CTD, Electronic CTD and eCTD
Providing Effective Guidance

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A Decade of Regulatory Harmonization in Africa: Where are we? Where do we go from here?

Outline

- About VECTOR Life Sciences
- Where we are Today
- Understanding the Difference between Formats
- The Benefits of Effective Guidance
- The Required Guidance Documents
- The Benefits of eCTD – The Ultimate Goals
- Harmonised Structures
A Decade of Regulatory Harmonization in Africa: Where are we? Where do we go from here?

About VECTOR Life Sciences

• Based in Pretoria South Africa
• Focused on Delivering eRegulatory Solutions for Africa
• Member of the AMRH Partnership Platform
• Assisted NEPAD with the AMRH M&E Software Requirements
• Authored eCTD Specifications for Australia & Thailand
• Authored eValidation Criteria for eCTDs and eSubmissions
• Consulted on Specifications for Canada & China
• Electronic Evaluation Training in 20+ Authorities
• System Configuration & Setup Consulting in 15+ Authorities
• eCTD Compilation Training at Companies around the Globe
• Industry eCTD Workshops around the Globe

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Where we are Today

• CTD Acceptance is High
• CTD Guidance is Available for many Countries/Regions
• Electronic CTDs are Requested/Required
BUT...
• “CTD” Has not Always been in line with ICH “Common”
• eSubmission/eCTD Guidance is Scarce or Insufficient*
• Policies are not Clear
• Conflicts between Regional and National Guidance
• Mixed Signals from Evaluators vs. Authorities

*South Africa is the only country with guidance on electronic submissions although the eSubmission Guidance is incomplete
7. One hard copies of Product Dossier (PD) should be submitted along with electronic copy.

8. The application form and the DOS-PD should always be in electronic word format.

Electronic submission of documentation on electronic storage media e.g. CD or DVD should be submitted in Microsoft Word (required for templates/summaries, e.g. QOS–PD, QIS, BTIF) or text-selectable PDF format (other documentation).

(to be submitted as one original hard-copy and one electronic copy (in pdf on a CD-Rom) including Modules 1 and 2 in MS-Word)

Guidance on eCTD submissions will be provided in future.

...going eCTD only....
CTD – **Common** Technical Document

- General Structure Specified by ICH (Module 2-5)
- Regional Structure Specified
  - Module 1 – Regional Administrative Data
  - 2.3.R / 3.2.R – Regional Information
- Content Guidance
  - Instructions on What should be Included
  - Examples where Special Formats are Expected
  - Information about Forms
- **CTD Guidance is Format Independent**
  - Paper / Electronic / eCTD

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Understanding the Difference between Formats

Electronic CTD (eSubmission)

- **Electronic CTD ≠ eCTD**
- A CTD Submitted in Electronic Format
- Unstructured eSubmission
  - No Guidance is Given on how Files are to be Structured and Provided
  - No Technical Validation is Possible
  - No Consistencies in Applications
- Structured eSubmission
  - Guidance is Provided on Granularity, Folder Structures, File Names, File Formats, PDF Requirements, Navigation, Media, Business Protocol, Validation, etc.
  - Technical Validation is Possible
  - Consistencies are Guaranteed
  - EU NeeS & VNeeS are Common Examples of Structured eSubmissions
- Electronic CTD Guidance is ALL ABOUT FORMAT
Understanding the Difference between Formats

eCTD

- ICH XML Based Format Enabling Advanced Electronic Functionality
  - Guidance is Provided on Administrative Data for Automation and Application Management, Granularity, Structural Elements, Leaf Titles, Lifecycle Management, File Formats, PDF Requirements, Navigation, Media, Business Protocol, Validation, etc.
  - Technical Validation is Defined
  - Consistencies are Guaranteed
  - Efficiencies through Lifecycle Management
    - Delta & Cumulative Views

- eCTD Guidance is ALL ABOUT FORMAT

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The Benefits of Effective Guidance

• Technical Validation
  • Enables Applicants to Self Validate prior to Submission
  • Improves Quality and Completeness of Submissions Received

• Predictable Structure

• Improved Quality of Files

• Improved Internal Document Navigation e.g. Bookmarks

• Insures Consistencies between Applications

• Enables Streamlined Internal Processes

• Achieves Predictable Timelines & Improves Measurability

• Makes a Region more Attractive for Applicants

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The Required Guidance Documents

• CTD Guidance - Content
• eSubmission Guidance – Format for Non-eCTD Electronic Submissions
• eCTD Guidance – Format for the ICH XML Advanced Format
• Validation Criteria – Check for Format and Content Compliance for both eSubmission and eCTD Applications
• Q&A – Protocol of Frequently Asked Questions Updated Regularly
The Benefits of eCTD – The Ultimate Goals

- Structured Applications
- Automatic Content Checks
- Validated File Formats and Formatting
- Current Cumulative View & Delta View
- Clear Communication of Changes
- Clear Understanding of Current “Approved” Application
- Bridge into Data Management – Application Management and Tracking
- Automation Automation Automation
Harmonised CTD Structure

- FIVE Structures are better than 55
- ONE Structure is better than FIVE

- Most Regions/Countries are asking for Similar Information but have Defined Different Structures
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Harmonised Structure

- Reduces Costs and Increases Efficiencies for Industry
- Increases Efficiencies on Harmonised Activities e.g. Joint Review, Mutual Recognition
- Makes Africa an Attractive Destination for Applicants
- The EU, GCC, ASEAN began with a Harmonised Structure (NTA, CTD, ACTD)

- DOES NOT Limit a Country’s Autonomy over Content
  - Country Specific Additional Data Section Defined by each Country
  - Additional Data Requirements added to Validation Criteria

- DOES NOT Mandate a Country use All Sections Defined
  - Required Sections Defined in Validation Criteria
Summary

• Understand the Difference between
  • CTD
  • Unstructured Electronic CTD
  • Structured Electronic CTD
  • eCTD

• We ARE far enough to take advantage of Electronic CTD

• The Establishment of Validation Criteria will:
  • Increase the Quality of Applications
  • Increase the Efficiency & Consistency of Evaluation
  • Reduce the Number of Screening Iteration – Faster Approval Times

• Harmonised Structure & Guidance
  • Reduces the Costs for Industry making Markets more Attractive
  • Increases Consistency and Quality across Regions
  • Makes Joint-Review Activities Easier
  • DOES NOT Reduce Autonomy over Country Required Content
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