

Transitioning to Electronic-Only Submissions in the MRP, DCP and National Procedures:

A Case Study for a Small Company Working with a Service Organisation

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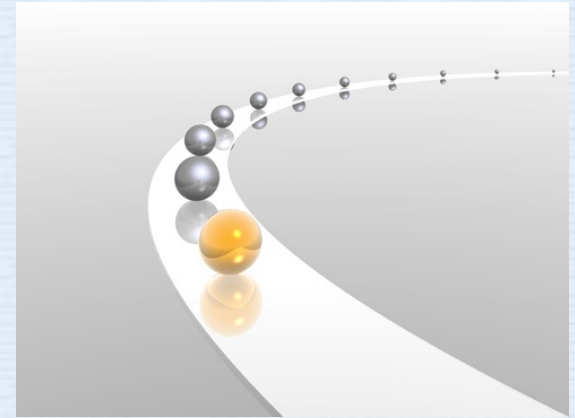
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Topics

- eCTD components & intro to case study
- Considerations for outsourcing eCTD compilation
- Managing a DCP with a service provider



Introduction Statement

- Generally, there is no difference
 - Between small and large companies regarding the eCTD requirements & main processes
- However
 - Specific factors especially at small companies impact the eCTD implementation strategy
 - Not only “real” SMEs (often biotech using the CP) are considered as small in this context

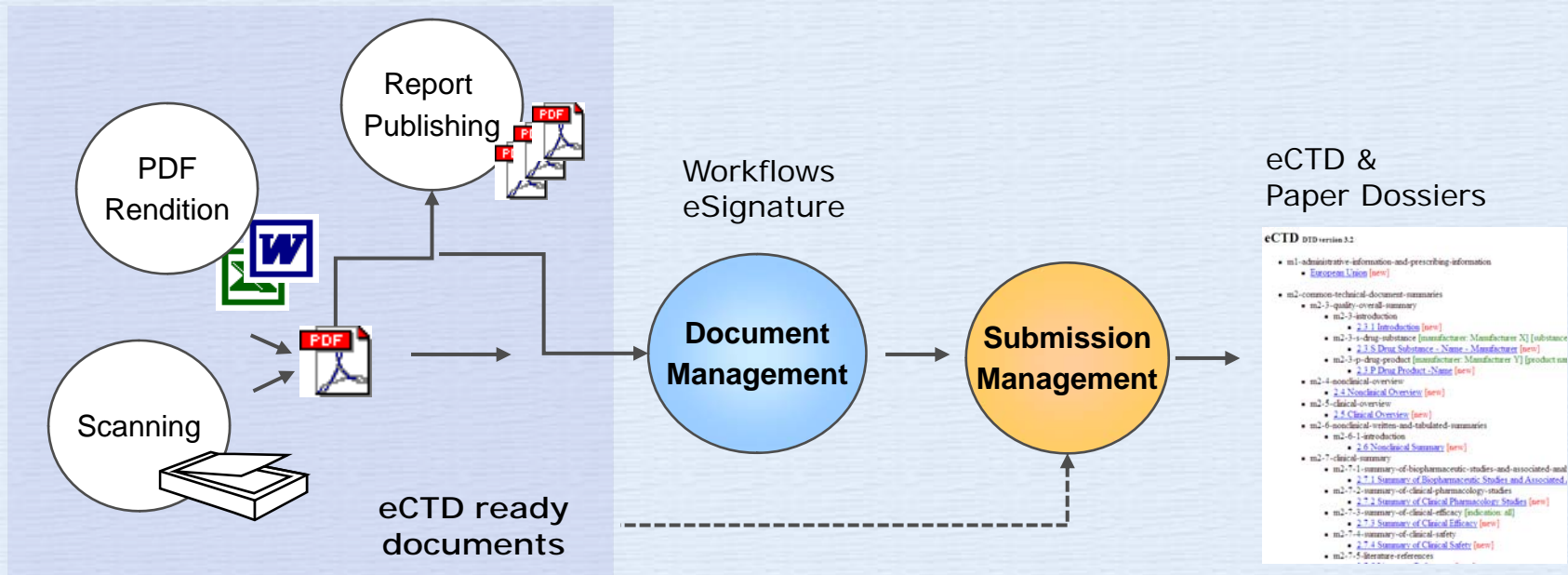


Topic

- eCTD components
& intro to case study



eCTD: Systems, Processes, People



Documents

- Style guide, document templates
- Hyperlinking approach
- Requirements for external partners
- Processing of legacy documents

People

- Specialised skills
- User training
- Support organisations: First, second level support
- Generally: Awareness about eCTD processes

Case Study - Background

- A pharmaceutical company successfully implemented the following eCTD strategy:
 - In-house Document Management
 - maintain responsibility for submission-ready documents
 - Management of electronic submissions for all procedures with external contract service organisation(s) - CSO
 - Furthermore, CSO supports document processing on request



Topic

- Considerations for outsourcing eCTD compilation



Flexibility and Cost

- High flexibility while building up strategic capabilities
- No time, costs, resources for implementation of internal systems
 - Instead, some effort for selection of appropriate CSO
- No cost of ownership, costs can be clearly allocated to specific projects



Focus on Core Competences

- Focus on regulatory content, critical business and product knowledge remains in-house
- As eCTD compilation is a "generic process" (the same for all products) it offers a very good outsourcing opportunity
- Regulatory affairs avoids becoming involved in discussions on IT systems



Access to Specialised Skills

- CSOs specialised on eCTD compilation benefit of a broad bandwidth of experience
- Ongoing experience with eCTD and related questions is required to deliver a high quality result
- The eCTD requirements follow specific rules leaving room for best practise interpretations



Submission Peaks

- Depending on number of products eCTD compilation is not required on a daily basis
 - CSOs can be contracted when needed
 - They have access to a pool of qualified resources (internal staff, freelancers, partners)
 - Alternatively, CSOs can support submission peaks by temporary onsite support



SME Specific Considerations

- SMEs are frequently companies that
 - only develop products up to particular development milestones
 - cooperate with partners that potentially could manage eCTD submissions
 - prefer investment in research instead of submission IT and related staff
 - lack awareness regarding eCTD processes and systems



Topic

- Managing a DCP with an external service provider



Case Study - Background

- For a DCP a comprehensive eCTD was re-build for the submission of the third sequence
 - Originally, “parallel national” Submissions (eCTD, paper) were provided to 15 countries per formulation (3) and trade name (max 5)
 - The validation phase was handled heterogeneously (eCTD sequence 0001 to RMS, paper, email)
 - Decision for final response (sequence 0002): Switch to 15 comprehensive eCTDs



Number of Submission, eCTDs

"Parallel National" - over 150 initial submissions

Instead -> 15 Comprehensive eCTDs

	RMS	CMS1	CMS2	CMS3	CMS4	CMS5	CMS6	CMS7	CMS8	CMS9	CMS10	CMS11	CMS12	CMS13	CMS14	RMS, CMS1 to CMS14
Formulation 1	Application 1/ tradename	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Application 2/ tradename	x	x	x	x		x	x	x	x	x		x	x	x	x
	Application 3/ tradename	x	x	x			x	x	x			x	x		x	x
	Application 4/ tradename	x			x	x		x	x	x			x	x	x	x
	Application 5/ tradename	x	x				x		x				x	x	x	x
Formulation 2	Application 1/ tradename	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Application 2/ tradename	x	x	x	x		x	x	x	x	x		x	x	x	x
	Application 3/ tradename	x	x	x			x	x	x			x	x		x	x
	Application 4/ tradename	x			x	x		x	x	x			x	x	x	x
	Application 5/ tradename	x	x				x		x				x	x	x	x
Formulation 3	Application 1/ tradename	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Application 2/ tradename	x	x	x	x		x	x	x	x	x		x	x	x	x
	Application 3/ tradename	x	x	x			x	x	x			x	x		x	x
	Application 4/ tradename	x			x	x		x	x	x			x	x	x	x
	Application 5/ tradename	x	x				x		x				x	x	x	x



Number of eCTD Sequences

	RMS	CMS1	CMS2	CMS3	CMS4	CMS5	CMS6	CMS7	CMS8	CMS9	CMS10	CMS11	CMS12	CMS13	CMS14	RMS, CMS1 to CMS14
Application 1/ tradename	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x (0000-0002)
Application 2/ tradename	x	x	x	x	x		x	x	x	x	x		x	x	x	x (0000-0002)
Example: Formulation 1 Application 3/ tradename	x	x	x			x		x	x			x	x		x	x (0000-0002)
Application 4/ tradename	x			x	x			x	x	x			x	x	x	x (0000-0002)
Application 5/ tradename	x	x				x			x				x	x	x	x (0000-0002)

- Submissions already done; re-build of eCTD
 - Initial submission -> 0000, Validation -> 0001
- First submission as comprehensive eCTD
 - Response to questions -> 0002
(together with 0000 and 0001)



Reasons for Comprehensive eCTD

- MRP/DCP Best Practice Guidance of April 2008
 - Initial application was submitted prior to release of guidance
- Improved internal control and efficiency by reducing the number of Submissions/eCTDs
 - While accepting effort for re-creating sequences 0000 and 0001
- Ability to consistently manage eCTD lifecycle in the future; adherence to DCP milestones



Outsourcing Requirements

- The example of this DCP compiled within very tight timelines demonstrated
 - Working with a CSO is a feasible scenario also for complex procedures
 - Some key requirements have to be considered for an efficient collaboration



Communication & Relationship

- Good communication
 - Trust based relationship is vital (!)
 - Project changes or problems have to be communicated immediately by both parties
- In-house contact should understand the basic eCTD principals
 - Helpful for discussions with CSO
- eCTD lifecycle benefits from long-term relationship



Document Transfer, eCTD Viewing

- Secure and efficient two-way document transfer required
 - VPN connections, encrypted e-mail, secure FTP, secure HTTP portals
 - Clear identification of submission documents
 - Procedures for managing and tracking document modifications
- Submission viewing (for review, approval) during compilation possible



Submission Hosting & Exchange

- Case study - submission hosting: electronic submission management completely outsourced
- In principle, transfer of eCTDs between Submission Management Systems possible
 - Submissions can be passed to CSO during lifecycle
 - Outsourcing of initial eCTD sequences followed by in-house implementation

Last but not least

"Make everything as simple as possible, but not simpler"

Albert Einstein



Topic

- Backup Slides
 - eCTD ready documents
 - DMS
 - SMS



eCTD Ready Documents (1)

- „eCTD readiness“ represents a major challenge
 - See Appendix 7 of eCTD specification 3.2.2 <http://estri.org/eCTD/>
 - Formal re-working of documents (e.g. Word formatting, PDF processing) is a time and resource consuming activity
 - Submission deadlines can be at risk by non-compliant documents



eCTD Ready Documents (2)

- Requirements for eCTD ready documents are independent from outsourcing
 - Style guide and document templates
 - Hyperlinking approach
 - Word training(s)
 - Processing of legacy documents
- Awareness of involved business areas and external partners
 - Key users supporting, monitoring processes



Document Management (1)

- DMS has many advantages such as
 - Structured processes / workflows
 - Controlled and secure global access (versioning, audit trails, central repository)
 - Centralized PDF rendition process
- However,
 - A DMS is not a must for eCTD capability
 - Defined and controlled processes for eCTD ready documents are critical



Document Management (2)

- SMEs often do not have a “regulatory” DMS due to cost / benefit considerations
 - Significant costs for implementation and validation (often higher than license costs)
 - Maintenance of systems represents a long-term investment
 - Management is hesitating as showing a financial benefit it difficult



Submission Management

- A SMS system is always needed
 - Creation of XML backbone requires specialized software
 - NeeS (without XML) is considered as temporary transitional format only
- A decision is required whether to
 - Implement SMS software and knowhow internally
 - Use a service provider for eCTD business



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