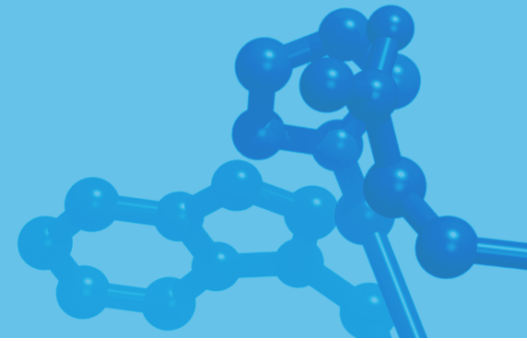


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“Outsourcing”

Nilda Badea-Patterson

Operations Specialist, Regulatory Affairs

CEREXA

Small Pharmaceutical Organization Characteristics

- Small Product Pipeline
- Approximately 200 Employees
- Virtual Company
- Three FTEs in Regulatory
 - 1 VP; 1 Dir RA; 1 RA Coordinator
- Two I.T. Generalists
- Two QA EDMS Admin

eCTD Outsourcing Requirements: Internal

- Support initial IND submission and following amendments
- Within budget including amendments and consultation
- Able to meet projected timelines (project specific)
- Minimal impact on existing IT infrastructure and resources
- Easy to convert from outsourcing to bringing software in house and implementing system

eCTD Outsourcing Requirements: External/Vendor

- Set Up Demonstration of software
- Discuss expectations from both company & vendor providing services
- Agree upon timelines and delivery of material
- Outsourcing provider focused on eCTD
- Part 11 compliant

eCTD Outsourcing Requirements: Responsibility and Control

- Have control over eCTD submissions
 - Maintain control of eCTD but allow vendor to contribute to the project process
 - Maintain quality of work
 - Maintain projected timelines – work well with vendor and deliver on time
 - Maintain open communication at all times
 - Update any changes to vendor ASAP

Solution: “Outsourcing” Approach

- Outsourcing as a Service:
 - Dedicated Project Manager
 - ISI provided initial test with agency to allow for our eCTD IND submission
 - Fee’s were discussed and agreed upon at initial kick off meeting
 - Due to the lack of man power outsourcing allowed for company to share responsibilities
 - Outsourcing allowed for vendor to provide IT infrastructure and validation
 - Client/Vendor controls submission activities and user accounts

Benefits of Outsourcing

- **Flexibility**
 - Outsourcing allowed for the eCTD to be built as well as company focusing on also purchasing the software
 - Allowed for us to maintain other eINDs while compiling our first eCTD with ISI
 - Allowed for us to grasp a better understanding of eCTD requirements
 - Allowed for us to familiarize ourselves with eCTD processes
- **Speed**
 - Time from decision to submitting the eCTD = 11/12 weeks
 - First proposal through contract finalization = 4 weeks
 - Implementation services through transfer of docs = 4 weeks
 - Compiling and submitting = 3 to 4 weeks
- **Compliance**
 - Shared compliance ownership with vendor and client

Conclusion

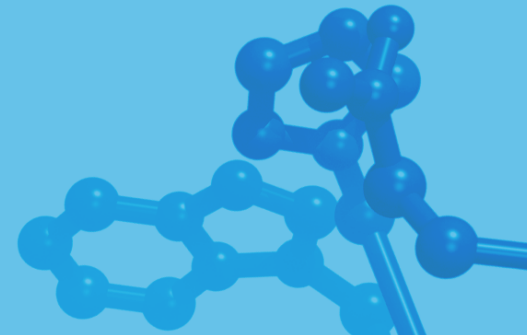
- Outsourcing an initial eCTD is a good solution for small pharmaceutical companies
- The benefits allow for better time management of project as well as a well compiled eCTD submission
- The options of outsourcing being flexible, fast to implement, and compliant allow for companies to continue focusing on other in house projects while compiling an eCTD submission
- Last but not least working with ISI was a great experience and their outsourcing capabilities were outstanding

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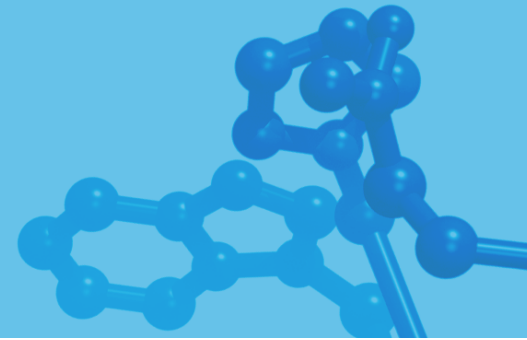
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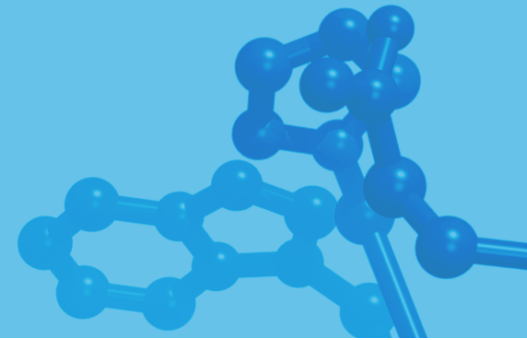


eCTD Publishing Software Purchasing & Installing

Steve Sharkey
Sr. Program Manager
Information Technology & Informatics
Theravance, Inc.

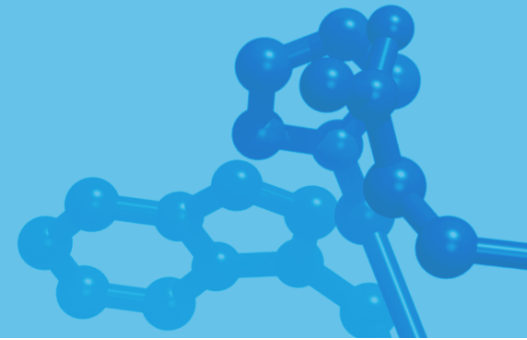


- **Rationale for Purchasing eCTD Publishing Software:**
 - **FDA Mandate:** As of January 1, 2008 all electronic applications (NDA, IND) are required in eCTD format.
 - Total control over the process and the surrounding activities.
 - Desire not to outsource / sub-contract a core process
 - Build in-house knowledge and expertise
 - Owning eCTD publishing software is the most cost effective and efficient solution for all future submissions (NDA, IND).



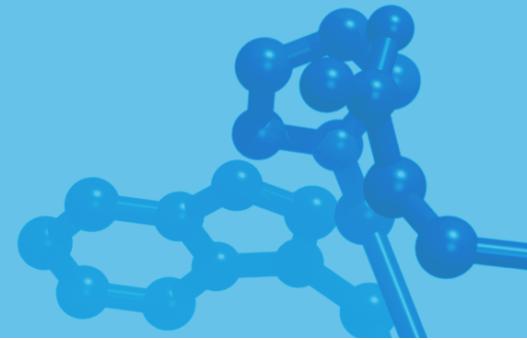
Internal Infrastructure to Support eCTD Application

- Theravance, Inc.
 - Approx. 300+ Employees
- Regulatory Affairs:
 - Preferred Approach (in-house application)
 - Approx. 4 Employees (Publishing)
- IT Department:
 - 20 Employees
 - Development Informatics Group
 - Program Manager & Application Specialist
 - Infrastructure Group
 - Technology Validation Manager

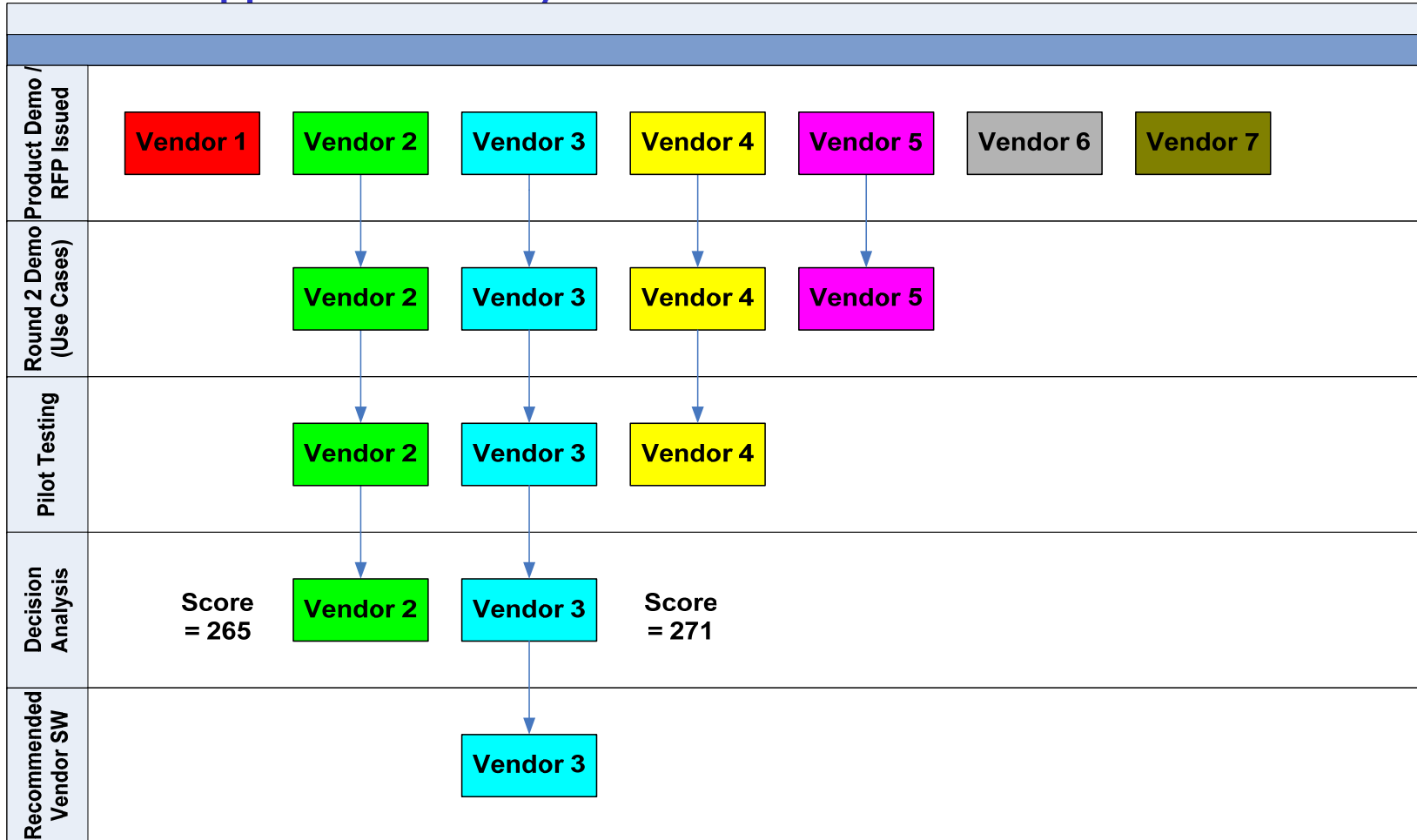


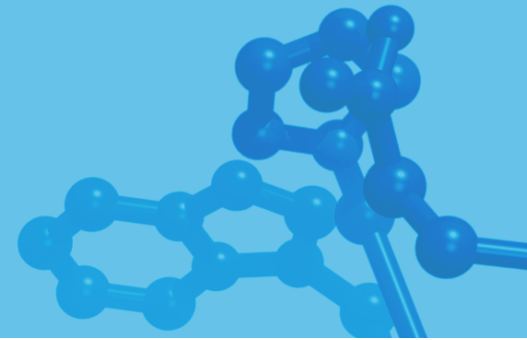
Project Team - Roles & Responsibilities Identified

- Project Sponsors (Division Heads - RA & IT)
- Project Owners (Department Directors / Mgrs.)
- Project Manager (Steve S.)
- Project Participants
 - IT: Tech Req./Needs (HW / Storage / Integration), Install
 - RA: User/Business Req., SOP's, SW Pilot
 - Quality: Vendor Verification, Document Mgmt.
 - Validation: Validation Plan, IQ, OQ, PQ
 - Purchasing: Contract Negotiation



Process Applied to Identify Best SW Solution:





Decision Analysis / Weights:

Decision Analysis

Clarify Purpose: <Insert Here>

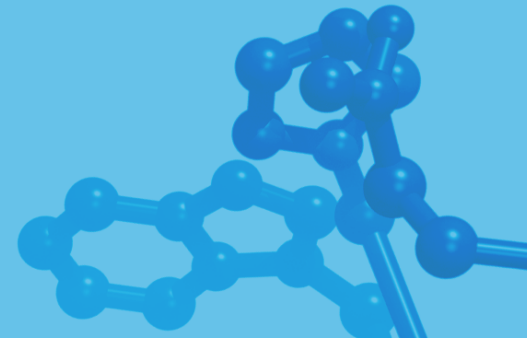
State the Decision

Objectives and Measures

	MUSTS	WANTS	Vendor 2		Vendor 3	
			Performance	Weighted Score	Performance	Weighted Score
1 Vendor SW offers IQ/OQ validation scripts and/or services	X		X	Limited package and no support services	X	X
2 Provides context sensitive direction regarding corrective actions (validation reports, etc.).		6	8	Navigate to issue...	10	Links directly to issue...
3 Detects and alerts to changes in source documents already built into submission (version control)		6	3	No continuous auto check	10	Continuous auto check
4		6	8		8	
5		9	9		7	
6		6	10		5	
7		2	5		5	
8	X		X		X	
9	X		X		X	
10	X		X		X	

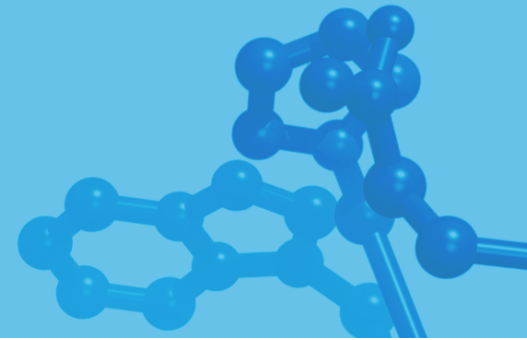
Weighted sum **265**

Weighted sum **271**



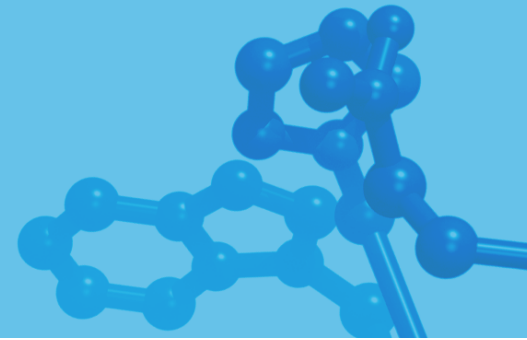
Decision Analysis / Risks:

Consider Risks		Make Decision	
First Highest Performing Alternative Vendor 3		Second Highest Performing Alternative Vendor 2	
		List the alternative you choose	
		Vendor 3	
If	U.S. based company. Does not have a large eCTD U.S. customer base.	If	Off-shore technical support (Europe). This model could pose support and/or response time issues.
Then		Then	
If		If	
Then		Then	



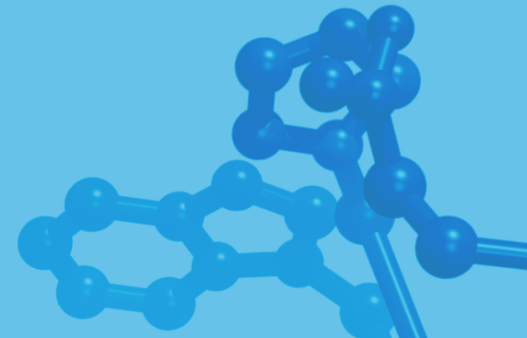
Things to Consider:

- **Implementation Effort: RA / IT / Validation**
 - Resources (time/manpower/expertise), Costs, etc.
- **Processes & SOP's: Develop and/or Redefine**
 - Submission Ready Documents
 - Regulatory Affairs / eCTD Publishing
 - Technical / Application Support / DMS Integration
- **Application: Upgrades / Change Control**
 - Ability to Support the Application (ongoing)
- **RA Expertise / Knowledge**
 - Super User / Strong Understanding the Application

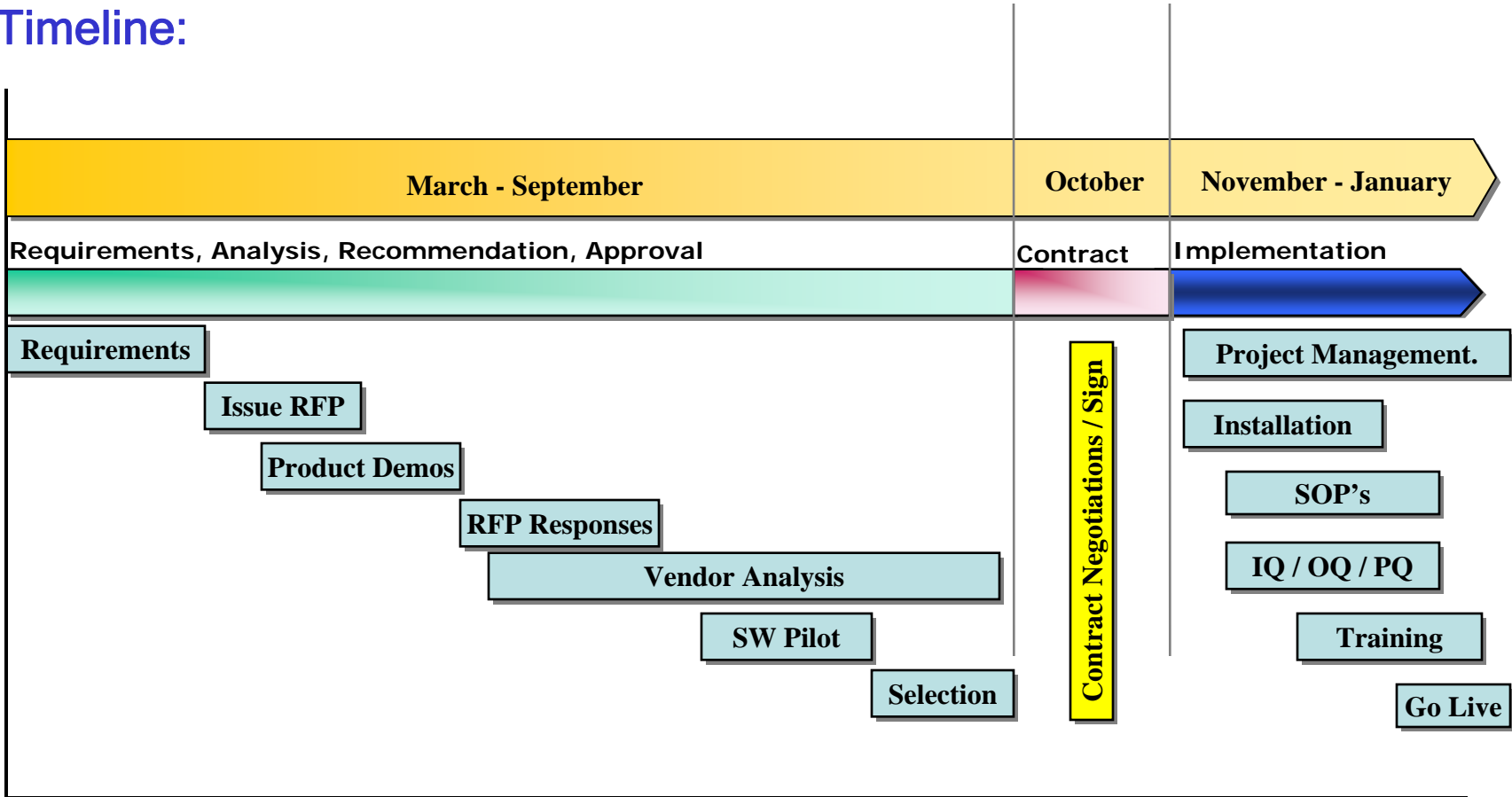


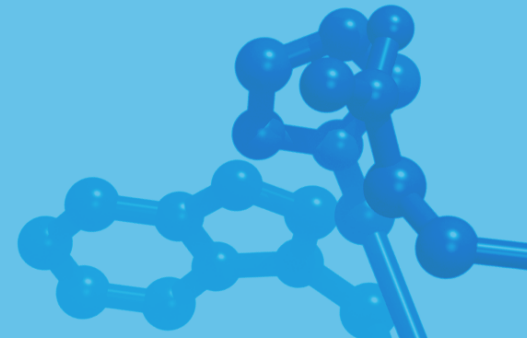
Things to Consider:

- Vendor Technical Support
 - Response to questions, issues, etc.
 - Crunch time
- Upgrades / Patches
 - Frequency of Releases / Ability to Assess Impact
- Validation Efforts for Upgrades / Patches
 - Resources to review & perform
- FDA Regulations / Changes
 - Vendor's ability to respond / implement changes



Timeline:





Wrap Up :

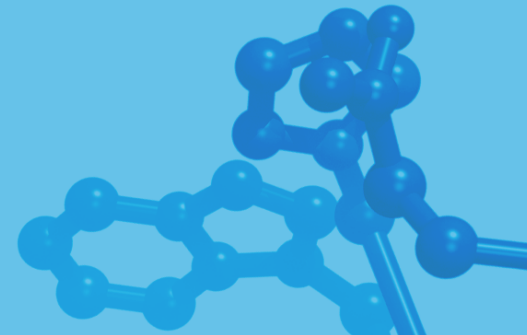
- Talk to Vendor References
 - Meet with Users / IT Team, etc.
- Installation Checklist (Vendor & Internal)
- Holistic View of Your Operation
 - Need to consider all business areas impacted
 - Ability modify behavior
 - Supporting the application
 - Time
 - Resources (people / \$\$)
 - Submitting to FDA (Gateway)
 - Output verification / tool

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“Renting” eCTD Software

Emily Onkka
Associate Director,
Regulatory Operations and Submissions
Cadence Pharmaceuticals, Inc.

Small Pharmaceutical Organization Characteristics

- Small Product Pipeline
- Approximately 45-50 Employees
- Virtual Company
- Eight FTEs in Regulatory
 - 1 VP; 1 Dir RA; 1 Mgr RA
 - 1 AD RO; 2 Proj. Mgr RO; 2 Publishers
- Two I.T. Generalists
- One QA EDMS Admin

Defining System Requirements



eCTD Solution Requirements: Software

- Support multiple large filings within 12-18 months
- Minimal impact on existing IT infrastructure and resources
- Within budget including implementation and validation services
- Fast to get up and running

eCTD Solution Requirements: Software

- Role-based software
 - User Admin manages user permissions and accounts
- Web-based software
 - More than one user can build and work on one submission at the same time
- Scalable
- Software provider focused on eCTD
- Part 11 compliant

eCTD Solution Requirements: Responsibility and Control

- Have control over eCTD submissions
 - Outsource scenarios may drive timelines
 - Do not want to need vendors for all eCTD submissions
- Use internal resources as much as possible
 - Augment staff to support workload peaks

Solution: “Rental” Approach

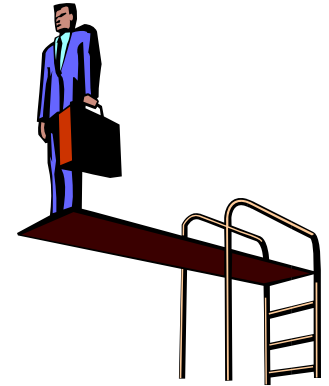
- Software as a Service (SaaS):
 - Dedicated hardware and software
 - One time set-up fee, monthly rental fee
 - Shared system ownership
 - Vendor provides IT infrastructure and validation
 - Client controls submission activities and user accounts



Software as a Service Benefits

- Flexibility
 - SaaS facilitates staff augmentation
 - Vendor can access submissions directly and augment publishing staff as needed
- Speed
 - Time from decision to pilot eCTD = 24 weeks
 - First proposal through contract finalization = 8 weeks
 - Implementation services through training = 8 weeks
 - PQ validation, process development, pilot = 8 weeks
- Compliance
 - Shared compliance ownership with vendor and client

Risks of SaaS



- System performance
 - Slow or interrupted internet connection
 - Slow download and upload of submission/documents
- Risk impact
 - Delay submission deadline
- Potential safeguard/mitigation
 - Pre-test system performance
 - Build minimum performance metrics into contract
 - Increase bandwidth/dedicated line
 - Build extended upload/download times into project timelines

Risks of SaaS

- Business Continuity
 - Failures in internet connection
 - Failure of hardware at vendor location
 - Software issues
 - Data corruption
- Risk impact
 - Delay submission deadline
- Potential safeguard/mitigation
 - Support metrics written into contract
 - In worst case scenario (ie, system totally inaccessible), vendor can generate submission
 - Backup/restore disaster recovery procedures in place to protect client

Risks of SaaS

- Validation
 - Do client and vendor policies match?
 - SaaS environment is not a “typical” validation environment for testing
- Risk Impact
 - Client will not have sufficient documentation to support the validated status of the system during an agency audit
- Potential safeguard/mitigation
 - Audit the vendor
 - Review documentation
 - Document plan for support and maintenance
 - Track system changes

Risks of SaaS

- New eCTD Solution
 - Very few clients in production
 - System details and service documentation in development
- Risk Impact
 - Client and vendor will learn together
- Potential safeguard/mitigation
 - Open communication with project manager

Conclusion

- Renting eCTD software is good for small pharmaceutical companies
- The benefits outweigh the risks
 - Many of the risks have feasible safeguards/mitigations
- Option is:
 - Flexible
 - Fast to implement
 - Compliant