IMDRF International Medical Device Regulators Forum

IMDRF Regulated Products Submission (RPS) WG Update for Open Stakeholder Day

Nancy Shadeed

Health Canada

Updates

- Close of IMDRF Table of Contents (ToC) Pilot
- Experience to date
- Proposed revisions to the ToCs
- Implementation options
- Electronic Submissions Interim Solution

IMDRF Pilot

- Pilot ended December 2017.
- Applications that have been received and reviewed to-date by region:
  - Australia: 1
  - Brazil: 7
  - Canada: 2
  - China: 4
  - EU: 1
  - USA: 2

Health Canada Regional ToC Pilot

Canada

Total of 56 applications

18 Class IV

38 Class III

28 new device licence applications

28 device licence amendment applications

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 Thoughts

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. As indicated in guidance, manufacturers should perform OCR (character recognition) before compiling the final PDF.

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. Less advantageous for minor amendments with less information to navigate, but if done properly with exclusion of irrelevant headings per guidance it works well.

Duplication of documents

Duplication of the same document in many headings – the granulation exists for a reason, if not followed, the structure become less efficient.

Manufacturer Feedback

- Some comments about technical limitations e.g. filepath length, character limits
  - Mostly due to hybrid nature of pilot → ToC structure used in a non-RPS environment
- Johnson & Johnson's use of ToC has been positive and plan to use ToC as a global template
- Other feedback has included request for more guidance and concerns about review times being lengthened

Challenges

- Manufacturers hesitant to invest in resources and infrastructure without knowing if ToC/RPS will be implemented
  - Using low-priority devices for Pilot

- Difficult for Pilot group to make an informed decision and recommendation with small sample sizes

Conclusion

Reviewers like the ToC format

The structure of ToC is adequate

File path length remains an IT risk

Issues encountered to date are considered minor and relate to applicants not strictly following guidance

Submissions are as good as the content

Revisions to the ToCs

- Many minor revisions to regional content including
  - Additional World Health Organization (WHO) elements
  - Additional China Food and Drug Administration (CFDA) elements
  - Revision of existing content for several other regulators, mainly updating of references and revising to address changes in regional guidance or regulation

Revisions to the ToCs

- 2 new headings have been recommended:

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 c) Traceability matrix linking cybersecurity controls to the cybersecurity vulnerabilities and risks
Interoperability	If the device can communicate with other devices. Evidence to support the interoperability should be provided.

Revisions to ToCs

- Further revision will be required once EU regulatory changes are final
- Singapore has indicated interest in inclusion and will be working to consider their region following finalization of the proposed ToCs

Implementation Options

- Without an commitment from IMDRF MC members on approach, further use of the ToC may be limited
- Industry will not invest if jurisdictions do not offer options to use ToC for medical device submissions in each of their regions
- Broadening the scope of applications types beyond those used in the pilot in some jurisdictions would also increase the use by industry

RPS Electronic Submissions

- RPS WG currently reviewing RPS testing results from Round 2 and preparing report for MC in September
- Industry RPS members have started industry outreach through an additional forum on electronic submissions for health products.
- Topics for upcoming discussions include:
  - IMDRF ToC Interim Electronic Format Discussion
  - Discussion of possible vendor forum for medical device submission publishing

Future of RPS Work

Current

•Decision on Implementation of ToC will determine if future work required on electronic submissions

Proposed

•Any future work on electronic submissions formats is dependent on the IMDRF MC decision regarding ToC implementation