific disorder, condition, or risk factor of interest (i.e. the analyte to be measured) is detected and the purpose provided by the device (e.g. screening, monitoring, diagnosis or aid to diagnosis). It should identify: i. Instruments on which the device can be used, ii. if the assay is automated or not, iii. is the IVD medical device qualitative or quantitative, iv. and the specimen types (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant) b) **Intended user:** Lay person or professional? c) Identify if the device is intended for **single or multiple use** d) **Indications for Use:** i. Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use. ii. If applicable, information about patient selection criteria. iii. If applicable, when/where the use of the IVD medical device should be avoided. iv. If applicable, information about intended patient population (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended. e) For amendments/supplements or changes to existing approvals, identify any changes to the previously approved intended use/intended purpose/intended user/indications. If there are no changes, this should be stated and a reference should be made to the precise regional regulatory tracking number associated with the previous submission/approval. **NOTES:** i. The statements of intended use and indications for use must be **as presented in the labelling**. ii. If more than one device is included, the information should be provided for each device	**USFDA** a) For Intended Use/Indication for Use see 21 CFR 809.10 **HC NOTE** The content of this section should be contained in a single body of text.
2.05.02	IMDRF, RF (ANVISA, EU, HC, HSA, TGA, USFDA)	2	Intended Environment/Setting for use	a) The setting where the device is intended to be used (e.g. home use, domestic use, self-testing, near-patient, point of care). Multiple options can be indicated. b) If applicable, environmental conditions that can affect the device's safety and/or performance (e.g. temperature, humidity, power, pressure, movement).	**USFDA PMA and 510(k)** FDA includes this information in the indications for use and product labelling

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2.05.03	Regional (USFDA)	2	Pediatric Use		**USFDA PMA** a) Description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure, b) The number of affected pediatric patients, as a whole and within each pediatric subpopulation. **OR** c) Statement that no pediatric subpopulation exists for the disease or condition for which the device is intended.
2.05.04	Regional (USFDA)	2	Contraindications for Use	If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile. **NOTE:** The statement if contraindications for the device must be as presented in the labelling.	**USFDA PMA and 510(k)** FDA includes this information in the indications for use and product labelling
2.06	IMDRF	1	Global Market History	**NO CONTENT AT THIS LEVEL**	
2.06.01	IMDRF	2	Global Market History	a) Up to date indication of the markets (all countries or jurisdictions) where the device is already marketed, including any marketing under compassionate use regulations. b) Should include history of the marketing of the device by any other entity in as much detail as possible, acknowledging that detailed information may not be available in all cases. c) If the subject device is different in any way (e.g. design, labelling, specifications) from those approved or marketed in other jurisdiction, the differences should be described. d) The month and year of market introduction in each country or jurisdiction where the device is marketed. If the device has been marketed for greater than 10 years, a statement of greater than 10 years can be made. e) For each of the markets listed in (a) above, and statement of the commercial names used in those markets OR a clear statement that the commercial names are the same in all jurisdictions. f) State the date of data capture for the market history data g) If the subject device has been the subject of any previous compassionate use and/or clinical studies this should be identified and, if applicable, relevant reference numbers provided.	**ANVISA and HC:** If there is any approval number, given to the device by the regulator authority of the markets (country or jurisdictions) where the device is already marketed, this identification must be informed. **EU** The commercial names used by the Original Equipment Manufacturer in case of Own Brand Labelling should be identified. **HC** a) If applicable, market history should include data for previous generations of the device. b) Information regarding any Canadian Investigational Testing Authorizations should be included. **HC NOTE:** In this context, compassionate use includes **any** Special Access Authorizations. **TGA** Any notifications to foreign regulators of substantial change to the device
2.06.02	IMDRF, RF	2	Global Incident Reports and Recalls	a) List adverse events/incidents associated with the device and a statement of the period associated with this data. b) If the number of events is voluminous, provide a summary by event type that state the number of reported events for each event type. c) List of the IVD medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case. d) A description of any analysis and/or corrective actions undertaken in response to items listed above. e) If there have been no adverse events/incidents, recalls and/or advisory notice to date, provide an attestation from device owner on company letterhead, that there have been no adverse events/incidents, recalls and/or advisory notice since commercial introduction of the device. **NOTES** i. It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF).	**USFDA 510(k) NOTE** Include when submitting a 510(k) to implement a design change to address a recall of a device in the US **HSA** a) If there is an ongoing adverse event or field safety corrective action for the medical device that has been reported to HSA, provide the HSA reference number.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
2.06.03	IMDRF, RF (HC, EU, HSA, JP, TGA)	2	Sales, Incident and Recall Rates	a) A summary of the number of units sold in each country/region and a statement of the period associated with this data. b) Provide the rates calculated as follows for each country/region: i. Incident rate = # adverse events/incidents divided by # units sold expressed as a percentage ii. Recall rate = # recalls divided by # units sold expressed as a percentage Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported. c) Critical analyses of the rates calculated (e.g. Why are they acceptable? How do they break down in terms of incidents? Is there some outlier data that has driven the rates up? Are there any trends associated with any sub-groups of the devices that are subject of the submission (e.g. size, version)?). **NOTES** i. It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF). ii. Sales in this context should be reported as the number of units sold.	
2.06.04	Regional (TGA, WHO PQ)	2	Evaluation/Inspection Reports		**TGA** Copies of Evaluation/Inspection Reports from other parties (e.g. Notified Body inspection reports). **WHO PQ** Copies of the last 2 Evaluation/Inspection Reports from other parties (e.g. Notified Body inspection reports, MDSAP).
2.07	IMDRF	1	Other Submission Context Information	Heading for other submission context information that may be important to the submission but that does not fit in any of the other headings of this chapter. **NOTE:** To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.	

CHAPTER 3 – ANALYTICAL PERFORMANCE AND OTHER EVIDENCE

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
3.01	IMDRF	1	Chapter Table of Contents	a) Includes major headings for the chapter, to the level of the custom headings. b) Specifies the page number for each item referred to in the table.	
3.02	IMDRF	1	Risk Management	a) A summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. The summary should address i. Possible hazards for the IVD medical device for example, the risk from false positive or false negative results and the risk of delays in availability of results ii. Indirect risks which may result from IVD medical device-associated hazards, for example, risk associated with instability, which could lead to erroneous results **or** user-related hazards, such as reagents containing infectious agents. b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits. c) Where a standard is followed, identify the standard.	**EU** A formal signed statement accepting the residual risk upon completing the risk-benefit analysis before placing product on the EU market. **WHO PQ** In addition, WHO PQ requires evidence that the risk analysis is part of the manufacturer's risk management plan.
3.03	IMDRF (ANVISA, NMPA, EU, HSA, JP, TGA, WHO PQ)	1	Essential Principles (EP) Checklist	a) An EP checklist established for the IVD medical devices, information about method(s) used to demonstrate conformity with each EP that applies, references for the method adopted and identification of the controlled document with evidence of conformity with each method used. b) For the controlled documents indicated which are required for inclusion in the submission: a cross-reference of the location of such evidence within the submission. c) If any EP indicated in the checklist does not apply to the device: a documented rationale of the non-application of each EP that does not apply. **NOTE:** Methods used to demonstrate conformity may include one or more of the following: a) conformity with recognised or other standards; b) conformity with a commonly accepted industry test method(s); c) conformity with an in-house test method(s); d) the evaluation of pre-clinical and clinical evidence; e) comparison to a similar device already available on the market.	**HSA NOTE** The checklist of conformity to the Singapore Essential Principles is to be submitted – refer to GN-16 available at www.hsa.gov.sg. Alternatively, the checklist to EU General Safety and Performance Requirements or Australian Essential Requirements can be submitted.
3.04	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	1	Standards	**NO CONTENT AT THIS LEVEL**	
3.04.01	IMDRF, RF (ANVISA, NMPA, EU, HC, HSA, TGA, USFDA)	2	List of Standards and Guidance Documents	This section should include: a) If applicable, a list the standards that have been complied with in full or in part in the design and/or manufacture of the device. i. At a minimum should include the standard organization, standard number, standard title, year/version, and if full or partial compliance. ii. If partial compliance, a list the sections of standard that • Are not applicable to the device, and/or • have been adapted, and/or • were deviated from for other reasons – discussion to accompany b) If applicable, a list of relevant guidance documents published by regulators and referenced in the design and/or manufacture of the device with the jurisdiction of publication, publication date and title identified. c) If applicable, a list of relevant clinical guidelines referenced in the design and/or manufacture of the device, the publisher, publication date and title identified.	**EU NOTE** An overview of used standards typically is added in the essential requirements checklist, including rationales for using standards that are non-harmonised or complied with only in part. This information needs only to be presented once in the application. **TGA** This list should include any medical device standard or conformity assessment standard that has been applied to the device; and, if no medical device standard or conformity assessment standard, or part only of such a standard, has been applied to the device — the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles. The information in this section may be presented in the Essential Principle Checklist and, if so, needs only to be presented once in the application. **USFDA PMA and 510(k)**

					If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) **HSA NOTE** The list of standards complied to can be submitted together with the Essential Principles Checklist. This information needs only to be presented once.
3.04.02	Regional (ANVISA, NMPA,HC, USFDA)	2	Declaration and/or Certification of Conformity		**NMPA** A declaration that the product complies with the current national standards, industrial standards. **ANVISA** IVDs for blood bank screening requires pre-submission analyses conducted by an official laboratory (INCQS/FioCruz – Instituto Nacional de Controle de Qualidade em Saúde) in Brazil. The reports of these analyses shall be part of the submission. **HC** The applicant is advised to prepare the Declaration of Conformity to recognized standards using Health Canada's Declaration of Conformity form. Refer to the Guidance Document: Recognition and Use of Standards under the Medical Devices Regulations and the current list of recognized standards for medical devices. **USFDA** Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards,
3.05	IMDRF	1	Analytical Performance	**NO CONTENT AT THIS LEVEL**	
3.05.01	IMDRF	2	Stability of Specimen(s)	Information regarding and studies to support the stability, storage and where appropriate, transport, of all of the specimen type(s) identified in the labelling, including any and all recommended additives (e.g. anticoagulants) is to be provided in this section. This should include: a) For each specimen type identified in the labelling, a description of the recommended storage parameters and when applicable, transport conditions (e.g. duration, temperatures and freeze/thaw cycles). b) A justification on the selection of the studies performed. c) Provide summary of the evidence that falls within this category d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A discussion of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject device	
3.05.01.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Level 3: Storage of serum samples for 7 days at 2-8°C or 4 days at -20°C. Level 4: Summary	

				Level 4: Full Report Level 3: Validation of 3 freeze/thaw cycles for serum samples Level 4: Summary Level 4: Full Report	
3.05.01.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.01.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.01.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.02	IMDRF	2	Validation of Specimens	Studies to support the validity of specimen type(s) used in the analytical and clinical studies as representative of all of the sample type(s) identified in the labelling, including any and all recommended additives (e.g. anticoagulants), as well as contrived specimens used in certain analytical studies are to be included in this section. This should include: a) A list of the specimen type(s) used, including any additives (e.g. anticoagulants), in each of the analytical performance studies. If the same specimens are used for all analytical studies this can be stated and the specimen type identified. b) For any or all of the analytical and clinical studies, if a particular specimen type(s) including additives (e.g. anticoagulants), has been chosen as representative of other specimen types identified in the labelling, this should be described and supported. c) If the preparation of the specimen has not followed the protocol described in the current labelling, this should be identified and validated. d) A justification of the selection of the studies performed. e) Provide summary of the evidence that falls within this category f) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** g) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device	**WHO PQ** In addition, information should be provided on the relationship of specimens collected by different methods. (Note: this applies, for example, to specimens that can be collected by a swab or by other means).
3.05.02.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.02.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.02.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)**

					If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.02.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.03	IMDRF	2	Metrological traceability of calibrator and control material values	Evidence that support the metrological traceability of values assigned to calibrators and trueness control materials. This should include: a) A description of all calibrators and trueness control materials associated with the system. b) A justification of the selection of the studies performed. c) Provide summary of the evidence that falls within this category, including for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation. d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of study is not applicable to this case. **NOTES:** i. Precision control materials used during analytical studies to establish the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	**EU** Where applicable, the accreditation status of laboratories used in physical and mechanical testing.
3.05.03.01	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.03.01.01	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.03.01.02	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.03.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is**

					advised to contact the specific review division for further guidance on the specific data format that is preferred. **NOTE: Do not place PDFs here.**
3.05.04	IMDRF	2	Accuracy of Measurement	**NO CONTENT AT THIS LEVEL** **NOTE:** The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness. While measurement **trueness**, affected by systematic error, is normally expressed in terms of bias, measurement **precision**, affected by random error, is naturally expressed in terms of standard deviation. Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement.	
3.05.04.01	IMDRF	3	Trueness	This section should provide a summary of information and evidence relating to the trueness of the measurement procedure. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. This should include: a) A rationale for the reference standard or method(s) used b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	**NMPA NOTE** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted. **USFDA 510(k)** This is equivalent to a "method comparison study"; 510(k)s can compare to a reference standard OR a predicate device. **JP** Provide comparison studies, if it is investigated by non-clinical samples.
3.05.04.01.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.04.01.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.04.01.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.04.01.01.03	Regional (USFDA)	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.04.02	IMDRF	3	Precision (Repeatability and Reproducibility)	A summary of evidence that support the precision characteristics of the measurement of the subject IVD medical device is to be included in this section. This should include: a) A justification of the selection of the studies performed.	**NMPA NOTE** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted.

				b) A summary of the evidence that falls within this category, including: i. Repeatability estimates and a brief summary about the studies used to estimate, as appropriate, within-run variability. ii. Reproducibility estimates and a brief summary of the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators (intended users) and instruments. Such variability is also known as **"Intermediate Precision".** c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** i. Studies should include the use of specimens that represent the full range of expected analyte (measured) concentrations that can be measured by the product, as claimed by the manufacturer. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device.	
3.05.04.02.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.04.02.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.04.02.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	
3.05.04.02.01.03	Regional (USFDA)	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here**.
3.05.05	IMDRF	2	Analytical Sensitivity	Evidence that support the analytical sensitivity of the subject IVD medical device is to be included in this section. This may include studies to establish the limit of blank (LoB), limit of detection (LoD), and/or limit of quantitation (LoQ). This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	**NMPA NOTE** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted. **EU** Where applicable, the accreditation status of laboratories used in physical and mechanical testing.

3.05.05.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.05.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.05.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.05.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here**.
3.05.06	IMDRF	2	Analytic Specificity	Evidence that support the analytical specificity (interference, including as appropriate, selectivity, and cross reactivity) of the subject IVD medical device is to be included in this section. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	**NMPA NOTE** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted. **EU** Where applicable, the accreditation status of laboratories used in physical and mechanical testing.
3.05.06.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.06.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.06.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.06.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.**

					NOTE: Do not place PDFs here.
3.05.07	IMDRF	2	High Dose Hook Effect	Evidence that supports the absence of a high dose hook effect or prozone effect. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	
3.05.07.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.07.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.07.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.07.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.08	IMDRF	2	Measuring Range of the Assay	Evidence that support the measuring range (linear and non-linear measuring systems). This measuring range should include the lower limit of quantification. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	**NMPA NOTE** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted. **EU** Where applicable, the accreditation status of laboratories used in physical and mechanical testing.
3.05.08.01	IMDRF	3	[Study description, study identifier, date	**NO CONTENT AT THIS LEVEL**	

			of initiation, date of completion]	This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.08.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.08.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.08.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.09	IMDRF	2	Validation of Assay Cut-off	Evidence that support the determining assay cut-off is to be included here. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	**EU** Where applicable, the accreditation status of laboratories used in physical and mechanical testing.
3.05.09.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.09.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.09.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.09.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**

3.05.10	IMDRF	2	Validation of the Assay Procedure	This section should provide a summary of information and evidence supporting the validity of the assay procedure in terms of important reaction conditions (e.g. reaction time, reaction temperature, reagent volume, reading time). This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	
3.05.10.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.10.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.10.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	
3.05.10.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.06	IMDRF	1	Other Studies	**NO CONTENT AT THIS LEVEL**	
3.06.01	IMDRF (ANVISA, NMPA, EU, HC, HSA, TGA, USFDA)	2	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be included in this section. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device	
3.06.01.01	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.06.01.01.01	IMDRF (ANVISA,	4	Summary	A summary of the specific study described in the custom heading above.	

	EU, HC, HSA, TGA, USFDA)				
3.06.01.01.02	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.06.01.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.06.02	IMDRF	2	Software/Firmware	**NO CONTENT AT THIS LEVEL** Studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished IVD medical device, are to be included in this section and the associated sub-sections. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling	
3.06.02.01	IMDRF	3	Software/Firmware Description	a) Specify the name of the software b) Specify the version of the software - The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided. c) Provide a description of the software including the identification of the IVD medical device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of Off-the-shelf software (if applicable), a description of the realization process. d) Provide a statement about software version naming rules; specify all fields and their meanings.	**USFDA 510(k) and HC** Identify the level of concern (minor, moderate, major) and include a description of the rationale for that level. **USFDA NOTE:** For guidance on what specific software documentation to submit, refer to the Guidance For industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
3.06.02.02	IMDRF	3	Hazard Analysis	The Hazard Analysis should take into account all device hazards associated with the IVD medical device's intended use, including both hardware and software hazards. **NOTE:** i. This document can be in the form of an extract of the software-related items from a comprehensive risk management documentation, described in ISO 14971. ii. Hazard analysis, should address all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the IVD medical device.	
3.06.02.03	IMDRF	3	Software Requirement Specification	The Software Requirements Specification (SRS) documents the requirements for the software. This typically includes functional, performance, interface, design, developmental, and other requirements for the software. In effect, this document describes what the Software Device is supposed to do. For example, hardware requirements, programming language requirement, interface requirements, performance and functional requirements,	
3.06.02.04	IMDRF	3	Architecture Design Chart	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	
3.06.02.05	IMDRF	3	Software Design Specification	The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. The SDS describes how the requirements in the SRS are implemented.	

3.06.02.06	IMDRF	3	Traceability Analysis	A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.	
3.06.02.07	IMDRF	3	Software Life Cycle Process Description	A summary describing the software development life cycle and the processes that are in place to manage the various life cycle activities.	
3.06.02.08	IMDRF	3	Software Verification and Validation	This heading should include: a) An overview of all verification, validation and testing performed prior to final release b) For each test presented, identify the testing environment (e.g. in-house, in a simulated or actual user environment). c) Discussion to support why the evidence presented is sufficient to support the application **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE** i. Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject IVD medical device	
3.06.02.08.01	IMDRF	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.06.02.08.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.06.02.08.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.06.02.08.01.03	Regional (USFDA)	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.06.02.09	IMDRF	3	Revision Level History	Revision history log, including release version number and date.	
3.06.02.10	IMDRF	3	Unresolved Anomalies (Bugs or Defects)	All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and performance, and any plans for correction of the problems).	
3.06.02.11	IMDRF (USFDA, HC, HSA)	3	Cybersecurity	Evidence to support the cybersecurity should be provided here. For example, but not limited to: a) Cybersecurity vulnerabilities and risks analysis b) Cybersecurity controls measures	**USFDA** Guidance for Industry and Staff – "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"

				c) Traceability matrix linking cybersecurity controls to the cybersecurity vulnerabilities and risks	
3.06.02.12	IMDRF (USFDA, HC, HSA)	3	Interoperability	If the IVD medical device can communicate with other devices. Evidence to support the interoperability should be provided.	**USFDA** Guidance for Industry and Staff – "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices"
3.06.03	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	2	Cleaning and Disinfection Validation	Contains information on the validation of cleaning and disinfection instructions for reusable devices, including evidence to support maintenance of performance when subject to this procedure over a number of cycles that is representative of the IVD medical device's expected useful life. Information to be included in this section includes: a) If applicable, a discussion of how the number of cycles that is representative of the IVD medical device's expected useful life has been determined. b) A justification of the selection of the studies performed. c) A summary of the evidence that falls within this category d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of laboratory study is not applicable to this case. **NOTES:** i. This applies most typically to devices intended for Point of care and/or home use (near patient testing) involving whole blood. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	
3.06.3.01	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.06.3.01.01	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	4	Summary	A summary of the specific study described in the custom heading above.	
3.06.3.01.02	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.06.3.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.06.04	IMDRF	2	Usability/Human Factors	Studies specifically assessing the instructions and/or IVD medical device design in terms of impact of human behavior, abilities, limitations, and other characteristics on the ability of	

				the IVD medical device to perform as intended should be included here. This should include: a) State the test environment and relation to the intended use environment b) A justification of the selection of the studies performed. c) A summary of the evidence that falls within this category d) A discussion and conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of laboratory study is not applicable to this case. **NOTES:** i. If a clinical study has been conducted that includes usability/human factors endpoints, **reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4 – Clinical Evidence.** ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	
3.06.04.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.06.04.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.06.04.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.06.04.01.03	Regional (USFDA)	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.06.05	IMDRF	2	Stability of the IVD	**NO CONTENT AT THIS LEVEL**	
3.06.05.01	IMDRF	3	Claimed Shelf-life	Contains details and evidence supporting the claimed shelf-life of the IVD medical device components (e.g. reagents, calibrators/reference materials, control material, any other components susceptible to degradation). Information provided in this section should include: a) A description of recommended environmental conditions for storage of the IVD medical IVD medical device (e.g. temperature, pressure, humidity, light conditions). b) A statement of the claimed shelf-life indicated as a period of time or any other means of appropriate quantification. c) An indication of the packaging used in any studies conducted in support of the shelf-life. If the packaging used in the studies differs from the final device packaging, a discussion of why the evidence can be consider valid in support of the claimed shelf-life.	**ANVISA, TGA,EU and HSA** For devices that do not have an expiration period (e.g. electromedical equipment or other devices of multiple use), information regarding the estimated mean "lifetime". This mean "lifetime" can be indicated as number of procedures to be performed with the device and/or its accessories, as a perioc of time or any other means of appropriate quantification.

				d) A description of the simulated transport conditions that the IVD was exposed to before the start of shelf-life studies. e) A justification of the selection of the studies performed. f) A summary of the evidence that falls within this category g) A discussion and a conclusion to support why the evidence presented is sufficient to support the claimed shelf-life. **OR** h) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject device.	
3.06.05.01.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.06.05.01.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.06.05.01.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.06.05.01.01.03	Regional (USFDA)	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.06.05.02	IMDRF	3	In Use Stability	Contains details and evidence supporting the stability during actual routine use of the IVD medical device (real or simulated), including all applicable components (e.g. reagents, reaction cartridges). This may include open vial stability and/or, for automated instruments, onboard stability. Information provided in this section should include: a) A description of recommended environmental conditions for use of the IVD medical device (e.g. temperature, pressure, humidity, light conditions). b) A justification of the selection of the studies performed. c) A summary of the evidence that falls within this category d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	**ANVISA, TGA. EU and HSA** For devices that do not have an expiration period (e.g. electromedical equipment or other devices of multiple use), information regarding the estimated mean "lifetime". This mean "lifetime" can be indicated as number of procedures to be performed with the device and/or its accessories, as a perioc of time or any other means of appropriate quantification.

3.06.05.02.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.06.05.02.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.06.05.02.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.06.05.02.01.03	Regional (USFDA)	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.06.05.03	IMDRF	3	Shipping Stability	Contains details and evidence supporting the tolerance of IVD medical device, or if provided separately, the components (e.g. reagents, calibrators/reference materials) to the specified or expected shipping conditions. Information provided in this section should include: a) An indication of environmental conditions for correct shipment of the IVD medical device (temperature, pressure, humidity, light conditions, mechanical protection etc.). b) A justification of the selection of the studies performed. c) A summary of the evidence that falls within this category d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	**ANVISA, TGA, EU and HSA** For devices that do not have an expiration period (e.g. electromedical equipment or other devices of multiple use), information regarding the estimated mean "lifetime". This mean "lifetime" can be indicated as number of procedures to be performed with the device and/or its accessories, as a perioc of time or any other means of appropriate quantification.
3.06.05.3.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.06.05.3.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.06.05.3.01.02	IMDRF	5	Full Report	The test report for the test described in the custo9m heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.06.05.3.01.03	Regional (USFDA)	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is**

					advised to contact the specific review division for further guidance on the specific data format that is preferred. **NOTE: Do not place PDFs here.**
3.07	IMDRF, RF (HC, HSA, USFDA)	1	Analytical Performance and Other Evidence Bibliography	a) A listing of published studies relevant to the context of this Chapter that involve this specific IVD medical device (e.g. analytical specificity, analytical sensitivity) b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements. c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement that no literature related to the IVD medical device was found.	
3.08	IMDRF	1	Other Evidence	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter. For example, for tests performed to ensure the safety and/or performance of the IVD medical device that are not delineated in the rest of the Chapter 3. In addition a) Describe the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test b) A justification of the selection of the studies performed. c) A summary of the evidence that is being submitted under this heading d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	
3.08.01	IMDRF	2	[Study description, study identifier, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.08.01.01	IMDRF	3	Summary	A summary of the specific study described in the custom heading above.	
3.08.01.02	IMDRF	3	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.08.01.03	Regional (USFDA)	3	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**

CHAPTER 4 – CLINICAL EVIDENCE

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
4.01	IMDRF	1	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
4.02	IMDRF	1	Overall Clinical Evidence Summary	a) This should be a brief (1-2 page) summary of the available clinical evidence being presented in support of the submission. The document should list the evidence presented, its characteristics (e.g. well-controlled studies, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, literature review) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section. b) If any of the study IVD medical devices differ from the IVD medical devices to be marketed, including competitors' IVD medical devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application. c) A discussion of the clinical evidence considered for the IVD medical device and support for their selection (i.e. what type of evidence was considered and why they were or were not used) d) Discussion to support why the evidence presented is sufficient to support the application. **NOTE:** Human factors testing that include patients should be included here.	**EU and TGA NOTE:** Clinical evidence is always required, regardless of risk class. **HC** a) Provide the Investigational Testing Authorization reference number for any clinical trials conducted under an Investigational Testing Authorization in Canada. b) If applicable, provide the clinicaltrials.gov reference number for any clinical studies registered witl clinicaltrials.gov. **USFDA PMA and 510(k)** Does not limit the page number for the summary of the clinical information submitted **USFDA, HC, ANVISA, JP and HSA** If no clinical evidence is being provided, discuss why this is acceptable. **HSA NOTE** Regardless of risk class, for medical devices with labelled use beyond the inherent performance of the device, clinical data should be provided to substantiate the proposed labelled use.
4.02.01	IMDRF	2	Expected Values/Reference Ranges	This section should include information on what values to expect in healthy normal patients versus affected patients.	
4.02.02	IMDRF (EU, NMPA, HSA, TGA)	2	Clinical Evidence Evaluation Report	a) A clinical evidence evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the IVD medical device. b) A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert.	
4.02.03	IMDRF	2	IVD medical Device Specific Clinical Studies	**NO CONTENT AT THIS LEVEL** Clinical study information under this heading should be grouped by study	
4.02.03.01	IMDRF	3	[Study description, protocol #, date of initiation, date of completion]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Level 3: EU Pilot Study, CT4203, 2010-10-10 Level 4: Clinical Study Synopsis Level 4: Clinical Study Report Level 3: NA Controlled Study, CT4584, 2011-01-23 Level 4: Clinical Study Summary Level 4: Clinical Study Report	
4.02.03.01.01	IMDRF	4	Clinical Study Summary	a) A summary of the specific study described in the custom heading above. b) 2-3 page summary document that presents a summary of:	**USFDA PMA and 510(k)** Does not limit the page number for the summary of the clinical investigations

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				i. The key characteristics of the study (e.g. title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, statistical design, interpretation of design, # patients, inclusion/exclusion criteria) and ii. Summary of the results of the analysis iii. Summary of conclusions related to the endpoints **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical study summary.	
4.02.03.01.02	IMDRF	4	Clinical Study Report	a) A clinical study report of the specific study described in the custom heading above. **NOTES:** i. The clinical study report should include elements such as the investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, analysis/results. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical study report.	**NMPA NOTE:** The clinical trial report should be in accordance with the Medical Device Registration Regulations, the Medical Device Clinical Trial Quality Management Specification, and relevant clinical guidelines. **USFDA PMA and 510(k)** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm#sugforforidepro
4.02.02.01.03	Regional (USFDA)	4	Clinical Study Data		**USFDA** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the clinical study and data provided in this section regarding the subject device. In this instance regional regulatory guidance refers to Special Controls in a device specific regulation, device-specific guidance document, special controls guidance, special controls guideline, and Statutory or Regulatory criteria. The Center for Devices and Radiological Health (CDRH) accepts and encourages the inclusion of clinical data in electronic (non-PDF) form as supporting material to a premarket (PMA or 510(k)) submission. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm
4.02.04	IMDRF (HC, HSA, JP, TGA, USFDA)	2	Clinical Literature Review and Other Reasonable Known Information	a) Clinical literature review that critically reviews available information that is published, available, or reasonably known to the applicant/sponsor that describes safety and/or performance of the IVD medical device b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements. **OR** c) A statement that no literature related to the IVD medical device was found. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the clinical study and data provided in this section regarding the subject IVD medical device	
4.03	Regional (USFDA)	1	IRB Approved Informed Consent Forms		**USFDA** Copies of IRB approved informed consent forms are to be provided here.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
4.04	Regional (HC, USFDA)	1	Investigators Sites and IRB contact information		**HC** List the clinical study sites including the name, description, and address. **USFDA** Investigators and study administrative structure information should be provided, including (as appropriate): a) Investigators (who signed the Investigator agreement)-name, address, telephone # (contact info), CV b) Sites-Site number as reflected in the study report in reference to the investigator, address if different from the above c) Sponsor-address and regulatory contact information d) Contract Research Organization (CRO), if applicable-name, address, and contact information e) Laboratory facilities (central lab and/or local lab that participated in the study)-name, address, contact information
4.05	IMDRF	2	Other Clinical Evidence	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.	

CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
5.01	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
5.02	IMDRF, RF (ANVISA, NMPA, EU, HC, HSA, TGA, USFDA)	Product/Package Labels	Samples of the primary and secondary packaging labels. **NOTES:** i. Do not include shipping labels. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject IVD medical device.	**ANVISA** a) According to Brazilian Legislation all information associated with the device, including labelling, shall be in Brazilian-Portuguese. b) Specific requirements of labelling content are established by ANVISA´s regulation. c) (PDFs of) the artwork of the labels will need to be provided for device. d) In case the product is marketed with original labels, (PDFs of) stickers with local information will need to be provided. **NMPA** a) Labels shall conform to the requirements of Medical Device Instructions and Label Management Regulations. b) Reagents labels must be in Chinese and batches of the sub-components must be marked on the label: c) The labels and the Chinese versions approved or recognized by overseas government competent departments shall be submitted as for imported products. **EU** a) (PDFs of) labels will need to be provided for device labels as well as labelling of primary and secondary packaging. b) For Own Brand labelling, packaging and IFU of both the OBL and the OEM will need to be provided. **HC NOTES** a) All labelling must be provided in English or French, both official languages are to be available upon request. b) Labelling for devices sold over-the-counter (OTC) or in a self-service display must be provided in French and English **TGA NOTES** The labels and instructions for use (including any package inserts) must a) meet the requirements of Essential Principle 13 b) be in English and legible when viewed on screen and printed c) include the Australian sponsor's contact details to meet Regulation 10.2 If the applicant is including draft labels, artist impression or mock-up labels, the applicant needs to provide: a) the mock-up as full size suitable for A3 printing b) a statement as to where and how the batch/serial number/ date of manufacture/expiry date/ will be displayed **USFDA PMA:** a) Follow device labelling regulations found in 21 CFR Part 801 and 21 CFR 809.10

					HSA NOTES Refer to GN-23 – available at www.hsa.gov.sg for labelling requirements. a) Copies of device and packaging labels are to be provided in original color. b) If representative labels are provided, variable fields on the artwork must be highlighted, and ranges of values for the variable fields should be indicated.
5.03	IMDRF, RF (ANVISA, EU, HC, HSA, TGA, USFDA)		Package Insert/Instructions for Use	Package Insert/Instructions for Use included in the package, when required or provide support for why this element is not applicable. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject IVD medical device	**ANVISA** a) According to Brazilian Legislation all information associated with the device, including labelling, shall be in Brazilian-Portuguese. b) Specific requirements of labelling content are established by ANVISA´s regulation. c) The current version of the instruction for use must be informed. d) (PDFs of) the artwork of the IFU will need to be provided for device. **NMPA** a) For domestic and imported products, the applicant/agent shall compile the product instructions in accordance with the relevant requirements of Compilation Guiding principles for Instructions of IVD Reagents, with reference to relevant technical guiding principles. b) For imported products, the applicants shall submit the original text and Chinese version of instruction approved or recognized by overseas government competent department. c) The product instructions shall be submitted in two copies and a declaration the two copies are identical text shall be submitted. **EU** a) At minimum the IFU in a relevant acceptable language, required by Notified Bodies following their national law, should be provided. Further language version will need to be available for verification during audits. b) (PDFs of) labels will need to be provided for device labels as well as labelling of primary and secondary packaging. c) For Own Brand labelling, packaging and IFU of both the OBL and the OEM will need to be provided. **HC NOTES:** a) All labelling must be provided in English or French, both official languages are to be available upon request. b) Labelling for devices sold over-the-counter (OTC) or at a self-service display must be provided in French and English c) Package inserts must include all relevant information, including a summary of the performance characteristics. d) The current version and date of the instruction for use must be stated. **TGA NOTES** The labels and instructions for use (including any package inserts) must d) meet the requirements of Essential Principle 13 e) be in English and legible when viewed on screen and printed f) include the Australian sponsor's contact details to meet Regulation 10.2 If the applicant is including draft labels, artist impression or mock-up labels, the applicant needs to provide: c) the mock-up as full size suitable for A3 printing d) a statement as to where and how the batch/serial number/ date of manufacture/expiry date/ will be displayed

					USFDA PMA NOTE: Package inserts include a summary of clinical data **HSA NOTE** Refer to GN-23 – available at www.hsa.gov.sg for labelling requirements.
5.04	IMDRF, RF (ANVISA, EU, HSA)	1	e-labelling	a) For eligible IVD medical devices and stand-alone software, the applicant needs to identify which form of e-labelling is being used in case of e-labelling (e.g. electronic storage system or built-in system, website). b) Provide details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here c) A description of the procedure and operations on providing IFU's when requested d) Provide written information for user Information on webpage where IFU and further information can be found in relevant languages. e) Description on how the requirements detailed for the website have been met. f) If a video/App is available to demonstrate how the test is to be performed and interpreted, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.	**EU** For fixed installed IVD medical devices provide text message / information which will be given on or with the device itself as well as description of place where it would be placed **HC NOTE:** If a video/App is available as described in f) above, the video should be available in both French and English. **HSA NOTE** Refer to GN-23 – available at www.hsa.gov.sg for e-labelling requirements.
5.05	IMDRF (HC, HSA, USFDA)	1	Patient Labelling	Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver	
5.06	IMDRF (ANVISA, EU, HC, HSA, TGA, USFDA)	1	Technical/Operators Manuals	Labelling directed to the technical users and operators of IVD medical devices focusing on the proper use and maintenance of the IVD medical device	
5.07	Regional (HC)	1	Product Brochures		**HC** a) Draft product brochures available at the time of application b) The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device
5.08	IMDRF (ANVISA, EU, HC, TGA, USFDA)	1	Other Labelling and Promotional Material	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.	

CHAPTER 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
6A.01	Regional (USFDA)	1	Cover Letter		**USFDA PMA** Any PMA submission (including modular PMAs) of quality system information would need a cover letter containing the information described in Chapter 1 under the Cover Letter heading **NOTE:** Quality Management System procedures included in a PMA submission to the USFDA are procedures for the design and manufacture of the specific device that is the subject of the PMA.
6A.02	IMDRF (TGA, JP USFDA)	1	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
6A.03	IMDRF (TGA, JP, USFDA)	1	Administrative	**NO CONTENT AT THIS LEVEL.** Administrative information needed to evaluate the premarket submission related to the QMS	
6A.03.01	IMDRF (NMPA, TGA, JP, USFDA)	2	Product Descriptive Information	Abbreviated description of the IVD medical device, operating principles and overall manufacturing methods	**USFDA PMA** Description of the device should also include pictures, proprietary name, common name, model numbers, product code and intended use.
6A.03.02	IMDRF, RF (ANVISA, NMPA, HC, HSA, JP, TGA, USFDA)	2	General Manufacturing Information	a) Address and contact information for all sites where the IVD medical device or its components are manufactured. b) Where applicable, addresses for all critical subcontractors, such as outsourced production, critical component or raw material production (e.g. antigens, monoclonal antibodies), and sterilisation, will need to be provided.	**USFDA PMA NOTE** This information is typically submitted to FDA in the Cover Letter.
6A.03.03	IMDRF, RF (TGA, USFDA)	2	Required Forms	Any regional specific forms to be completed associated with Quality Management Systems in the premarket review process	
6A.04	IMDRF (TGA, USFDA, WHO PQ)	1	Quality management system procedures	High level quality management system procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents and records ***ISO 13485 Elements– SOPs to satisfy clause 4***	**USFDA PMA** Quality System Procedures (outline of the quality system documentation structure) **WHO PQ** a) A list of all current quality management SOPs b) Risk management
6A.05	IMDRF (TGA, USFDA)	1	Management responsibilities procedures	Procedures that document the management commitment to the establishment and maintenance of the QMS by addressing quality policy, planning, responsibilities/authority/communication and management review. ***ISO 13485 Elements – SOPs implementing clause 5***	
6A.06	IMDRF (TGA, USFDA, WHO PQ	1	Resource management procedures	Procedures that document the adequate provision of resources to implement and maintain the QMS including human resources, infrastructure and work environment. ***ISO 13485 Elements – SOPs implementing clause 6***	**WHO PQ** a) Staff organogram
6A.07	IMDRF (TGA, USFDA)	1	Product realization procedures	High level product realization procedures such as those addressing planning and customer related processes ***ISO 13485 Elements – SOPs implementing sub clause 7.1 and 7.2***	

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
6A.08	IMDRF (TGA, USFDA, WHO PQ) 1	Design and development procedures	Procedures that document the systematic and controlled development of the IVD medical device design from initiation of the project to transfer to production. ***ISO 13485 Elements – SOPs for implementing sub clauses7.3***	**USFDA PMA** 21 CFR 820.30 Design Controls **WHO PQ** a) Change control and Change notification SOPs
6A.09	IMDRF (TGA, USFDA, WHO PQ) 1	Purchasing procedures	Procedures that document that purchased products/services conform to established quality and/or product specifications. ***ISO 13485 Elements – SOPs to implement sub clause 7.4***	**USFDA PMA:** a) Purchasing Controls - Procedures b) Acceptance Activities Procedures **WHO PQ** a) Supplier evaluation and control b) Verification of purchased product
6A.10	IMDRF (TGA, USFDA) 1	Production and service controls procedures	Procedures that document the production and service activities are carried out under controlled conditions. These SOPS address issues such as cleanliness of product and contamination control; installation and servicing activities; process validation; identification and traceability; etc. ***ISO 13485 Elements – SOPs implementing sub clause 7.5***	**USFDA PMA** a) Production and Process Controls b) Servicing Procedures
6A.11	IMDRF (TGA, USFDA) 1	Control of monitoring and measuring devices procedures	Procedure that document that monitoring and measuring equipment used in the QMS is controlled and continuously performing per the established requirements. ***ISO 13485 Element- SOPs for implementing sub clause 7.6***	**USFDA PMA** Inspection, Measuring & Test Equipment Procedures
6A.12	IMDRF (TGA, USFDA, WHO PQ) 1	QMS measurement, analysis and improvement procedures	Procedures that document how monitoring, measurement, analysis and improvement to ensure the conformity of the product and QMS, and to maintain the effectiveness of the QMS. ***ISO 13485 Element – SOPS for implementing clause 8***	***USFDA PMA:*** a) *CAPA Subsystem Procedures* b) *Nonconforming Product Procedure(s)* c) *Complaint Handling Procedures* d) *Quality System Audit Procedures* **TGA** Note that the following should be included in this section: a) Procedures for the notification to TGA and other regulatory authorities of substantial changes to the QMS or to the kinds of medical devices manufactured b) Procedures for the issue of advisory notices, including the required notification to regulatory authorities for product recall c) Procedures for required notification to the TGA and other regulatory authorities of adverse events and changes to the QMS **WHO PQ** a) Complaint handling and vigilance b) Control of non-conforming goods/processes
6A.13	IMDRF (TGA, USFDA) 1	Other Quality System Procedures Information	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.	

CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
6B.01	IMDRF	1	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
6B.02	IMDRF (TGA, USFDA)	1	Quality management system information	Documentation and records specific to the subject IVD medical device that results from the high level quality management system procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents, noted in Chapter 6A ***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 4***	
6B.03	IMDRF (TGA, USFDA)	1	Management responsibilities information	Documentation and records specific to the subject IVD medical device that result from the implementation the management responsibilities procedures noted in Chapter 6A ***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 5***	
6B.04	IMDRF (TGA, USFDA)	1	Resource management information	Documentation and records specific to the subject IVD medical device that result from the implementation the resource management procedures noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 6***	
6B.05	Regional (HC)	1	Device Specific Quality Plan		**HC** The review requirement for a quality plan are not met by the ISO 13485 certificate alone, instead refer to ISO 10005. A quality plan should specify "which processes, procedures and associated resources will be applied by whom and when to meet the requirements of a specific project, product, process or contract…". This information may be provided in an application in the form of a flow chart, process map, document matrix, table or text description. A quality plan specific for the subject device should link device requirements to the processes, resources and projects used by the manufacturer in producing that device.
6B.06	IMDRF (TGA, USFDA)	1	Product realization information	Documentation and records specific to the subject IVD medical device that results from the implementation of the high level product realization procedures noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.1 and 7.2***	
6B.07	Regional (ANVISA, TGA, USFDA)	1	Design and development information	Documentation and records specific to the subject IVD medical device that results from the implementation of the design and development procedures noted in Chapter 6A. The source of this information is the Design and Development Records (e.g. DHF - Design History File). And "summary of changes" can be sent as a table indicating the change requested and how it impacts on design and process information previously informed. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.3***	**USFDA PMA and ANVISA** Design Control Information a) Design Outputs - List of Essential Design Outputs b) Design Validation- Justification for use of non-production units in validation testing, if applicable **ANVISA** a) Receiving and Acceptance Activities defined for critical row materials. "Critical raw materials" ar those related with the "essential design outputs" indicated at the Design and Development Control For example, if among the essential design outputs reference is made to specifications of raw material, this is considered a "critical raw material".
6B.08	IMDRF (TGA, USFDA)	1	Purchasing information	Documentation and records specific to the subject IVD medical device that results from the implementation of purchasing procedures noted in Chapter 6A.	**TGA** List of suppliers of goods or services that affect product conformity with requirements (critical suppliers) and a description of how purchasing requirements are fulfilled for these suppliers

				ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.4	**USFDA PMA** a) List of Suppliers for the subject device b) Receiving and Acceptance activities for select suppliers
6B.09	Regional (ANVISA, HC, HSA, JP, TGA, USFDA, WHO PQ)		Production and service controls information		**ANVISA, HC and TGA:** a) Detailed Manufacturing Flow Diagram b) Summary of in-process acceptance activities for subject device c) Process Validation Master Plan d) List of processes that have not been validated e) For each process validation considered critical to the safety and effectiveness of the device: i. Protocols/Procedures for the validated process ii. Process validation report iii. The procedures for monitoring and controlling the process parameters of a validated process should be fully described. iv. State the frequency of re-validation **HC NOTES:** a) Manufacturing flow diagram should provide a description of the methods used in, and quality controls used for, the manufacture, processing, packaging, storage and, where appropriate, the installation of the device. Sufficient detail must be provided to enable the judgement of the appropriateness of the quality controls in place. b) If multiple facilities are involved in the manufacture of a device, the applicable information for eac facility must be submitted. If the information is identical for a number of sites, this should be statec **JP** a) A description of quality control tests and standards in manufacturing for the final product. Examples are following: i. Analytical Sensitivity Test ii. Accuracy Test iii. Repeatability Test b) Explain the rationale for setting the tests and standards. This should include the description why th tests and standards are sufficient to ensure the effectiveness. c) Provide the test reports. **OR** d) A discussion of why this category of study is not applicable to this case. **USFDA PMA** a) Description of the use of standards in manufacturing the PMA device b) Detailed Manufacturing Flow Diagram c) Summary of in-process acceptance activities for subject device (optional) d) Process Validation Master Plan e) List of processes that will not be validated f) Protocols/Procedures for each validated process g) Completed process validation reports (optional/if available) **WHO PQ** a) Full address, including latitude and longitude of the manufacturing facility(s) b) Site floor plan c) Manufacturing flowchart including in-process control points

					d) List of critical raw materials (including details of the supplier of each material) List of outsourced processes with direct product impact (e.g. outsourced manufacturing of components (conjugated antibodies, strips, reagents…), outsourced laboratory testing, packaging, printing, etc) including details of the supplier for each process ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.5*** **HSA** a) Information on the manufacturing process should be provided in sufficient detail to allow understanding of the manufacturing process. Detailed proprietary information is not required. Manufacturing process may be presented in the form of a process flowchart showing an overview of production, controls, assembly, in-process and final product testing, and packaging of the finished IVI medical device. b) If the manufacturing process is carried out at multiple sites (including contract manufacturers), the manufacturing activities carried out at each site should be clearly identified. c) For Class D IVD medical devices, the batch release plan should be provided to demonstrate that eac batch consistently identifies the relevant antigens, epitopes, and antibodies. The batch release plan sha be provided as an annex, with detailed information on the establishment of the batch release panel.
6B.10	IMDRF (TGA, USFDA)		Control of monitoring and measuring devices information	Documentation and records specific to the subject IVD medical device that results from the implementation of the control of monitoring and measuring device procedures noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.6***	
6B.11	IMDRF (TGA, USFDA, WHO PQ)		QMS measurement, analysis and improvement information	Documentation and records specific to the IVD medical subject device that results from the implementation of the QMS measurement, analysis and improvement procedures noted in Chapter 6A ***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 8***	**WHO PQ** Batch/lot release SOPs
6B.12	IMDRF (TGA, HC, USFDA)		Other Device Specific Quality Management System Information	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this Chapter.	

DOCUMENT REVISION HISTORY

Version	Description of Changes	Author	Date
PD1	Version for Public Consultation	B. Dowling & IMDRF's RPS ToC WG Members	9 September 2013
R1	Final Version following public consultation and piloting	B. Dowling & IMDRF's RPS ToC WG Members	27 May 2014
R2	Revisions for NMPA requirements, WHO PQ inclusion, addition of "Cybersecurity" and "Interoperability" headings to software section, other minor revisions based on review and experience	B. Dowling & IMDRF's RPS ToC WG Members	27 March 2018
R3	Addition of Singapore (HSA) requirements, revised summary definition, other minor editorial changes.	B. Dowling & IMDRF's RPS ToC WG Members	21 March 2019