

ICH REGIONAL PUBLIC MEETING
Tuesday, October 21, 2008

@-Review

Modernizing Canada's Regulatory System

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eCTD

electronic Common Technical document

Update on Current Specifications

- Most recent posting on the ICH web site
- ICH eCTD Specification v3.2.2
- ICH STF Specification v2.6.1
- ICH eCTD Q&A document v1.15.1

- Changes are mostly editorial to bring clarifications and to reflect Q&As and change requests received

- The DTD and style sheet are unchanged

Recommendation for eCTD Next Major Version

- Work is already initiated to gather requirements for the next major release of the eCTD specifications:
 - Requirement gathering should be finalized at the ICH November meeting
- Substantial changes are expected:
 - Life cycle management
 - Two way communication
 - Message technical architecture

Recommendation for eCTD Next Major Version

- The message standard development will be done in collaboration with HL7:
 - The HL7 scope will cover more product types than ICH mandate, e.g. Medical Devices, Veterinary Drugs, Natural Health Products, Food etc...
- Implementation guidance documents will remain the responsibility of ICH:
 - For product types within ICH mandate.
- There is a recommendation that ICH, HL7 and ISO/CEN form a joint initiative to progress the eCTD Next Major Version.
- This will result with having the next eCTD major release as an ISO standard.

SENTRI

Standards Everyone Needs for the
Transfer of Regulatory Information



M2 Recommendations for Media

- ICH withdraws the following recommendations:
 - Floppy Disk (availability/cost, security)
 - DVD-RAM (limited use, added value not shown)
 - CD-R (commonly used already)
- It is considered that the acceptable formats (above + CD-R) for media should now be defined on a regional basis:
 - Regional IT architectures are the driver



PDF Version Migration

- Migration from pdf v1.4 to v1.7 was considered
 - Some regions using later versions for content outside of M2-M5.
 - Some regions experience delayed support from vendor.
- No consensus to move at present.
- Workplan to investigate pros / cons again in 2009.