

# 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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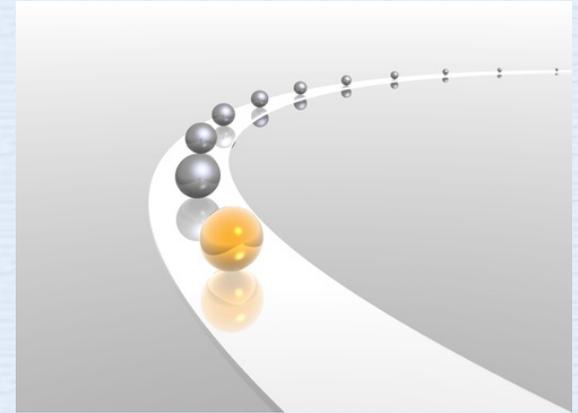


**exalon**  
Electronic Submission Services

# Topics

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



# Introduction Statement

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- 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



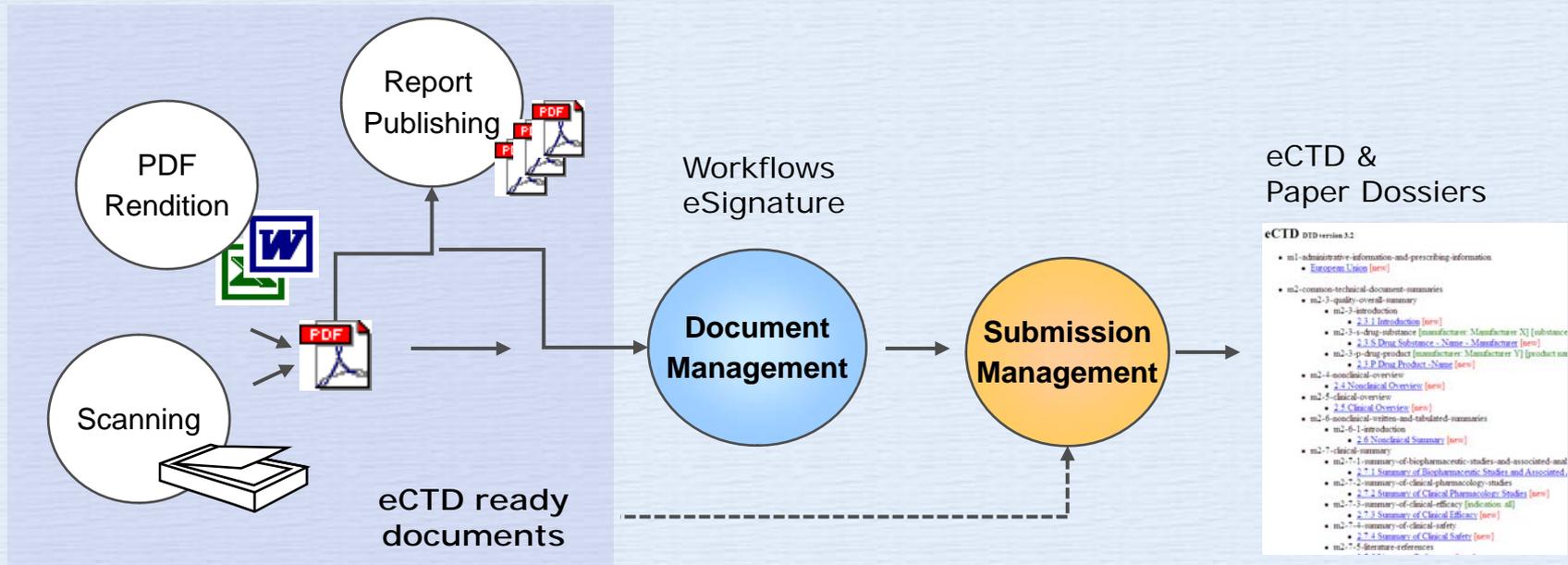
# Topic

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- 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

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- 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

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- Considerations for outsourcing eCTD compilation



# Flexibility and Cost

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- 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

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- 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

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- 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

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- 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

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- 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

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- Managing a DCP with an external service provider



# Case Study - Background

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- 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
Application 1/ tradename	x	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	x
Formulation 1 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
Application 1/ tradename	x	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	x
Formulation 2 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
Application 1/ tradename	x	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	x
Formulation 3 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

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- 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

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- 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

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- 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

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- 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

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- 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

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

Albert Einstein



# Topic

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- Backup Slides
  - eCTD ready documents
  - DMS
  - SMS



# eCTD Ready Documents (1)

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- „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)

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- 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)

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- 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)

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- 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 is difficult



# Submission Management

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- 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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