IMDRF International Medical Device Regulators Forum

ToC

Feedback from Canada, Australia and Brazil

Patrice Sarrazin

Senior Scientific Evaluator

IVDD Evaluation Division, Medical Devices Bureau

Health Canada

ToC Pilot

Comments received

Canada

Total of 56 applications

18 Class IV

38 Class III

28 new device licence applications

28 device licence amendment applications

Australia

Brazil

Benefits of ToC

Consistent structure

The well defined chapters in the ToC along with the regional classification matrix makes the process of navigation and access to the required data more efficient

Information easy to find

Non-clinical study format of summary followed by full report (protocol and report) makes the pre-assessment and assessment process more efficient.

ToC format preferred to the STED format

Referencing the application

The folder numbering hierarchy allows easier referencing to a document in the assessment report.

Reviewer's Pet Peeves

Search Capabilities

The ToC is less searchable compared to dossier in a single pdf file. Using keyword search in single files brings up relevant information more quickly, even when it is located in other component section (i.e. sterility or clinical reports) – this will not be feasible in ToC as the file split into different folders.

Unsearchable PDF file. Manufacturers should perform OCR (character recognition) before compiling the final PDF.

Combination products are out of the scope

Considering a fair percentage of devices are covered under this category it will be appropriate to include a new heading under Chapter 3 - Non clinical studies - Medicinal substance and add requirements as per the regional requirements.

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Reviewer's Pet Peeves

Requirements for Amendment Application

ToC does not provide guidance on what information is required for an amendment application. Not all chapters will be required

Better for large application

More useful for application with large amount of data (e.g. new application) as the ToC format is more structurally organized. Applications with less data are easier to navigate in a single pdf file with proper labelled bookmarks.

Duplication of documents

Duplication of the same document in many headings.

Conclusion

Reviewers like the ToC format

The structure of ToC is adequate

Submissions are as good as the content

Thank you

Brazil

Detailed Comments

- Reviewing of the documents was a good experience;
- Need time to get used to the new structure and to navigate through the folders;
- Some sub-headings (folders) were created by the applicants to add content;
- In a few cases one document containing information from more than one heading;
- Duplication of the same document in many headings;
- Non standardized “study description, identifier and date of initiation” for some headings;
- Unnecessary justification for the no presentation of “Non required” items;
- Content inserted on headings with the statement “No content at this level”;
- Some documents without proper pagination.

Australia

Detailed comments

- The well defined chapters in the ToC along with the regional classification matrix makes the process of navigation and access to the required data more efficient as we know exactly what information is present under the reelvant chapter.
- Non clinical study format of summary followed by full report (Protocol and report) makes the pre-assessment process more efficient as the summary alone gives sufficient information to make a recommendation on requirement of assessment.
- the most helpful aspects of the formatting is the folder numbering hierarchy; it makes it substantially easier to reference a document in our report

Australia

Detailed comments

- As medicinal substance is included in this submission, the Toc fails to ask for Letter of Authoristion to access to CEP checklist or any other relevant to authorisations. It is noted that the drug device combinations are out of the scope of this document. Considering a fair percentage of devices are covered under this category it will be appropriate to include a new heading under Chapter 3 - Non clinical studies - Medicinal substance and add requirements as per the regional requirements
- Classification matrix and IMDRF ToC description fails to ask for rationale/justification in cases where the testing has not been conducted. For example: If biological safety testing has not been conducted then the rationale for not conducting it which may be in certain cases safety history of components in the device, testing done on a predicate already approved and clean post market history.
- The ToC is very appropriate for new application type; however if it is a change or recertification application it does not provide guidance on what sought of information is required. If the application is change or recertification then the information required by the regulatory body will not be all of the applicable chapters.
- Some documents contained text that were not searchable. It would be great if manufacturers perform OCR (character recognition) on them before compiling the final PDF.
- More useful for application with large amount of data (e.g. new application) as the ToC format is more organised. Application with less data is easier to navigate in a single pdf file with proper bookmarks labelled (as detailed in the next column).
- The ToC is less searchable compared to dossier in a single pdf file. Using keyword search in single files bring up relevant information more quickly, even when it is located in other component section (i.e. sterility or clinical reports) – this won't be feasible in ToC as the file split into different folders.