IMDRF International Medical Device Regulators Forum

Regulated Product Submissions (RPS)

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DITTA Workshop on RPS

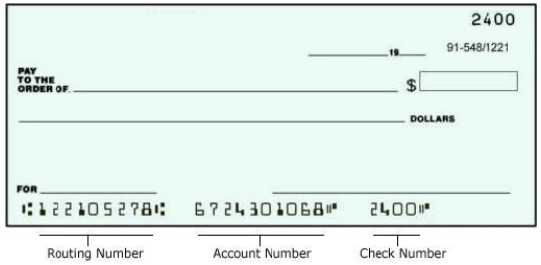
March 23, 2015

Topics

1. Background and Context for RPS
2. What is RPS?
3. Harmonized Submission Structure (TOC)
4. Business Case
5. CDE (Common Data Elements to ID a Device)
6. Questions & Discussion

Paying with cash

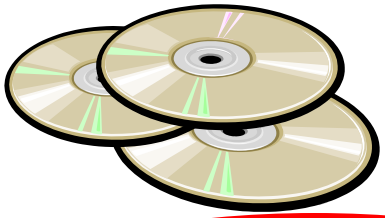
Handwritten checks



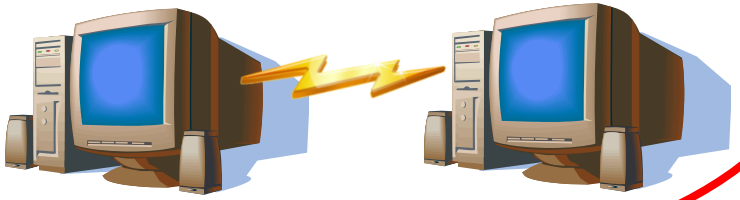
Online banking

Paper Submissions

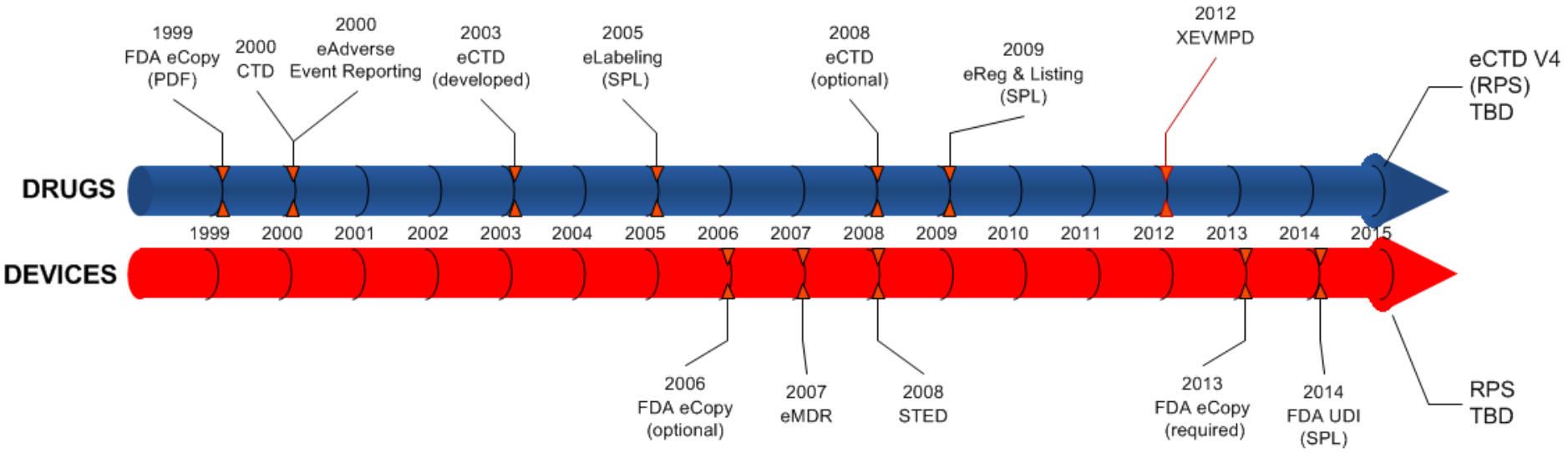
Submissions on CD or Uploaded Documents



Structured Information sent system to system



Submission Evolution



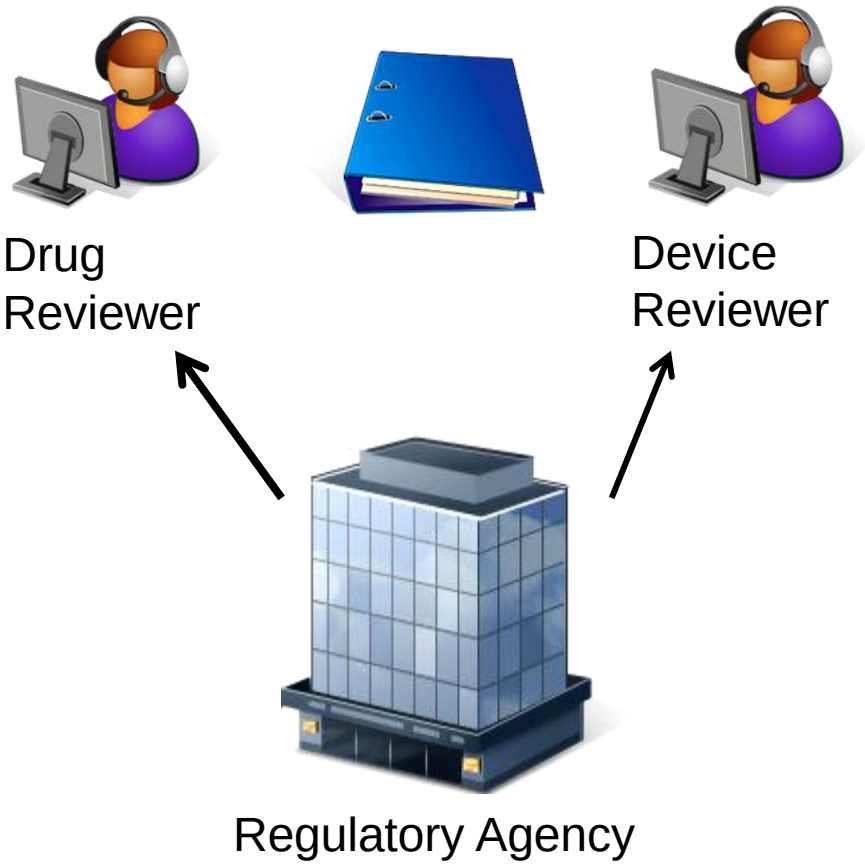
The electronic submission evolution for drugs gives us a window into device direction

Regulated Product Submission (RPS) is a submission format that will be common to drugs and devices

- For pharma RPS is eCTD version 4

RPS Drivers

- Regulator IT costs
- Combination Products
- Reviewer desire for tools to aid in review and consistency in submission structure & content
- Expectations that regulators track information effectively across the product lifecycle



RPS Stakeholders

IMDRF International Medical Device Regulators Forum

US (CBER and CDRH)
Canada (HC)
Japan (PMDA)
Brazil (ANVISA)
Australia (TGA)
EU (Notified Bodies & CAs)
China
Industry Associations

ICH harmonisation for better health

US (CDER)
Japan (MHLW)
Australia (TGA)
EU (EMA)
Canada (HC)
Industry Associations

HL7 INTERNATIONAL

ISO

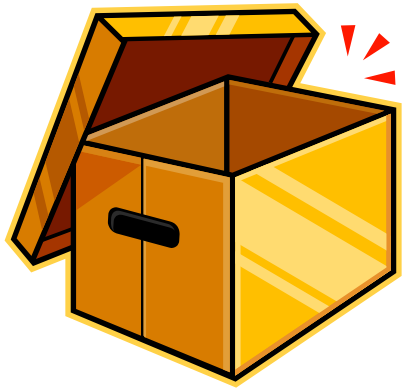
Multiple Software Vendors

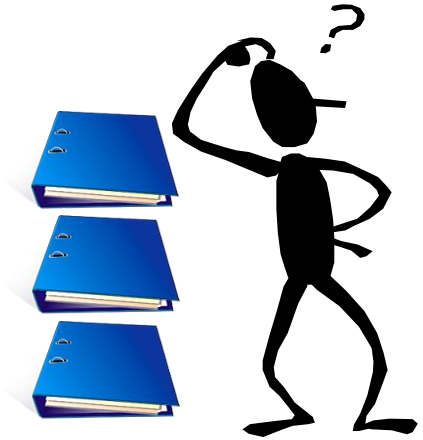
Parexel
GlobalSubmit
Lorenz
Extedo
CSC

2. What is RPS?

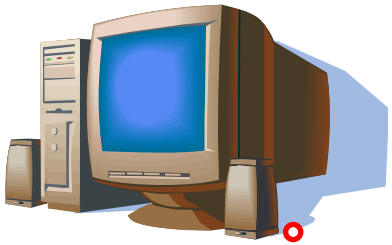
An HL7 standard that supports electronic submission of information for regulated products

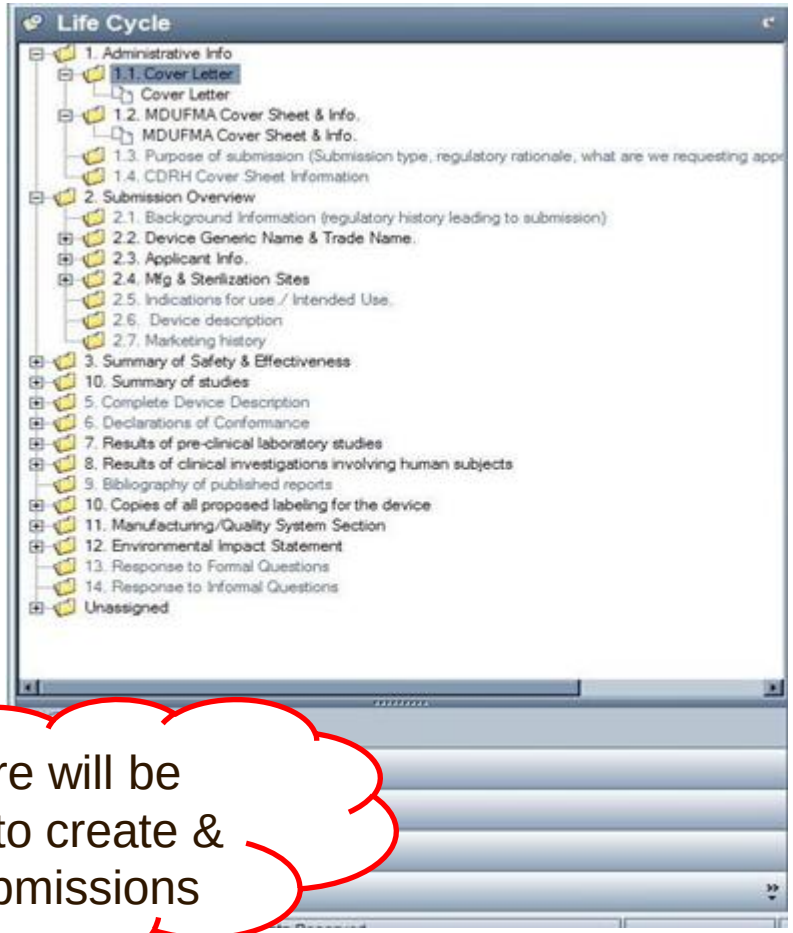
- Provides context for how the submission should be routed and reviewed (i.e. this is a supplement to an existing PMA)
- Allows a lifecycle of submission content (i.e. Document A replaces Document B)
- Acts as a “packing slip” for submissions





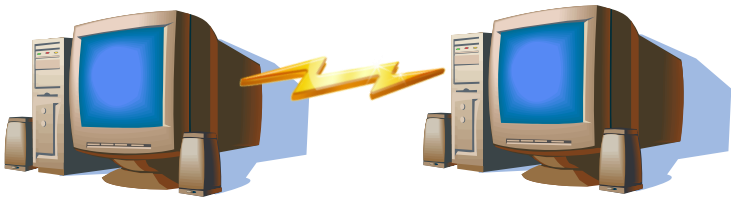
The RPS standard covers just the XML file





Software will be required to create & view submissions

3. Harmonized TOC



- RPS submissions require a consistent submission structure
- This means a harmonized Table of Contents (TOC) for submissions
- The TOC Guidance has been finalized for both IVDs and non-IVDs
  - A TOC pilot is underway in Canada.
  - An IMDRF pilot will be proposed later this year.

IMDRF TOC

- The TOC provides a master list of submission contents (regardless of submission type)

- For a specific submission the master list would be filtered based on the type of country, product risk class and type of submission

CH2.2 General Summary of Submission

CH2.3 Summary and Certifications for Premarket Submissions

CH2.4.1 Comprehensive Device Description & Principle of Operation

CH2.4.2 Description of Packaging

CH2.4.3 History of Development

CH2.4.4 Reference and Comparison to Similar and/or Previous Generations of the Device

CH2.4.5 Substantial Equivalence Discussion

CH2.5.1 Intended Use / Intended Purpose / Intended User

CH2.5.2 Intended Environment for use

CH2.5.3 Indications for Use

CH2.5.4 Pediatric Use

CH2.5.5 Contraindications For Use

CH2.6.1 Global Market History

CH2.6.2 Global Incident Reports and Recalls

CH2.6.3 Incident and Recall Rates

CH2.7 Other Submission Context Information

US Class III, PMA View

CH2.2 General Summary of Submission

CH2.3 Summary and Certifications for Premarket Submissions

CH2.4.1 Comprehensive Device Description & Principle of Operation

CH2.4.2 Description of Packaging

[redacted]

CH2.5.1 Intended Use / Intended Purpose / Intended User

[redacted]

CH2.5.3 Indications for Use

CH2.5.4 Pediatric Use

C[redacted]

CH2.6.1 Global Market History

CH2.6.2 Global Incident Reports and Recalls

C[redacted]

CH2.7 Other Submission Context Information

Canada Class III, New License View

CH2.2 General Summary of Submission

[redacted]

CH2.4.1 Comprehensive Device Description & Principle of Operation

CH2.4.2 Description of Packaging

CH2.4.3 History of Development

CH2.4.4 Reference and Comparison to Similar and/or Previous Generations of the Device

[redacted]

CH2.5.1 Intended Use / Intended Purpose / Intended User

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CH2.5.5 Contraindications For Use

CH2.6.1 Global Market History

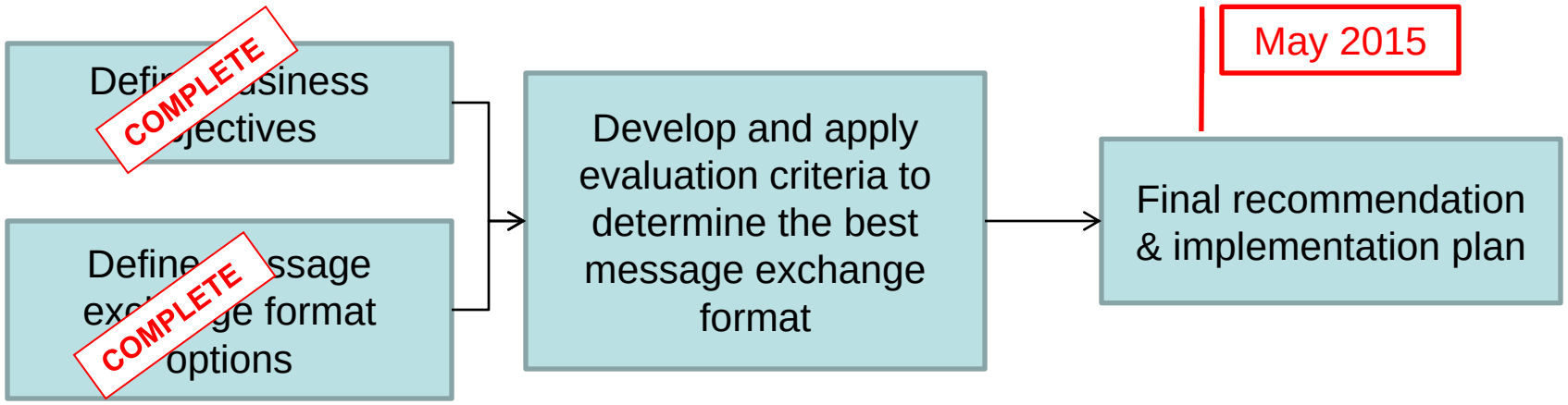
CH2.6.2 Global Incident Reports and Recalls

CH2.6.3 Incident and Recall Rates

CH2.7 Other Submission Context Information

Business Case

- Implementation of any harmonized e-submission format will require investment of resources for both regulators and industry
- A formal business case document will recommend the format to be implemented for devices



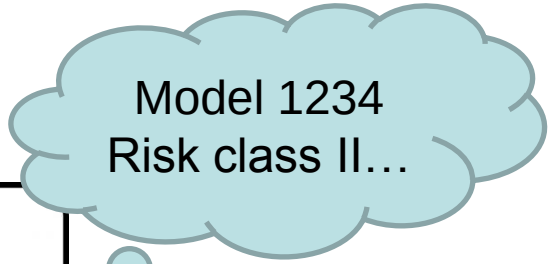
High Priority Business Objectives

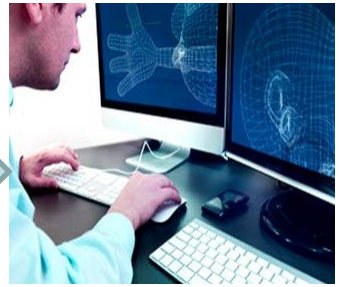
Challenge Area	Objective	Impact
No harmonized common message exchange format for submissions	Identify a single technical exchange format, or a solution to efficiently support multiple technical exchange formats across different IMDRF regulators	Industry
Managing Submission & Content Lifecycle	Enable a clear view to the lifecycle of Application content over time, as well as the ability to quickly see the most current version of an Application.	Regulators and Industry
	Include additional metadata on submission content for better discovery in the future (i.e., TOC headings and keywords).	Regulators
	Enable regulators and industry to consistently and clearly identify / communicate how a submission relates to previous applications	Regulators & Industry

Challenge Area	Objective	Impact
Use of Paper by some stakeholders as a preferred format in management of submissions	Enable efficient access (for appropriate parties) to information provided electronically in submissions	Regulators & Industry
Submission log-in / Acknowledgements	Enable reduction of resources / time required for manual login (data entry, record creation) of submissions	Regulators

5. CDE

- Defining product information that could be submitted in a structured way at each point in the regulatory lifecycle
- Each submission type may require different information
- But we have to be able to identify all the submissions that relate to the same product
- UDI is one point in the post-market lifecycle…..





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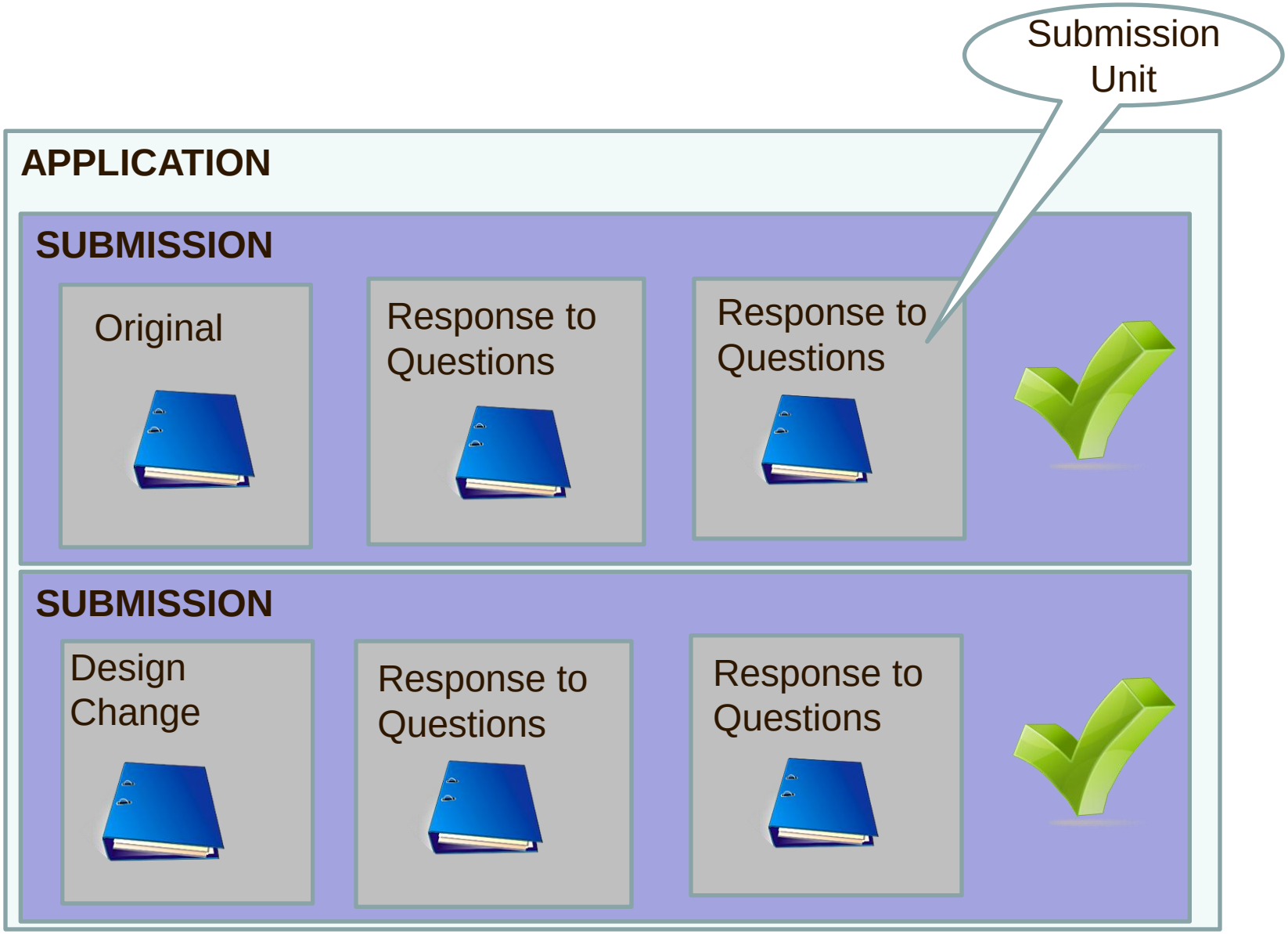
Backup Slides

RPS Submission Hierarchy

Submission Unit: Each package of submitted information that comes in together – the “fed-ex box”

Submission: The collection of submission units upon which a regulatory action is taken

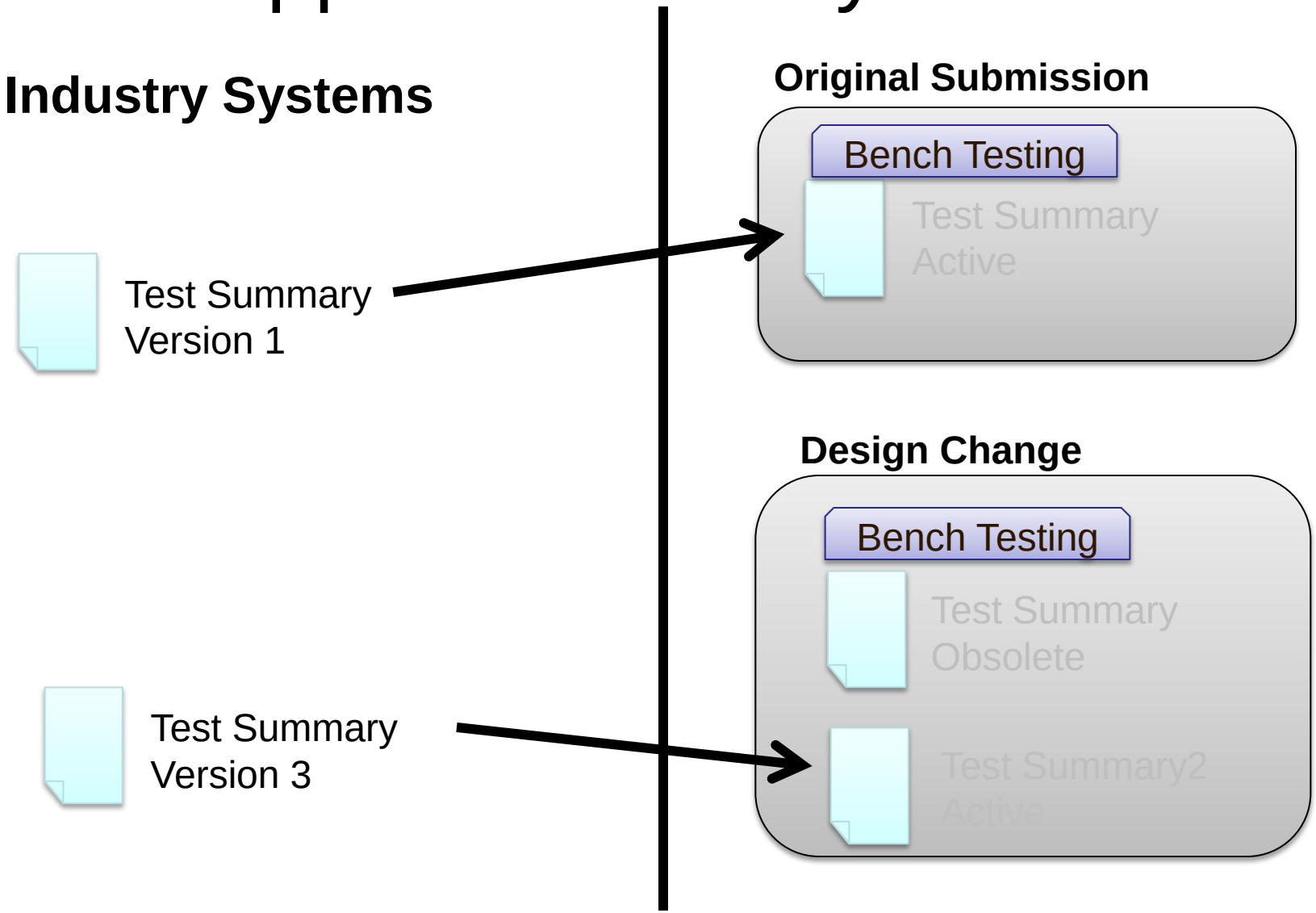
Application: A collection of related Submissions


Submission Unit
APPLICATION
SUBMISSION
Original
Response to Questions
Response to Questions
SUBMISSION
Design Change
Response to Questions
Response to Questions

Example Regulator Mapping

APPLICATION		SUBMISSION
	PMA 510(k) IDE HDE	Original PMA, 510(k), IDE, or HDE PMA, IDE and HDE Supplements Annual Reports Periodic Reports
	Notification Application Registration Application	Primary Submission Amendment for Change Request Renewal Request Cancel Request
	License Investigational Testing Special Access	License Application License Amendment License Renewal Investigational Protocol Amendment

Application Lifecycle



Submission Views

Lifecycle allows regulators to use different views of an Application to aid in their review

For Example:

- **Life Cycle View** - displays every file ever submitted
- **Current View** – displays only active files within the Application
- **Regulatory Activity View** – displays all files within a Submission

Life Cycle View

CH.3.3 – Non-Clinical Studies

CH.3.3.1 - Physical and Mechanical Characterization – Device Study A, Study#002, December 2010

CH.3.3.1.1 – Summary, STUDY A

Study A Summary (Original Submission) OBSOLETE

Study A Summary (version2, response to questions) OBSOLETE

Final version from initial approval

Study A Summary (version3, revised, response to questions) OBSOLETE

CH.3.3.1 - Physical and Mechanical Characterization – Device Study B, Study#111, December 2013

CH.3.3.1.1 – Summary, STUDY **B**

Summary from a 2nd study to support a line extension

Study B Summary (Line Extension) ACTIVE

CH.3.3.1 - Physical and Mechanical Characterization – Device Study C, Study#321, December 2015

CH.3.3.1.1 – Summary, STUDY **C**

New study to support design change. Study A no longer applies

Study C Summary (Design Change) ACTIVE

Regulatory Activity View

CH.3.3 – Non-Clinical Studies

CH.3.3.1 - Physical and Mechanical Characterization –
Device Study A, Study#002, December 2010

CH.3.3.1.1 – Summary, STUDY A

Study A Summary (Original Submission) OBSOLETE

Study A Summary (version2, response to questions) OBSOLETE

Study A Summary (version3, revised, response to questions) OBSOLETE

Original Submission

CH.3.3.1 - Physical and Mechanical Characterization –
Device Study C, Study#321, December 2015

CH.3.3.1.1 – Summary, STUDY **C**

Study C Summary (Design Change) ACTIVE

Design Change (supplement 3)