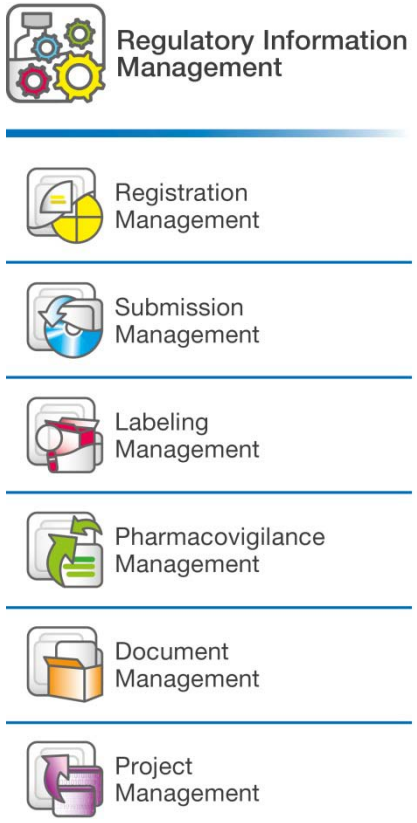
Get ready for eCTD in South Africa

Going from CTD to eCTD

Anita Smal, 14 & 15 February 2013



Agenda

- The goal
- Planning
- Prepare submission ready documents
- PDFs
- eCTD content planning
- eCTD structure planning
- Navigation planning
- Technology
- Points to consider in selecting a software vendor

The Goal

- To provide the evaluators with high quality evaluator-friendly submissions that will allow:
  - Focus on the content, not the format
  - Navigation with ease
  - Search functionality
  - Improved evaluator efficiency
  - Improved handling and archiving of submissions
  - Accessibility to documents across modules
  - Support of life cycle management
  - Reduced time to approval!

Planning

- The ZA eCTD will be different from EU / US eCTD's
  - Local requirements in modules 2 to 5 have to be complied with
  - Regional requirements - Module 1 and 3.2.R
- Careful planning will be required – get it right first time!
  - Paper is forgiving – can slot in extra pages or replace documents just before submission
  - eCTD is not forgiving – last minute changes will lead to checking of hyperlinks, re-validation, re-export
- Use the Reviewer's Guide in the letter of application (or annex) to assist the evaluator – provide a road map to your eCTD
- Include sufficient information in the sequence tracking table in the letter of application (or annex) to give the evaluator an overview of the dossier life cycle (amendment history)

Prepare submission ready documents

- Content meets current requirements
- Existing paper copies – OCR scan to PDF
- Existing electronic files
- Newly created files – templates with correct layout, standards, styles
  - Improved quality & consistency
  - Comply with eCTD specifications
  - Can spend more time on content and less on formatting
- Fonts and colours are as per the General Information and General and Module 1 guideline
- Include intra document hyperlinks and bookmarks
- Hyperlinks
  - Blue text or rectangles using thin lines

Prepare submission ready documents

- Page size: A4 (210 x 297 mm)
- Margins: At least 2,5 cm on left and right side
- Headers and footers: unique header or footer that briefly identifies subject matter
- Page numbering: page numbers for the document and PDF file should be the same, start at 1 and number consecutively
- Page orientation: portrait pages should be portrait and landscape should be landscape prior to saving PDF document in final form

PDFs

- Don’t use password protection / security / compression
- Intelligent PDFs where possible
  - Bookmarks from each item listed in the ToC
  - Hyperlinks
- Avoid scanning where possible
  - If you have to scan, scan at resolution of 300 dpi
  - Don’t use greyscale or colour
  - OCR where possible
  - Correct granularity
- Open dialog box: set initial view to *Bookmarks* and *Page*
- PDF version 1.4, 1.5, 1.6 or 1.7
- Max file size 100 MB
- Optimise for fast web view

eCTD content planning

- File names
  - Use only “a to z”, “0 to 9” and “-”
  - No upper case, spaces or special characters
  - Module 1 - according to SA Specification for eCTD Regional - Module 1
  - Modules 2 to 5 - according to ICH eCTD Specifiation
  - File names do not exceed 64 characters

eCTD content planning

- Folder names
  - Use only “a to z”, “0 to 9” and “-”
  - No upper case, spaces or special characters
  - Total folder/file path does not exceed 180 characters
  - Modules 2.3.S and 3.2.S may be repeated
  - Modules 2.3.P and 3.2.P may be repeated
  - Module 3.2.P.4 may be repeated for each excipient
  - Module 5.3.5 may be repeated for each indication

eCTD structure planning

- Take time to understand the eCTD structure and how it applies to your product and submission, especially with
  - Multiple manufacturers
  - Dosage strengths
- How granular do you go?
  - Only entire documents can be replaced in eCTD, not sections or pages within a document
  - Your initial granularity choices affect future updates and / or amendments

  (Refer to the ICH Granularity Document, Annex to M4: Organisation of the CTD)
- Once granularity and structure has been decided, they generally can't be changed during the life cycle
- Module 2.3 and 3 metadata (e.g. API & FPP name and manufacturers – choose names that will most likely not change during the life cycle)
- Document strategy in the Reviewer's Guide

Navigation planning

- Provide functional & sufficient hyperlinks
- Document ToCs should contain hyperlinks to corresponding sections within the document
- Supply descriptive and brief bookmarks
- Have at least the same amount of bookmarks as there are items in the ToC
- Planning hyperlinks
  - Who sets hyperlinks – authors or regulatory?
  - Who does the QA check on hyperlinks?
  - When should hyperlinks be set? During authoring?
  - How many hyperlinks should be set?
  - How do you set hyperlinks?
  - How can hyperlinks be automated?


Don't ask
But yes, I could use some help

Technology

- It is not feasible to produce an eCTD without a software solution
- There are many software solutions on the market
  - Not all are ready to support the South African Specification yet
  - Some may never support South Africa (focus on US and/or EU)
- One size doesn’t fit all - chose a software solution that fits corporate structure, IT strategy and processes
  - Complex integration with document management systems running on central servers
  - Standalone systems running on PCs utilising a shared area
- The software solution should take care of all the technical issues, leaving regulatory people free to focus on content

Points to consider in selecting a software vendor

- Does the software support the South African Specification?
- Is there proven compliance with South African validation criteria (actual testing has been performed)
- Can you perform validation at any stage in the software tool?
- Are hyperlinks supported?
- Does the software take care of file and folder naming conventions?
- Does the software take care of PDF requirements?
- Does the software support various submission types, e.g. paper CTDs, eCTDs, other dossier formats?
- Ease of use of software
- What support, escalation mechanisms and training are available?

Why are we going from CTD to eCTD.....

EXTEDO eRegulatory Affairs

Submission Management

Thank you!

Anita Smal
Abex Pharmaceutica (Pty) Ltd
Professional partners of EXTEDO in South Africa
Phone: +27 12 997 6974
Fax: +27 86 511 9636
E-mail: asmal@abexpharm.com

EXTEDO GmbH
Einsteinstraße 30
85521 Ottobrunn / GER
Phone: +49 (89) 189454-0
Fax: +49 (89) 189454-999

EXTEDO, Inc.
1235 Westlakes Dr., Suite 285
Berwyn, PA 19312
Phone: +1 (855) 328 3500
Fax: +1 (610) 240 9301

E-mail: info@extedo.com
Internet: www.extedo.com