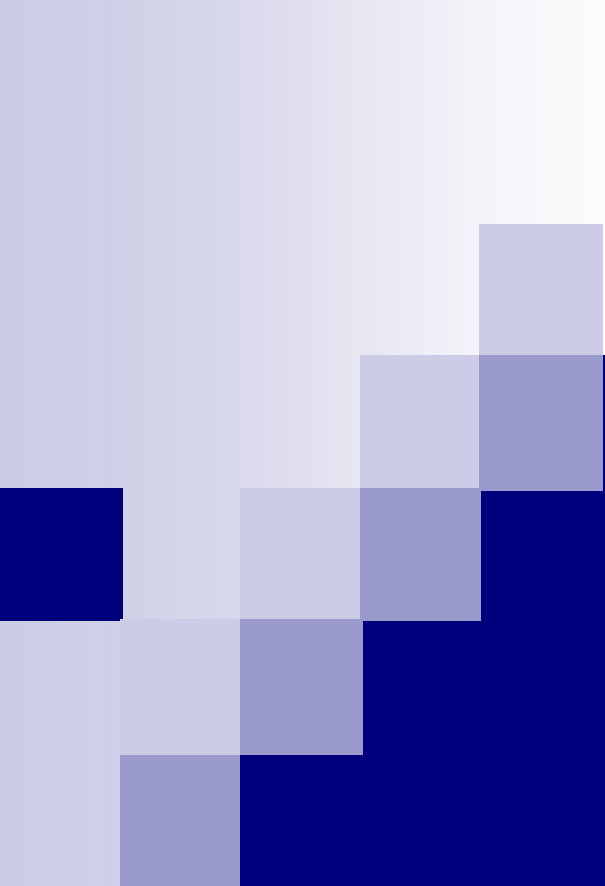




Update on the eCTD

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Requirements for Registration of Pharmaceuticals for Human Use





The Electronic Common Technical Document or eCTD

The ICH eCTD Specification is based on the ICH M4 Common Technical Document (CTD)

- The CTD was agreed in November 2000 and is divided into four separate sections detailing the Organisation (M4), Quality (M4Q), Safety (M4S) and Efficacy (M4E) sections of the harmonised dossier
- The Common Technical Document (CTD) provides for a harmonised structure and format for new drug product applications
- The agreed upon implementation date for the Common Technical Document in the three ICH regions was July 2003



The Electronic Common Technical Document or eCTD

The ICH eCTD Specification is based on the ICH M4 Common Technical Document (CTD)

- The eCTD was agreed in October 2003
- The eCTD Common Technical Document (CTD) allows for the electronic submission of the Common Technical Document (CTD)
- The eCTD table of contents is consistent with the CTD and provides a harmonised technical solution to implementing the CTD electronically
- Information on the eCTD can be found at <http://estri.ich.org/>

Maintenance of the eCTD

- The ICH eCTD Implementation Working Group (IWG) is a subgroup of the ICH M2 group and is responsible for the continued oversight and development of the technical aspects of the eCTD
- Experience and ICH Change Requests have identified numerous area for improvement
- Additional needs have been identified in all ICH regions
- Current Activities include:
 - redefining existing ICH requirements
 - documenting new ICH requirements
 - leading the development of Next Major Version of the ICH eCTD (eCTD NMV)



Requirement Development Areas

- Envelope / Module 1 Metadata Harmonization
- Two-Way Communication
- Regional and Harmonized (ICH) Validation
- Document and File Life Cycle Considerations
- File Metadata, Security, Integrity and Usability
- Current and Future Compatibility

eCTD NMV

- ICH eCTD requirements will be submitted through the SDO Joint Initiative into the HL7 Regulated Product Submission (RPS) standard, Release 2
 - RPS R2 is currently under development to provide a single electronic message standard for multiple regulated industries
 - Human Drug Products
 - Veterinary Drug Products
 - Medical Devices
 - Food Products
 - RPS R2 is not restricted to a single dossier format
 - RPS R2 will not impact the CTD dossier structure
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ICH M2 Group Focus

- Ensure inclusion of globally harmonised medicinal product requirements
- Identify subset of RPS R2 relevant to ICH needs
- Create implementation guidance to provide improved instruction for creating eCTDs
 - Promote more efficient usage
 - Improved validation
 - Eradicate tool interoperability issues