Regulated Product Submission - RPS

Agência Nacional de Vigilância Sanitária

IMDRF International Medical Device Regulators Forum

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Composed of two complementary components:

- ✓ Beta testing of RPS Standard to confirm it is fit for purpose for medical devices;
- ✓ Develop common, modular Table of Content (ToC) for device applications (IVD and non-IVD).

Meant for worldwide use: same model for all product types, all regulatory agencies.

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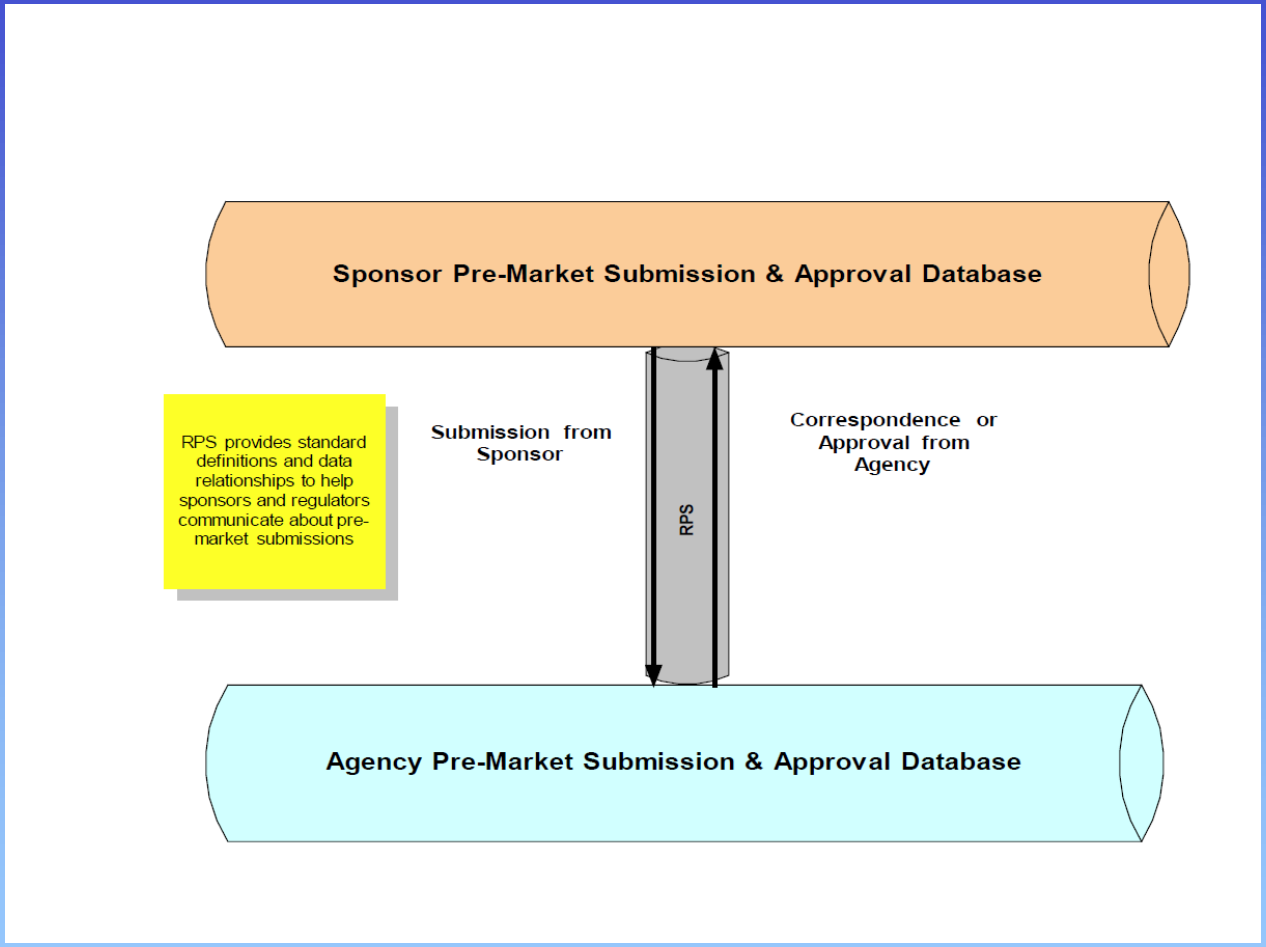

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Why is this important?

- ✓ RPS will allow for unprecedented functionality in terms of the review and management of regulated product information over the entire product life cycle;
- ✓ Use by regulatory agencies across product lines provides for resource savings and greater efficiencies, including with respect to the training of reviewers;
- ✓ Expected to increase the efficiency and effectiveness of regulatory processes internationally.

nIVD MA ToC - Chapters

The ToC is divided into 7 different chapters:

- ✓ Chapter 1 – Regional Administrative
- ✓ Chapter 2 – Submission Context
- ✓ Chapter 3 – Non-Clinical Evidence
- ✓ Chapter 4 – Clinical Evidence
- ✓ Chapter 5 – Labelling and Promotional Material
- ✓ Chapter 6A – QMS Procedures
- ✓ Chapter 6B – QMS Device Specific Information

nIVD MA ToC - Heading Characteristics

- **Heading Level** – levels are assigned in the document. Along with the location this defines the hierarchy of the ToC.
- **Heading Class –** Headings are classified as either IMDRF or Regional.

- 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 –** 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 etc.)

– **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.

nIVD MA ToC - Content

Example 1

- ✓ Heading: General Submission Summary
- ✓ IMDRF Heading – Common (left) and Regional (right)Content

Heading Class & Level		Heading	Common Content	Regional Content
IMDRF	1	Chapter ToC	Includes all headings and sub-headings for the chapter. Links are recommended.	USFDA PMA 21 CFR 814(b)(2)
IMDRF	1	General Summary of Submission	a) Statement of the device name, its general purpose, and a high-level summary of key supporting evidence b) Summary of submission, informing the type of submission (new, amendment, change of existing application, renewal…). c) If amendment/supplement, the reason of the amendment/supplement; d) If change to existing approval, description of the change requested (e.g., changes in design, performance, indications, etc) e) 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 given by Anvisa for the device or family of devices and the number of the original application must be informed. EU If renewal, amendment or change, identification of the CE certification given to the product (family) of the currently approved products must be detailed. HC If amendment or new submission based on currently licenced device(s), the Canadian Medical Device Licence Number(s) should be provided along with the description of the change requested.

nIVD MA ToC - Content

Example 2

- ✓ Heading: User Fees
- ✓ Regional Heading – Regional Heading used by USFDA, Anvisa, EU – there is no common content under this heading, although the heading term “User Fees” is harmonized.

Heading Class & Level		Heading	Common Content	Regional Content
Regional (USFDA, Anvisa, EU)	1	User Fees		USFDA PMA and Traditional 510(k) a) FDA User Fee Form https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref Anvisa a) Receipt of the User Fee payment. Information about User Fee available at: http://s.anvisa.gov.br/wps/s/r/n8 EU a) Signed quote and agreement for dossier review /audits

Pilot Plan

- ✓ Two phase plan
- ✓ Both phases will involve industry creating submission using the ToC and Regulators evaluating the product
- ✓ Historical submissions to be used and restructured
- ✓ Phase 1 (April – May) – Preliminary evaluation of a single submission for a single jurisdiction by a single manufacturer
- ✓ Phase 2(June – Sept) - Involve more industry and a variety of different device risk classes and jurisdictions

Consultations

http://www.imdrf.org/consultations/consultations.asp

http://www.imdrf.org/consultations/cons-rps-toc.asp

Consultation item	Working Group	Coordinator	Closing date
Regulated product submission (RPS) Table of contents	Regulated product submission (RPS) Working Group	Mr Mike Ward	21 June 2013

Comments are invited by **Friday 21 June 2013** to imdrf.toc@gmail.com

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Obrigada!

Fontes:

- The Regulated Product Submission: Progress Update
- IMDRF Presentation – IMDRF RPS Update

Mike Ward - Chair, IMDRF RPS Working Group

http://www.imdrf.org/