

RPS R2 - Scope Discussions

The Next Lifecycle: Preparing for
the Atlanta/September 2009
WGM

September 1, 2009



ICH Requirements



ICH Requirements

- Need to conduct analysis of requirements list (delta since last evaluation earlier this year)
- Approximately 129 line item requirements in the following categories:
 - Application Lifecycle, Lifecycle, Logical Groupings
 - Author-Review
 - Backward Compatible
 - Document Formatting, Document Metadata, Document Reuse
 - Envelope, Structure
 - Regional requirements
 - Harmonization
 - Hyperlinking
 - Language
 - Physical File Rules
 - Technology
 - Terminology
 - Transfer/Security
 - Two-way Communication



Master Files



Master Files: Two-Way Communication

- International requirements introduced some complexities with additional information requests that may involve content from both the master file owner and the sponsor
- Others?



Master Files: Referencing

- Do we have all the scenarios covered if we have a reference to/from applications?
- When the application is not owned by the Sponsor – what are the rules for this type of linking (this applies to more than Master Files – this is just the most likely).
- Others?



Confidentiality



Confidentiality vs Public Availability

- Submissions that have confidential information at the document level – is there a way to mark documents confidential?
- Is this done by keywords?



Multi-Regulator



Multi-Regulator Submissions

- Need to discuss and review this in conjunction with the ICH requirements
- Comments?



Structure and Linking

XML -

- Scientific data – common across regulators – regional information has become part of the
 - Regional Information is the driving XML backbone with references and
 - Reuse of M2-M5; Common Information would get better reuse



File and Folder Rules

- Folder Structure?
- What are the business requirements?
- Need additional information
- Is this the flat versus structured (i.e., hierarchical) file placement?
- EU – agencies have adopted ICH folder structure (isn't this an implementation issue?)



Hyperlinking

- Between document hyperlinking
- Broken links
- Is this in scope?

Open Discussion

- Missing any scope topics?
- Do we need to add time to the WGM schedule?
Q1 Thursday?



Questions?