Preparation of Drug Submissions in the eCTD Format

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Drug Submissions in the eCTD Format Overview

- **Guidance Document Preparation of Drug Submissions in the eCTD format**
  - **What it is, what it is not, next steps**
- **Module 1**
  - **DTD**
  - **Guidance document**
- **HC-SC 3011 application form**
  - **Demo of eHC-SC 3011**

Drug Submissions in the eCTD Format

- **The Draft Guidance for Industry: (May 14, 2004)**
  - **Preparation of Drug Submissions in the eCTD Format**

- **Developed in collaboration with the WGES.**
- **Released for a 60 day consultation period.**
- **It is the first of several versions of this guidance.**
- **Will be revised as experience is gained and the scope is expanded.**

Drug Submissions in the eCTD Format

Guiding principles in the development

- **Does not replace the guidance for the *Preparation of a New Drug Submission in the CTD format.***
- **It offers an OPTIONAL format to submit.**
  - **E-submission is not mandatory.**
- **Based in ICH eCTD specifications.**
- **Describes regional requirements.**
- **First step to be expanded.**
- **Must have NO negative impact on review performance (backlog reduction not compromised).**

Drug Submissions in the eCTD Format

Scope

- **Cover NDS, SNDS, ANDS, SANDS**
- **NC for previously filed eCTD**

- **Not Covered at this time**
- **CTA, DMF, most NC, DIN etc…**
  - **Future guidance to be developed**

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Implementation

- As of September 1st , 2004 eCTD can be filed without providing the platform to support it. (i.e. no laptop)
- At this point in time, a paper co-submission is required.
- Paper submission is still the legally valid submission

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File Format

- **Health Canada will accept file format described in the ICH M2 guidance**
- **In addition, in Module 1 and 2 files can be submitted in the word processor format**
- **Both WordPerfect format 6,7,8,9,10 and MS Word 2000 and 2003 are acceptable.**

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Electronic Signature

- **Documents requiring signature must come in paper format**
- **Regulations will need to be amended to allow e-signature.**
- **The guidance will be updated when these provisions are in place.**
  - **(minimum 2 years)**

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Module 1

- **The content and structure of Module 1 is the same as the paper submission with one exception**
  - **No longer a need for a place holder for electronic files within the eCTD.**
- **Module 1 DTD verion 0.9 published in Dec 2003. Version 1.0 now available, no significant difference with version 0.9**

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Module 1

- **Module 1 guidance document will be published by the end of June 2004.**
- **A preliminary version was distributed to WGES members for comments.**
- **Several COTS tools can already support Canadian Module 1, more to come shortly.**

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HC-SC 3011

- **A builder tool for the latest version of the HC-SC 3011 application form is under development.**
- **A beta version was released to WGES members for testing**
- **This version will be demonstrated here in a few minutes.**

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Testing your eCTD

- **It is strongly recommended that you test your e-submission in the Health Canada IT environment.**
- **We will provide support to test a sample submission prior to official receipt.**
- **This is to test the technology, it will NOT be considered an official submission**

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Testing your eCTD

- **A partially ready submission is acceptable for testing.**
- **Any “bugs” or error message will be provided to the sponsor.**
- **We recommend a 4 week lead time to do the IT testing.**
- **Can or not be done in conjunction with pre-submission meeting.**

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Testing your eCTD

- **To schedule a test, contact the submission office near you…**
  - **i.e. the same people you contact for the paper submission.**
- **They will coordinate internally with the IT team assigned to the testing.**

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WGES Industry member issue#1

- **Paper co-submission is an extra burden**
- **Recommendations**
  - Hybrid Submission: Modules 1 and 2 only submitted both paper and electronic but the body of the submission, Modules 3 to 5 would be submitted in electronic format only.
  - The sponsor would be committed to print on demand portions of the submission

Drug Submissions in the eCTD Format

WGES Industry member issue#1

- **Paper co-submission is an extra burden**
- **Recommendations**
  - Not submitting paper and electronic together
  - Paper and electronic submissions to be submitted on different dates as long as the electronic submission is received in HC within one month after acceptance at screening.

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WGES Industry member issue#2

- **Additional data packages for a single product (life cycle management)**
- **Recommendations**
  - A (partially populated) eCTD backbone should be submitted with all data packages. Whenever possible, the body of the information submitted should be placed in the appropriate place holder in the module 2 to 5 using the life cycle operation attribute specified by ICH M2 (i.e. new, delete, replace and append).

Drug Submissions in the eCTD Format

WGES Industry member issue#2

- **Additional data packages for a single product**
- **Recommendations**
  - When the answer is in Q&A format and can not be broken down to parts of the modules 2 to 5, it should be placed with the covering letter and should use the operation attribute new.
  - The covering letter accompanying all these data packages should also be attached to Module 1. An attestation letter confirming that both versions (paper and electronic) are identical will accompany all data packages.

DEMO

Questions ?