Aquila's Lunch-And-Learn
RPS – The Future of eCTD

Host: Josh Boutwell, MBA, RAC
CEO Aquila Solutions, LLC

Disclosure Note

This free training session will be placed on Aquila's website after the session is complete. The video may include your webex name, your questions and any answers.

By participating you agree to allowing Aquila to publish this information.

Joshua Boutwell, MBA RAC

15 years of experience in research, Regulatory Affairs, Regulatory Operations and Publishing
Founded Aquila Solutions in 2010

Today's Topics

1. **What is RPS?**
2. Differences between eCTD and RPS
3. Major Components to RPS
4. New Features
5. Implementation
6. Timeline
7. Questions
8. The Next Lunch-And-Learn

What is RPS

Regulated **P**roduct **S**ubmission

Intended to replace eCTD and allow:

2 way communication

All regulated product types including Medical Devices

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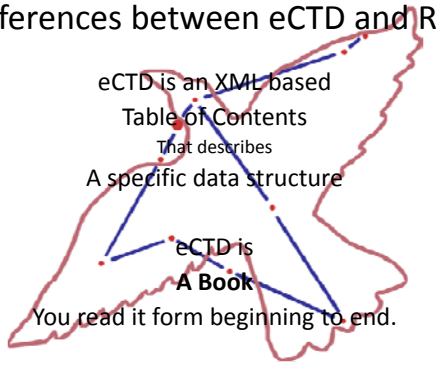
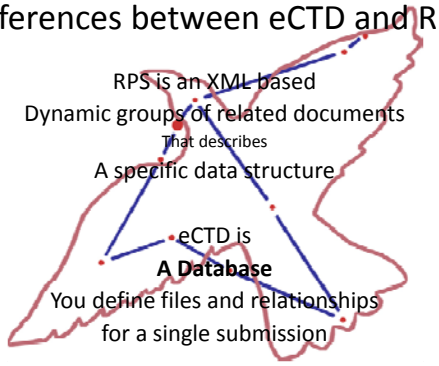
Differences between eCTD and RPS



eCTD is an XML based
Table of Contents
That describes
A specific data structure

eCTD is
A Book
You read it form beginning to end.

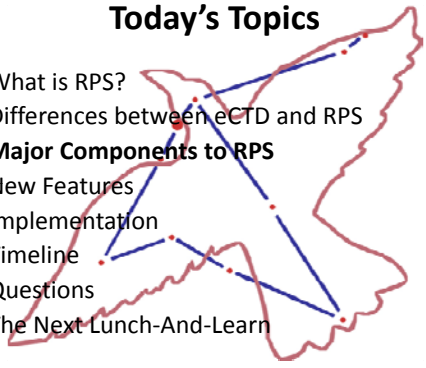
Differences between eCTD and RPS



RPS is an XML based
Dynamic groups of related documents
That describes
A specific data structure

eCTD is
A Database
You define files and relationships
for a single submission

Today's Topics



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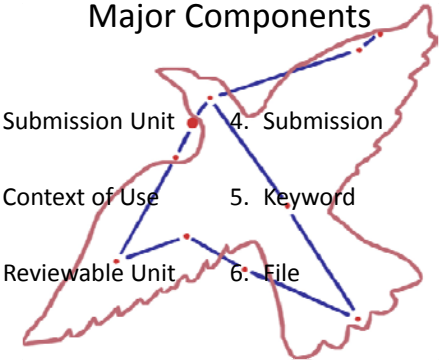
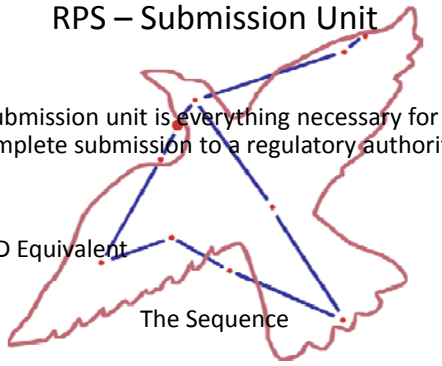
Major Components



1. Submission Unit
2. Context of Use
3. Reviewable Unit
4. Submission
5. Keyword
6. File

RPS – Submission Unit

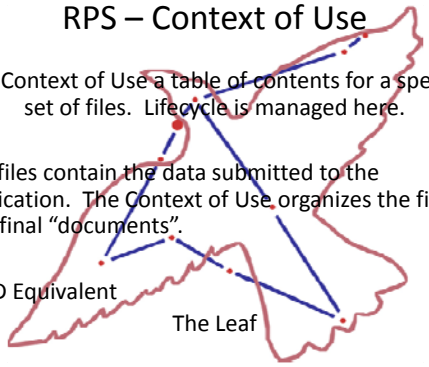


A Submission unit is everything necessary for on complete submission to a regulatory authority

eCTD Equivalent

The Sequence

RPS – Context of Use



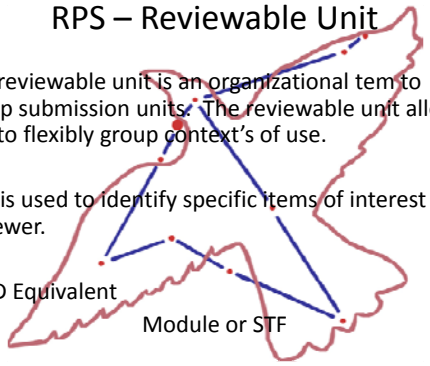
The Context of Use a table of contents for a specific set of files. Lifecycle is managed here.

The files contain the data submitted to the application. The Context of Use organizes the files into final "documents".

eCTD Equivalent

The Leaf

RPS – Reviewable Unit



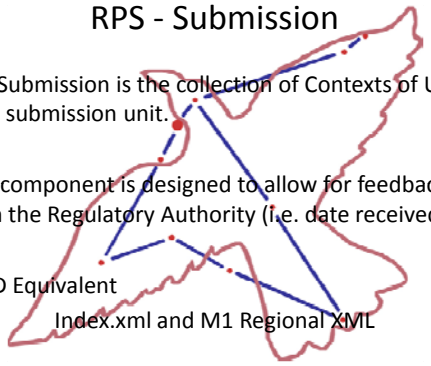
The reviewable unit is an organizational tem to group submission units. The reviewable unit allows you to flexibly group context's of use.

This is used to identify specific items of interest to a reviewer.

eCTD Equivalent

Module or STF

RPS - Submission



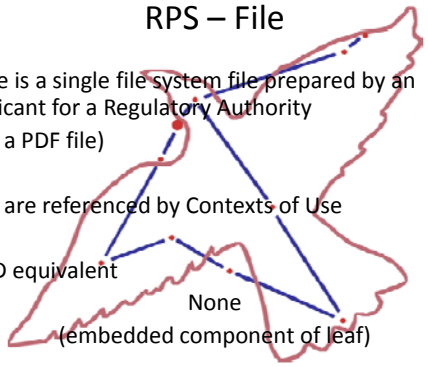
The Submission is the collection of Contexts of Use for a submission unit.

This component is designed to allow for feedback from the Regulatory Authority (i.e. date received)

eCTD Equivalent

Index.xml and M1 Regional XML

RPS – File



A File is a single file system file prepared by an applicant for a Regulatory Authority (e.g. a PDF file)

Files are referenced by Contexts of Use

eCTD equivalent

None

(embedded component of leaf)

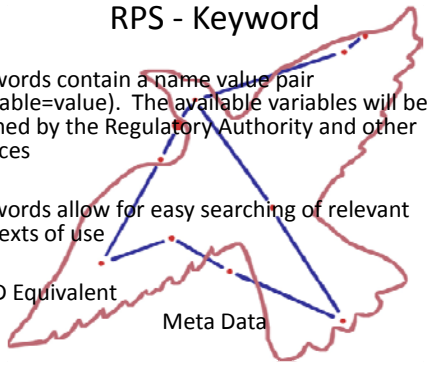
RPS - Keyword

Keywords contain a name value pair (variable=value). The available variables will be defined by the Regulatory Authority and other sources

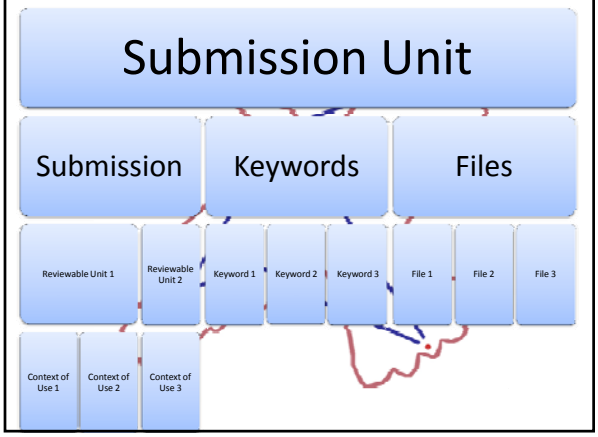
Keywords allow for easy searching of relevant contexts of use

eCTD Equivalent

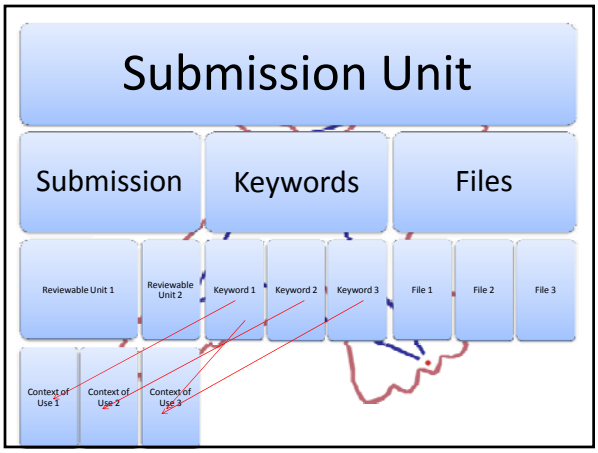
Meta Data

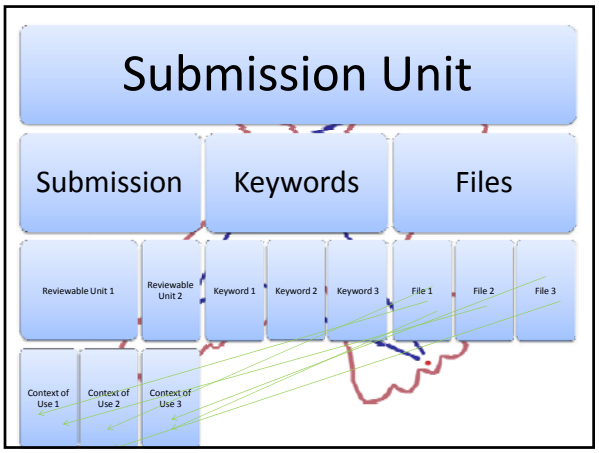


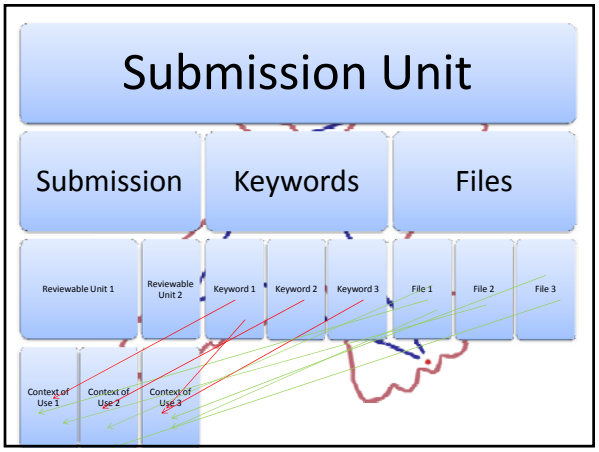
Submission Unit



Submission Unit




Submission Unit
Submission
Keywords
Files
Reviewable Unit 1
Reviewable Unit 2
Keyword 1
Keyword 2
Keyword 3
File 1
File 2
File 3
Context of Use 1
Context of Use 2
Context of Use 3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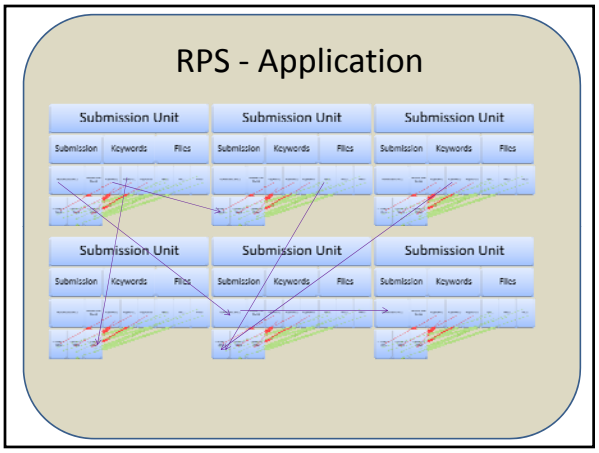
RPS - Application
Submission Unit
Submission Unit
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Submission Unit
Submission Unit
Submission Unit

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New Features

Minimal DTD definitions
Structure is defined by lists of variables provided by the regulatory authority.

Absolute flexibility
There are no required naming or folder structures built into the standard itself

Option of Regulatory Authority Response Messages
Submission dates and potentially even response letters and other communications.

Updated Features

MD5 is retired
Security vulnerabilities discovered recently means the SHA1 or SHA256 is recommended

Leaf id is now universal and unique
Leaf ids are now applied to every single element and are now UUID's in the format XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX

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Implementation

Major System Updates
Contact your Vendor at least 1 year before RPS implementation

Workflow Updates
The flexibility of RPS means that pre-planning your submission becomes even more difficult

Regulatory Publisher
RPS is essentially a database. If used well it can save a huge amount of time and money. If used poorly it can be a disaster. It will take a highly technical regulatory publisher to manage an RPS.

Training
There will be a huge demand for RPS training. Medical Devices (50% of the market) will now have a new pure electronic format with no experience.

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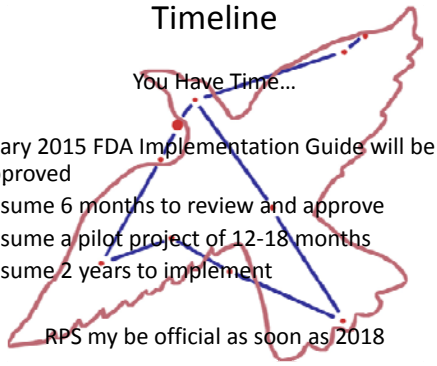
Timeline



You Have Time…

January 2015 FDA Implementation Guide will be approved

- Assume 6 months to review and approve
- Assume a pilot project of 12-18 months
- Assume 2 years to implement

RPS my be official as soon as 2018

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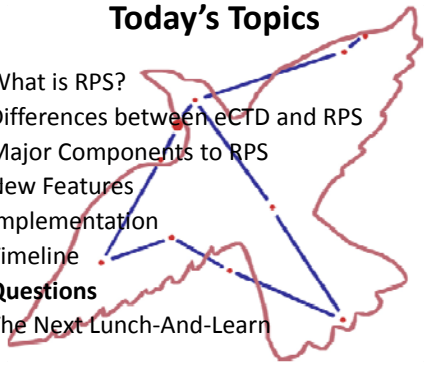

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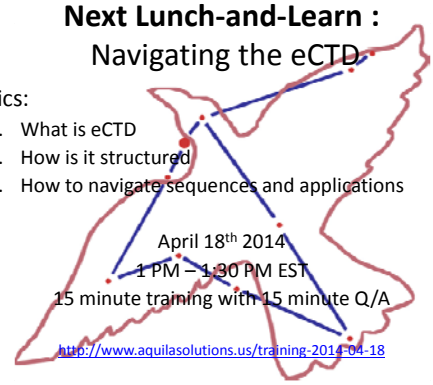
Next Lunch-and-Learn : Navigating the eCTD



Topics:

1. What is eCTD
2. How is it structured
3. How to navigate sequences and applications

April 18th 2014
1 PM – 1:30 PM EST
15 minute training with 15 minute Q/A

http://www.aquilasolutions.us/training-2014-04-18