How to create a validated eCTD submission based on the new guidelines and specification - Part 2

eCTD - readiness at Industry
- some aspects -

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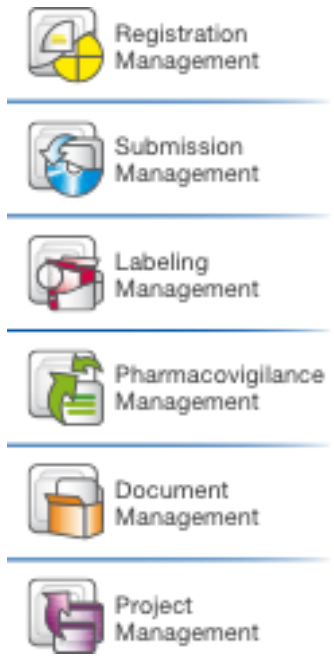
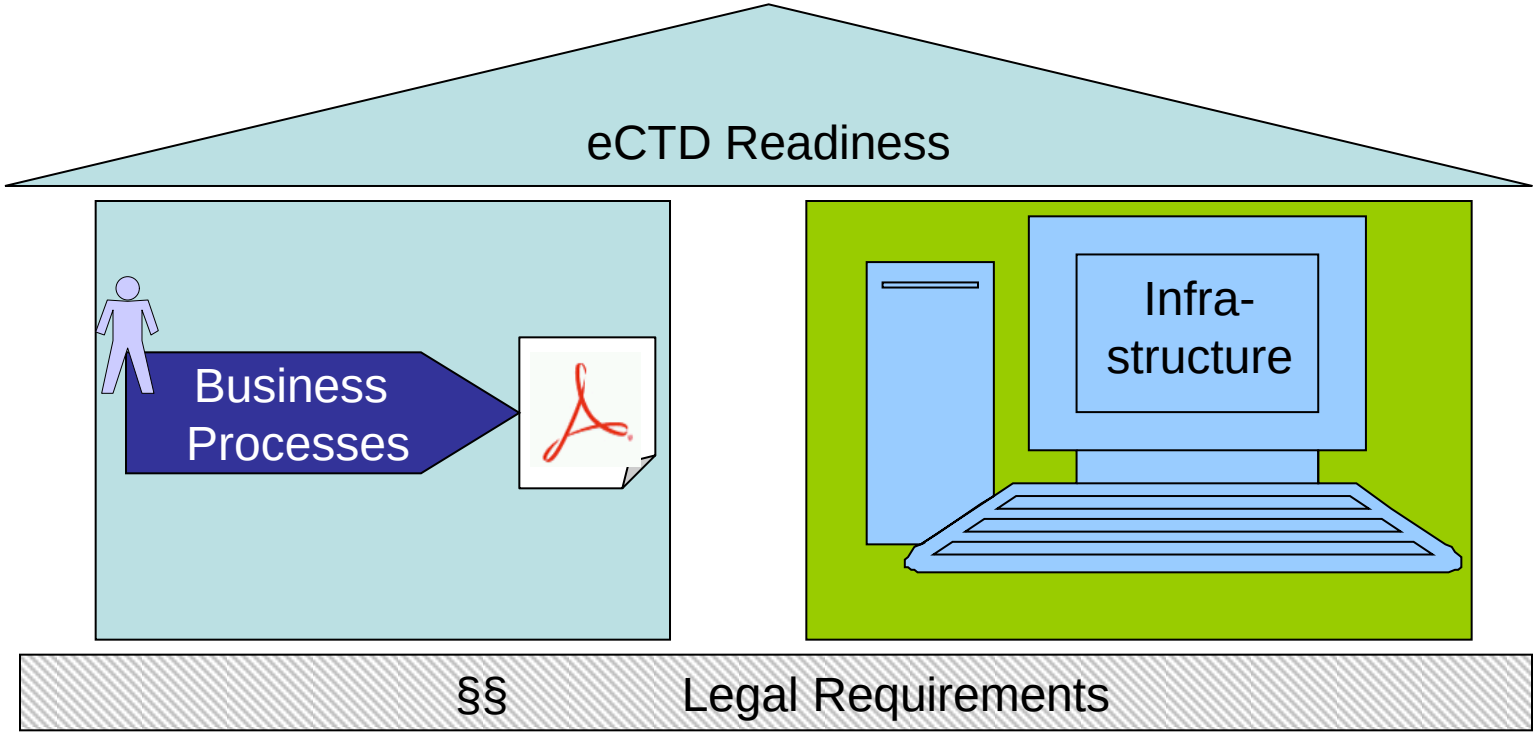


Agenda

Is my company eCTD ready?

- Infrastructure requirements
- Business requirements
- Legal requirements

eCTD - readiness



A path to eCTD readiness - A list of questions…

Infrastructure – Corporate IT strategy

- There is a corporate IT Strategy!
- HR aspects
- Hardware aspects
- Software aspects
  (platform strategy: Windows , Linux Server, DMS, CRM, eCTD compiler)
- Analyze & understand the current Business Challenge
  (from paper to e…)
  and the influence on the infrastructure
- Any other Project Part ongoing, eCTD readiness can be part of?
  (e.g. SAP project)

- Does the (new?) IT strategy cover requirements from the Regulatory Affairs w/regards to
  - Document creation
  - Document handling
  - Document archiving
  - Document approval
  - Document Workflow
  - Centralized storage of documents, no local copies, Access to that server for authorized users
  - Document Management System
  - Client requirements (e.g. a central regulatory database)
  - Access Rights (user /groups/teams) for network & applications

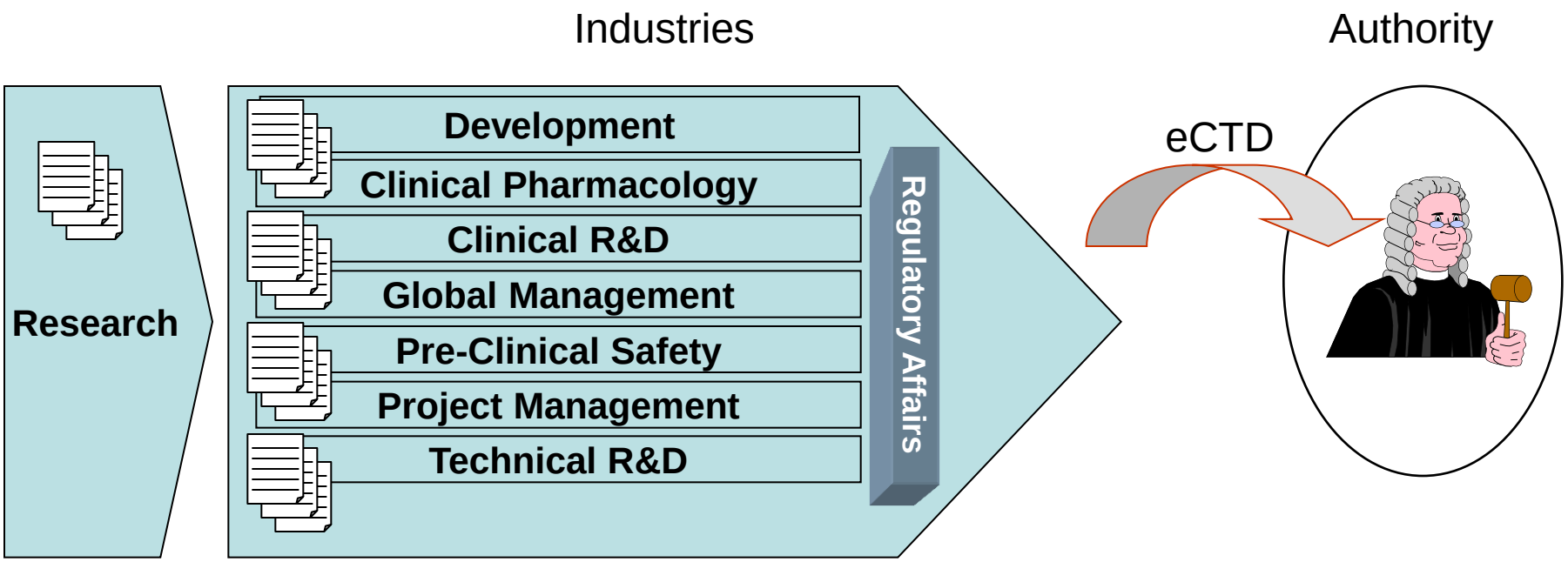
- Some ideas to spend about a DMS system
  - DMS is not mandatory for eCTD
  - If you have a DMS – can I use it for my eCTD project
  - If you do NOT have a DMS in place: which departments can I win to join a DMS project (a DMS just for eCTD is not recommended – no island solutions)
  - Does the DMS cover Document Lifecycle
  - Supports your eCTDcompiler this DMS
  - Does the DMS provide a long-term archiving strategy (= NOT on FileShare)
- Long-term strategy:
  - integration of other leading systems and DMS in your eCTD compilation tool

- Define requirements for your DBMS
- Therefore also your eCTD compilation tool should support on that database server
- Is there any DBMS already in place, I can use?
- Benefits (e.g. of ORACLE)
  - performance of a big Database server
  - security of a "real" database (instead of MS Access)
  - using integrated Oracle functions for
  - archiving (not document archiving)
  - backup
  - user management

Business Processes

- Regulatory Affairs is responsible to transfer authorities interests into your company
- Which business processes produce eCTD-relevant documents?
- Which Business Roles & Responsibilities are involved?
- How should the process interfaces be defined to achieve optimal document quality?
- Develope escalation mechanisms
  - Time lines (when shall I start)
  - Quality issues (what issue initiates the escalation)
  - Escalation path

Business processes matching authorities needs



- Inconsistencies within the technical documentation
  - may lead to non-compliance with the format-specific requirements
  - may cause major delay in publishing and submission.
- If the delay occurs in the phase of submission publishing, this means loss of money.
- The sooner a document/submission is validated the less impact on submission process!

- SOPs (Standard Operating Procedure)
  - Recommendation: create a matrix covering all regulatory-relevant SOP's.
  - Update existing SOP's
  - Create missing SOP's
  - Consolidate SOP framework (business process chain)
    -> Management Task!
  - existing orientation program -> knowledge transfer
  - train new / changes on SOP's to all colleagues

- Document templates
  - define templates for regulatory relevant documents
  - next steps to complete missing templates
  - take care for consistency
  - Fonts ,Font size,
  - Corporate identity,
  - document meta data,
  - content restrictions (base on eCTD structure),
  - Granularity
  - Buy or develope?
- Document naming conventions
  - E.g. DocType_Title_Deptartment_Author_Languange_Version-#_LifeCycleState.doc

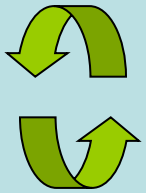
- A collection of important document specifications
  - On document level
    - margins
    - page numbering
    - header and footer
    - section breaks
    - macros
    - hyperlinks
    - fields
  - On chapter level
    - text alignment
    - headings
  - On character level
    - font type
    - character size and color
    - page and table numbering

- Results
  - Overall quality aspects of documents (increase quality)
  - Quality workflow (draft- 4-eyes – approving finalizing - publishing)
  - Tools for document quality
  - Dossier compilation process is specified and in place to speed up the process of document creation
  - Dossier Lifecycle process must be established

Dossier Publishing of SW
(eCTD export, high speed printing)

Dossier Management of SW
(creation of NDAs, post approval maintenance)

Document Lifecycle



Regulatory Affairs
Clinical R&D,
Pharmacology,
QM
(Industries document creation)

Legal Requirements

Legal Requirements

- Identify all legal requirements
- Define resposibilities to cover all legal requirements
  - For document content
  - For submission planning
  - For Submission building
  - For Submission maintenance
- Identify responsibe roles for all legal requirements

- Educate all users of different departmants
  to cover all legal requirements
  - New/ updated regulatory requirements
    - Internal
    - Regulatory know how
  - New/ updated processes
  - New/ updated tools
  - New/ updated technologies
  - New/ updated strategies

Danke	Inkomu
Baie Dankie	Ndo livhuwa
Ngiyathokoza	Ro livhuwa
Ke a leboha	Enkosi
Ke a leboga	Ngiyabonga
Siyabonga	Thank You