IMDRF International Medical Device Regulators Forum

IMDRF Regulated Products Submission (RPS) WG Update

Hospitalar

São Paulo, 22 de maio de 2019

Adaptado da apresentação de Nancy Shadeed – Health Canada

Updates

- Revisions to the IMDRF ToC
- Regional implementation update
- Future of RPS

Updates to ToC

- The ToC has been revised with the primary purpose of adding content from Singapore
- Opportunity taken to revise based on Health Canada's recent review as part of their regional guidance development, including
  - Revision to definition of summary
  - Editorial changes including updated numbering to remove CH leading characters
  - Addition of the following regional heading for HSA:
    - 1.08-Expedited Review Documentation

Revision to Summary definition

- 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)

Additional Heading

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

ToC Implementation

- Health Canada has published complete implementation guidance for the use of the ToC using a folder structure implementation

- Effective April 1, 2019 Health Canada will no longer accept STED as a submission format

ToC Implementation

- Some jurisdictions have indicated a willingness to accept the ToC structure as an optional format while others are reviewing its feasibility

- Further commitments from other jurisdictions will improve adoption and is encouraged

RPS

- Working group considering options for moving forward
- Sub-group exploring the possibility of an industry survey to gauge positions on electronic submissions
- RPS standard may be changing from HL7 to FHIR (Fast Healthcare Interoperability Resources)

Questions/comments

Thank you!