



**IMDRF**

International Medical  
Device Regulators Forum

# Regulated Product Submissions (RPS)

**Nancy Shadeed**

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

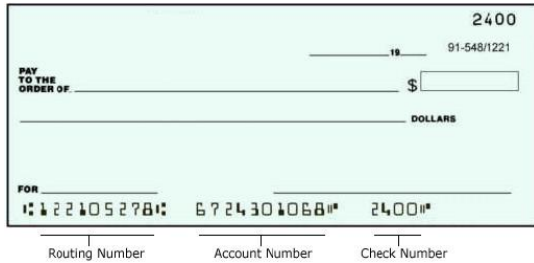
# Paying with cash



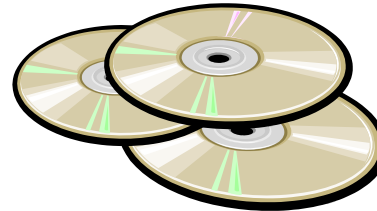
# Paper Submissions



# Handwritten checks



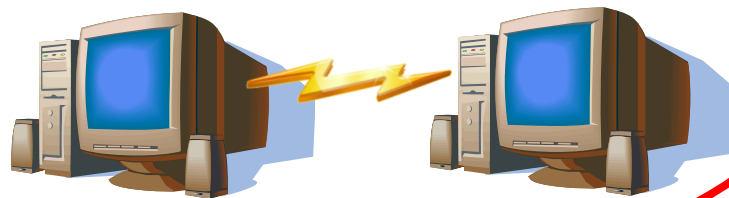
# Submissions on CD or Uploaded Documents



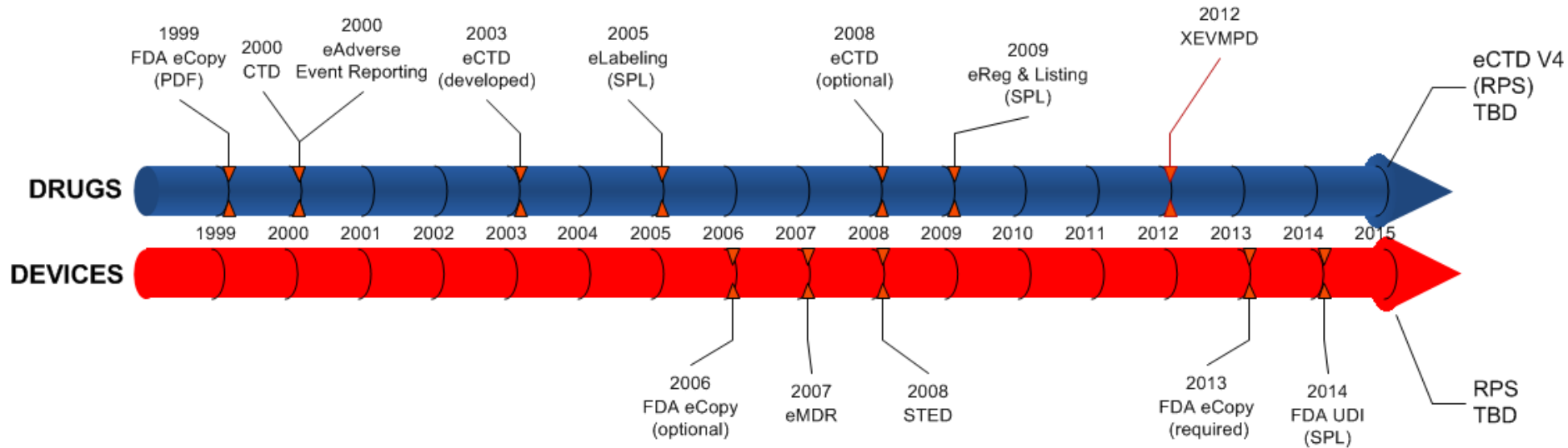
# Online banking



# 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

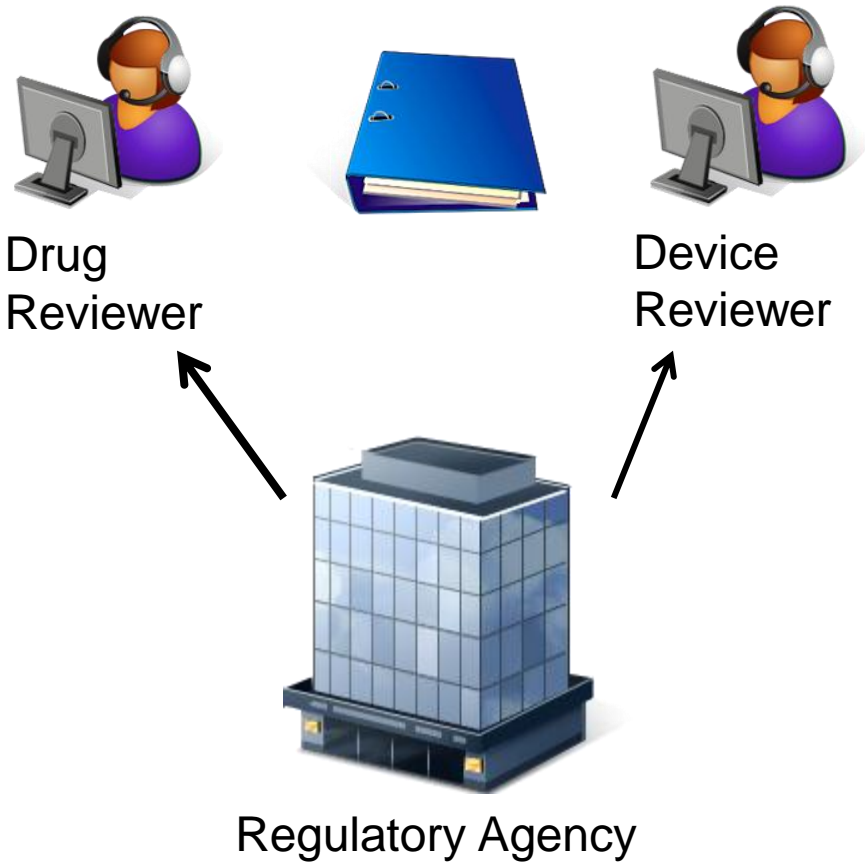


# IMDRF

International Medical  
Device Regulators Forum

## 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





# IMDRF International Medical Device Regulators Forum

## RPS Stakeholders



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



Multiple Software Vendors

Parexel  
 GlobalSubmit  
 Lorenz  
 Extedo  
 CSC



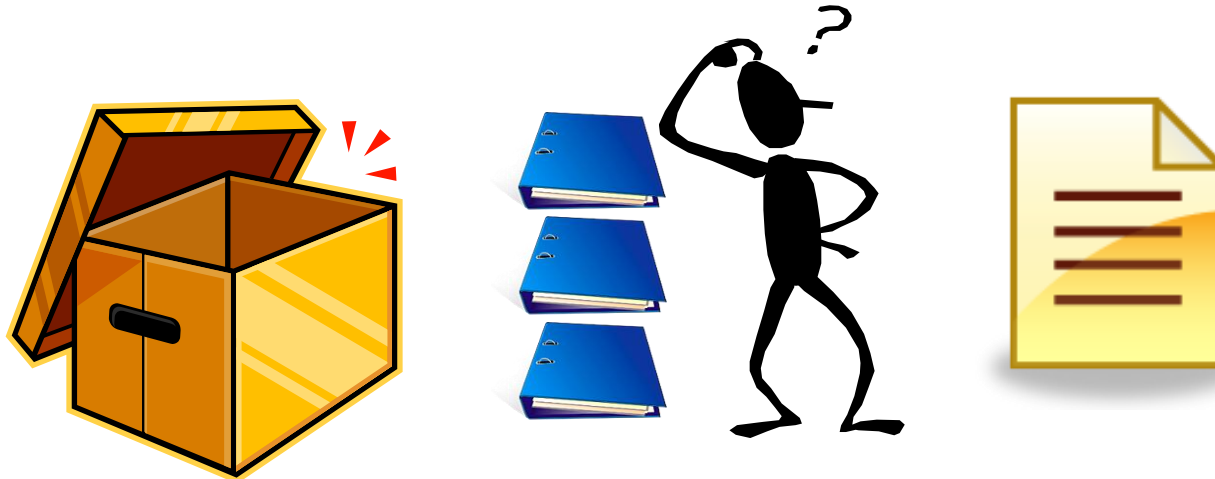
US (CDER)  
 Japan (MHLW)  
 Australia (TGA)  
 EU (EMA)  
 Canada (HC)  
 Industry Associations



## 2. What is RPS?

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

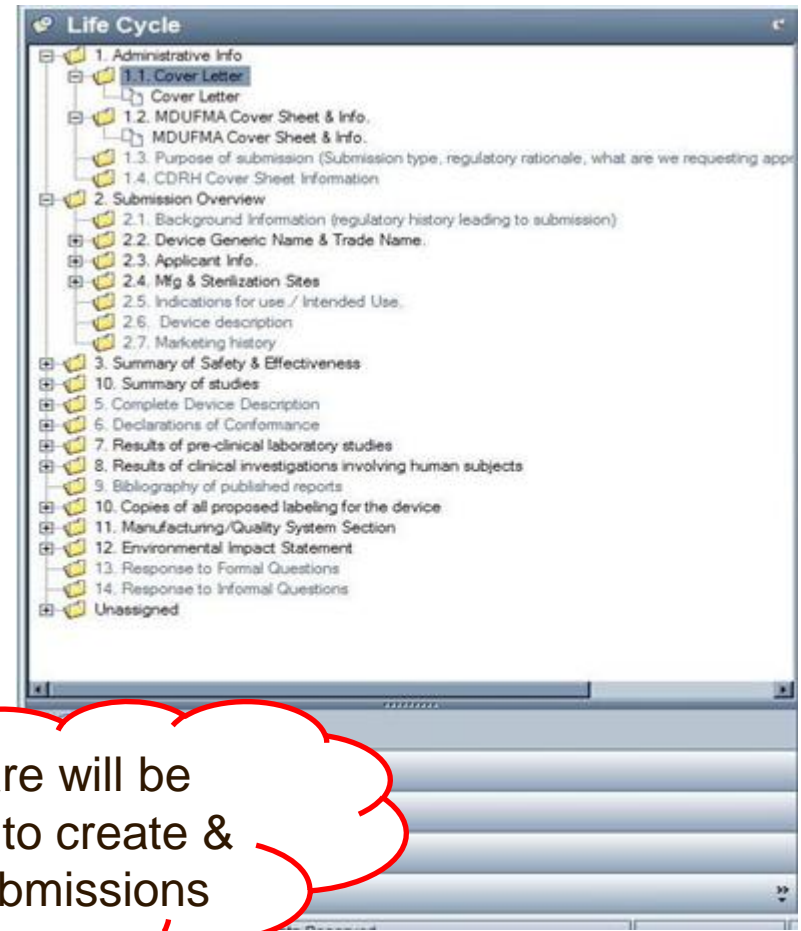
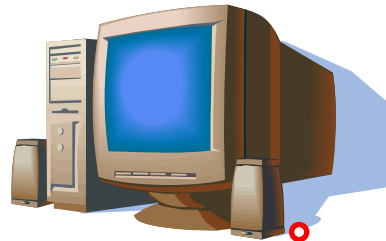
- Provides context for how the submission should be routed and reviewed (i.e. this is a supplement to an existing PMA)
- Allows a lifecycle of submission content (i.e. Document A replaces Document B)
- Acts as a “packing slip” for submissions





# IMDRF International Medical Device Regulators Forum

The RPS standard covers just the XML file

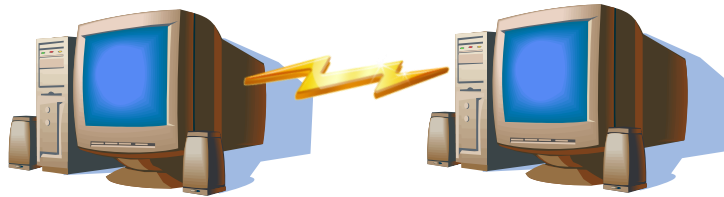


Software will be required to create & view submissions





## 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

CH2.5.1 Intended Use / Intended Purpose / Intended User

CH2.5.3 Indications for Use

CH2.5.4 Pediatric Use

C

CH2.6.1 Global Market History

CH2.6.2 Global Incident Reports and Recalls

C

CH2.7 Other Submission Context Information

# Canada Class III, New License View

CH2.2 General Summary of Submission

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

CH2.5.1 Intended Use / Intended Purpose / Intended User

CH2.5.2 Intended Environment for use

CH2.5.3 Indications for Use

CH2.5.5 Contraindications For Use

CH2.6.1 Global Market History

CH2.6.2 Global Incident Reports and Recalls

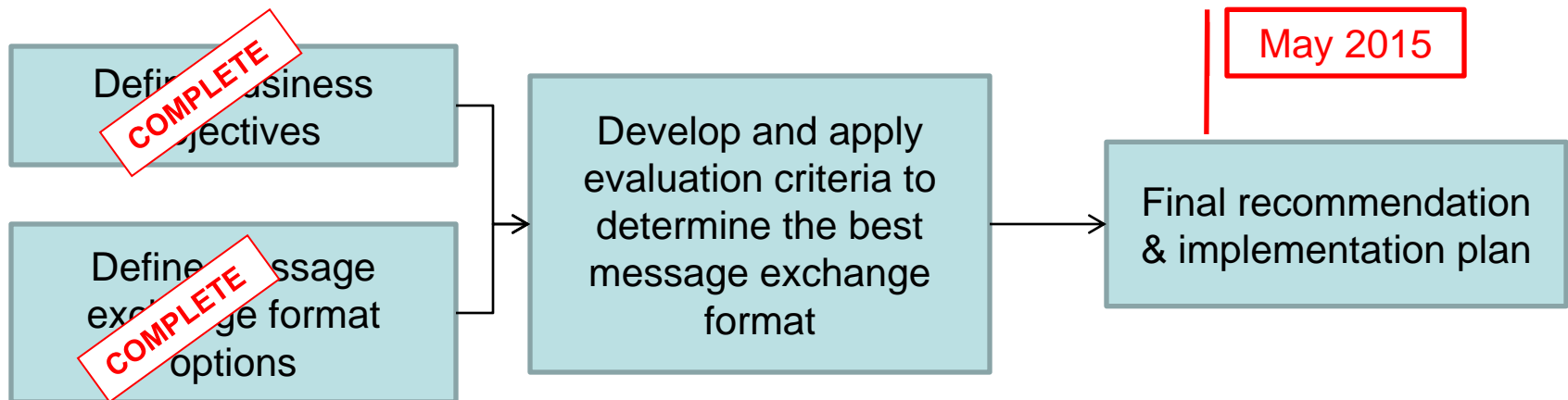
CH2.6.3 Incident and Recall Rates

CH2.7 Other Submission Context Information



# 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



# IMDRF

## International Medical Device Regulators Forum

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.....

Model 1234  
Risk class II...





# IMDRF

International Medical  
Device Regulators Forum

## FOR ADDITIONAL INFORMATION:

Nancy Shadeed

[Nancy.Shadeed@hc-sc.gc.ca](mailto:Nancy.Shadeed@hc-sc.gc.ca)

Karin Sailor

[karin.sailor@medtronic.com](mailto:karin.sailor@medtronic.com)

Maria Carleton, TOC Lead

[imdrf.toc@gmail.com](mailto:imdrf.toc@gmail.com)





**IMDRF**

International Medical  
Device Regulators Forum

# Backup Slides



**IMDRF**

International Medical  
Device Regulators Forum

## 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

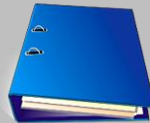
## APPLICATION

### SUBMISSION

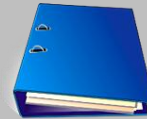
Original



Response to  
Questions



Response to  
Questions

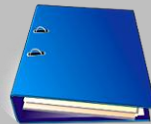


### SUBMISSION

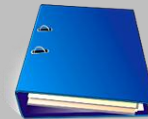
Design  
Change



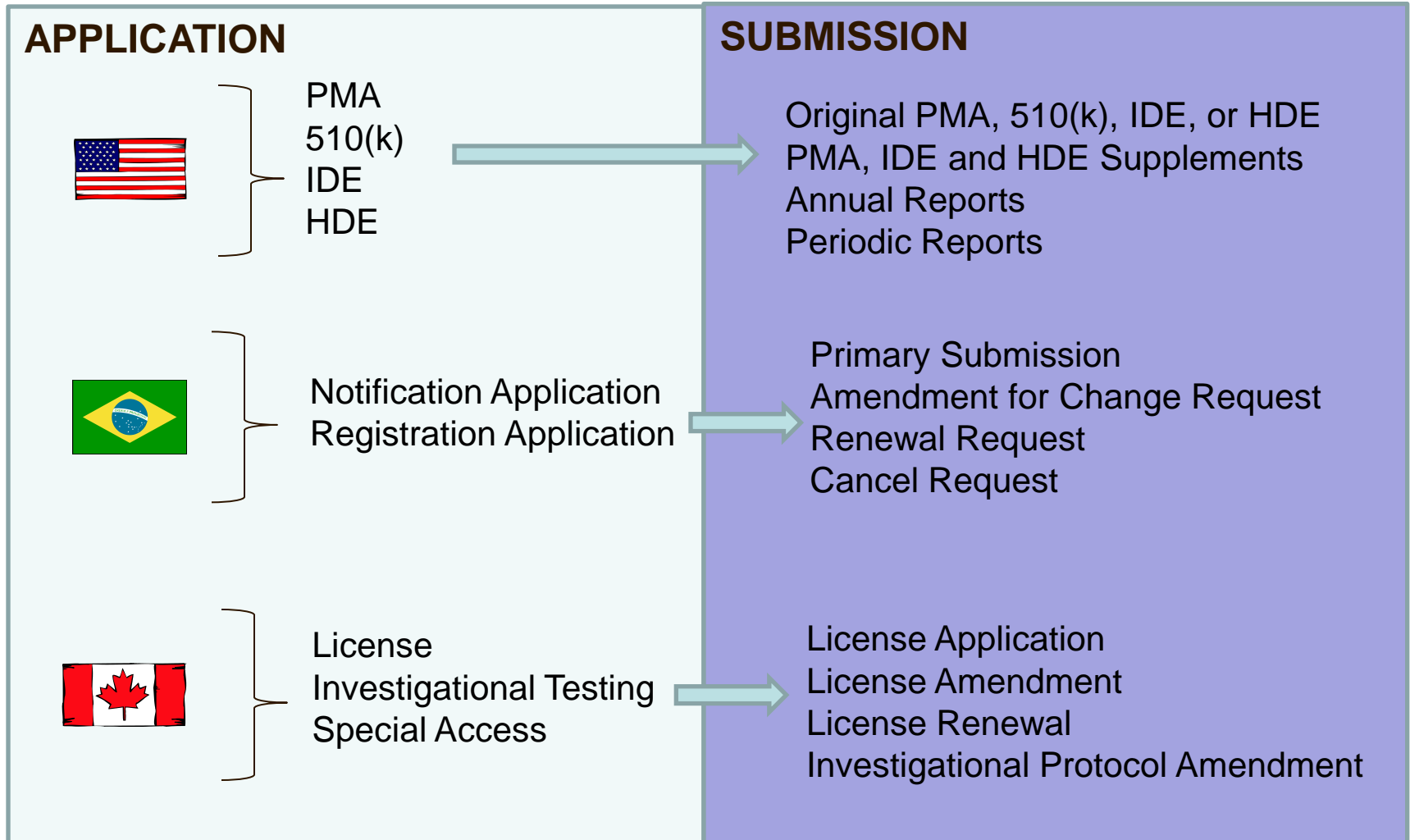
Response to  
Questions



Response to  
Questions



# Example Regulator Mapping



# Application Lifecycle

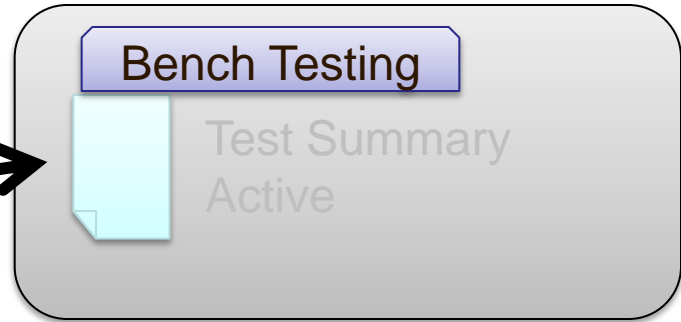
## Industry Systems



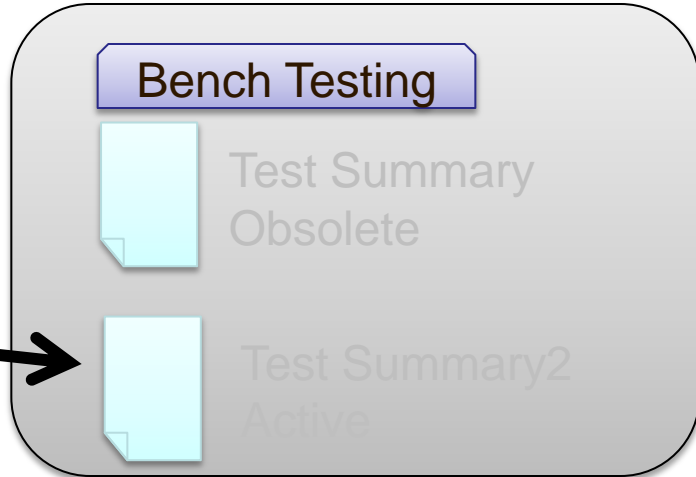
Test Summary  
Version 1



### Original Submission



### Design Change



Test Summary  
Version 3





## 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**



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

**Final version from initial approval**



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



CH.3.3.1.1 – Summary, STUDY B



Study B Summary (Line Extension) **ACTIVE**

**Summary from a 2<sup>nd</sup> study to support a line extension**



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**

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

# 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)