| eCTD Next Major Version Business Requirements (11-JUN-09) | | |
|---|---|---|
| ICH Req No. | TOPIC | Requirement |
| ICH01 | APPLICATION LIFECYCLE | A regulated product application may have one or more regulatory activities associated with it |
| ICH02 | APPLICATION LIFECYCLE | It must be possible to define a 'Regulatory Activity' to which a group of sequences will belong |
| ICH03 | APPLICATION LIFECYCLE | A regulatory activity may have one or more sequences associated with it |
| ICH04 | APPLICATION LIFECYCLE | The message should support the ability to provide one sequence to multiple regulatory activities which may span more than one application. |
| ICH05 | APPLICATION LIFECYCLE | Each sequence should have a unique identifier |
| ICH06 | APPLICATION LIFECYCLE | Capability to identify which eCTD sequences were used at which step of agency review. |
| ICH07 | APPLICATION LIFECYCLE | The message should not restrict adoption/implementation of the standard at any point in a product's lifecycle. |
| ICH08 | APPLICATION LIFECYCLE | Compatible both to US/EU product-wise lifecycle and to Japan application-wise lifecycle. |
| ICH09 | ARCHIVE | It must be possible to review and to archive the submission without need for transformation |
| ICH10 | AUTHOR-REVIEW | It should be possible to review the eCTD |
| ICH11 | AUTHOR-REVIEW | The specification should not restrict the types of file formats which can be submitted for use with the standard (allowed file formats are defined by each implementation and are not defined by the exchange specification). |
| ICH12 | AUTHOR-REVIEW | It should be possible for the reviewer to have access to the entire submission from any part of the submission. |
| ICH13 | AUTHOR-REVIEW | Clear definition of submission views (cumulative, current) |
| ICH14 | BACKWARD COMPATIBLE | Elements and attributes defined by V3.x should be able to be mapped to v4.0 constructs |

| | | |
|---|---|---|
| ICH15 | BACKWARD COMPATIBLE | Submitted information does not need to be resubmitted because of a change to the specification; information created using previous versions of the Specification can continue to be utilized using the subsequent versions of the specification without modification (or resubmission) of the previously provided sequences |
| ICH16 | BACKWARD COMPATIBLE | The message should support continued use of the information and documentation provided with previous regional implementations, e.g., Module 1, STF. |
| ICH17 | DATASETS | It should be possible to provide data definitions for data sets. |
| ICH18 | DOCUMENT FORMATTING | It should be possible to support the inclusion of scanned documents, primarily for legacy documents |
| ICH19 | DOCUMENT METADATA | It must be possible to describe, in free text, the titles of the files being submitted |
| ICH20 | DOCUMENT METADATA | It must be possible to uniquely identify a file being submitted, within a submission |
| ICH21 | DOCUMENT METADATA | It must be possible for a Submitter to provide user defined information or identifier for a file |
| ICH22 | DOCUMENT REUSE | The message should support the reuse of electronic files from a previously submitted instance within an application. |
| ICH23 | DOCUMENT REUSE | The message should support the reuse of electronic files from a previously submitted instance across applications. |
| ICH24 | DOCUMENT REUSE | It must be possible to include by reference, a file that physically resides in another submission (eg. cross-product submission support) |

| | | |
|---|---|---|
| ICH25 | DOCUMENT REUSE | It must be possible to include, by reference, a file that has been submitted in a previous sequence and to be able to identify that this is not new but is being used in a different context |
| ICH26 | ENVELOPE | It must be possible to assign an identifier to a submission |
| ICH27 | ENVELOPE | It must be possible to identify the regulatory agency for which a specific submission is intended |
| ICH28 | ENVELOPE | It must be possible to identify the applicant making the submission |
| ICH29 | ENVELOPE | It must be possible to assign an application number to the submission |
| ICH30 | ENVELOPE | It must be possible to assign a submission type being used for the submission |
| ICH31 | ENVELOPE | It must be possible to describe, in free text, the submission (include a short description of the submission in the administrative section) |
| ICH32 | ENVELOPE | It must be possible to define the Procedure type being used for the submission |
| ICH33 | ENVELOPE | It must be possible to assign an invented name (trade name) for the product covered by the submission |
| ICH34 | ENVELOPE | It must be possible to assign an international non-proprietory name(s) (inn) for the drug substance(s) covered by the submission |
| ICH35 | EU-REGIONAL | It must be possible to identify to which specific country a file is relevant |
| ICH36 | EU-REGIONAL | It must be possible to identify that a file is relevant to all countries covered by a submission |
| ICH37 | EU-REGIONAL | It must be possible to identify for which country(ies) a specific submission is intended |
| ICH38 | HARMONISATION | The message should support ICH-harmonized content (documentation and metadata) and ICH-regional content |
| ICH39 | HARMONISATION | Need to provide a structure that supports all terminologies for dossier (all regulatory activity related to a product) and regulatory activity (collection of sequences that lead to a decision by the regulatory agency (NDS, SNDS)) which can be mapped to individual ICH-regional regulatory processes |
| ICH40 | HARMONISATION | Files should only need to be submitted once to a Health Authority and can be included by reference in multiple regulatory submissions to support multiple regulatory actions even across applications |

| | | |
|---|---|---|
| ICH41 | HARMONISATION | Ability to reuse of eCTD submitted in other regions. e.g. reuse of leaf files, XML instance by module, eCSR. To achieve this, it is critical to distinguish global part and regional part even in Module2-5, not only in Module1. |
| ICH42 | HARMONISATION | When the same documentation is provided, it should be submitted in the same way across HAs. For example, when a study report is submitted in US it is submitted using the STF which is not acceptable in other HAs. This minimizes reuse capabilities and adds to Industry costs to prepare globally harmonized dossiers. |
| ICH43 | HYPERLINKING | It should be possible for the applicant to include hyperlinks between information |
| ICH44 | HYPERLINKING | It should be possible to utilise relative addressing for all links. |
| ICH45 | HYPERLINKING | When a file is replaced, hyperlinks referencing that file can be redirected to the 'replacement' file or retired. |
| ICH46 | HYPERLINKING | Need to support relative links across the product lifecycle |
| ICH47 | ICH PROCEDURE | For validation purposes,<br>- It should be able to uniquely identify:<br>- where in CTD a leaf belongs<br>- the relationship between leafs<br>- the lifecycle relationship (append, delete, or replace) between files<br>- the relationship between submissions<br>- the relationship between applications<br>- the type of relationship (parent-child, reference, etc) |
| ICH48 | JP-REGIONAL | Message should support the ability to provide second and subsequent sequences which contain only additional information in XML Instance |
| ICH49 | LANGUAGE | It must be possible to assign a language to a document included in the submission |
| ICH50 | LANGUAGE | It must be possible to (incorporate unicode character sets) to deal with languages such as Bulgarian and Greek |
| ICH51 | LANGUAGE | It must be possible to include files with 1 or 2 byte characters, or a mixture of both |
| ICH52 | LANGUAGE | eCTD viewer should recognize section titles defined in CTD, e.g. "2.5 Clinical Overview". It should have an interface capable to show CTD section titles in any |
| ICH53 | LIFECYCLE | The message should support the addition of metadata to a previously submitted |

| | | |
|---|---|---|
| ICH54 | LIFECYCLE | The message should support the deletion metadata from previously submitted instances, e.g., related sequences, submission type, operation attribute, manufacturer name, etc. |
| ICH55 | LIFECYCLE | The message should support the updating of any metadata from previously submitted instances, e.g., related sequences, submission type, operation attribute, manufacturer name, etc. |
| ICH56 | LIFECYCLE | Information provided in the message ( i.e., metadata) used to categorize documentation (e.g., attributes of drug substance, manufacturer, etc) or supplied in the regional envelope (e.g., Company Name, Sponsor) can be modified (i.e., added, edited, removed) during the life cycle of the application. |
| ICH57 | LIFECYCLE | Replacement of multiple leafs with single leaf and vice versa should be supported in eCTD. |
| ICH58 | LIFECYCLE | The process for concatenating individual sequences into a combined sequence view (i.e., the current view and the cumulative view) must be unambiguously defined |
| ICH59 | LOGICAL GROUPINGS | Provide ability to group a collection (or set) of files that together represent a document or reviewable grouping (e.g, all files related to a study report, all files related to a labeling document, all files related to a manufacturer or manufacturing component (e.g., container closure)) |
| ICH60 | LOGICAL GROUPINGS | Provide ability to treat a grouping of files as a single entity and to be treated as if it were a single file (complete with all descriptive attributes e.g., title) for all life cycle operations and relationship management and reuse needs |
| ICH61 | PHYSICAL FILE RULES | Filenames can include underscores |
| ICH62 | PHYSICAL FILE RULES | It should be possible to constrain the contents to ensure there are no security settings, such as passwords. |
| ICH63 | PHYSICAL FILE RULES | The physical file structure. (file/folder structure) should be minimal |
| ICH64 | PHYSICAL FILE RULES | The technical message should not restrict the types of files that may be transferred. However, implementation guides may restrict the types of files and versions of file formats to be transferred or may specify unique file formats for that region. |

| | | |
|---|---|---|
| ICH65 | PHYSICAL FILE RULES | It should be possible to support file systems of different operating systems |
| ICH66 | PHYSICAL FILE RULES | It must be possible to constrain the maximum size of any file included in a submission (reword to reflect ICH minimum standard) |
| ICH67 | SCOPE | Allow the capacity to modify the ICH CTD organizational structure (ToC) without modifying or changing the eCTD message structure |
| ICH68 | SCOPE | It should be possible to compile an eCTD equivalent to the CTD |
| ICH69 | STANDARDS | The message should interoperate with other healthcare standards, e.g. use controlled vocabularies from established standard-based vocabularies |
| ICH70 | STANDARDS | It should be possible to restrict the technology utilized to use open (ISO, W3C, IETF) standards when ever possible. |
| ICH71 | STRUCTURE | It must be possible to constrain the inclusion of documents at inappropriate locations in the submission structure (eg. at highest levels of eCTD) |
| ICH72 | STRUCTURE | The message should allow for the control/enforcement of document/structural granularity. |
| ICH73 | STRUCTURE | It must be possible to assign 'attributes' to the contents of specific sections in the submission to support ICH CTD organizational structure (e.g., repeating section 3.2.S) |
| ICH74 | STRUCTURE | It must be possible to ensure that all files submitted are defined and referenced |
| ICH75 | STRUCTURE | It must be possible to validate the contents of a submission against the CTD (e.g., module 6 is invalid) |
| ICH76 | STRUCTURE | It should be possible to easily identify all of the files included in a specific section of the submission. |
| ICH77 | STRUCTURE | It should be possible to review the submission in its entirety or in sections. |
| ICH78 | TECHNOLOGY | The standard must not be constrained by the need for delivery via a particular medium |
| ICH79 | TECHNOLOGY | It should be possible to include colour and black & white images |
| ICH80 | TECHNOLOGY | It should be possible to support the introduction of new technology to aid in the review process. |

| | | |
|---|---|---|
| ICH81 | TERMINOLOGY | The message should support the use of controlled vocabularies for harmonized metadata |
| ICH82 | TERMINOLOGY | The message should support the use of controlled vocabularies for regional metadata. |
| ICH83 | TERMINOLOGY | It should be possible to specify date values in an unambiguous manner. |
| ICH84 | TRANSFER/SECURITY | The message should support a means to enable the validation of the integrity of the electronic files within an instance |
| ICH85 | TRANSFER/SECURITY | The message standard should not restrict the mechanism for transmitting the message (e.g., media type, network) |
| ICH86 | TRANSFER/SECURITY | The message standard should not restrict or prevent regionally implemented secure electronic message delivery standards |
| ICH87 | TWO-WAY COMMUNICATION | The message should support submission of an instance from a regulator to a regulated party. |
| ICH89 | TWO-WAY COMMUNICATION | Deliverables of communication between agency and applicant |
| ICH90 | TWO-WAY COMMUNICATION | It should be possible to define the security methods to be used for transmission to the agencies and acknowledgement from the agency. |
| ICH91 | US-REGIONAL | The message should support the identifIcation of the role of the instance within the identified regulatory activity, e.g. presubmision, application, amendment, etc. |
| ICH92 | US-REGIONAL | The message should support the identification of the regulatory activity associated with the instance, e.g. original-application, labeling-supplement, etc. |
| ICH93 | VALIDATION | It must be possible to define unambiguously, the validation criteria for a submission |
| ICH94 | VALIDATION | Message should contain sufficent information to unambiguously identify which version(s) of the DTD/Schema and controlling vocabularies was used to create the instance |
| ICH95 | VALIDATION | The message should not require the submission of the DTD/Schema and controlling vocabularies with each instance |

| | | |
|---|---|---|
| ICH96 | USABILITY - VIEWING | The instance should be viewable without access to specialized tools or internet |
| ICH97 | COMPATIBILITY | It should be possible for an applicant to build on an eCTD lifecycle started using the eCTD 3.2.x specification and continued using the eCTD NMV specification |
| ICH98 | COMPATIBILITY | No applicant should be required to resubmit data in the eCTD NMV specification if it has previously been submitted using the eCTD 3.2.x specification. (It is recognised that in the future, further major versions of the eCTD specification may require data migration guidance to ensure the use of data over the life of a drug product) |
| ICH99 | COMPATIBILITY | Tools designed to view eCTD NMV submissions must also be able to view a lifecycle started with the eCTD 3.2.x specification. However, the reverse requirement is not needed (i.e. it is not needed that tools for the eCTD 3.2.x specification should be able to view submissions created using the eCTD NMV specification). |
| ICH100 | COMPATIBILITY | It is expected that once an eCTD lifecycle is transitioned to the eCTD NMV specification, then no further submissions/sequences will be made in the eCTD 3.2.x specification. |
| ICH101 | COMPATIBILITY | The implementation guide must state how lifecycle relationships can be maintained from eCTD 3.2.x to eCTD NMV. |
| ICH102 | COMPATIBILITY | Ability to reuse content; files submitted in eCTD sequences can be referenced in eCTD NMV submission units |
| ICH103 | COMPATIBILITY | The eCTD 3.2.x elements/attributes must be mapped to the eCTD NMV elements/attributes |
| ICH104 | DESIGN CONCEPTS | The file format of the message should be xml-based. |
| ICH105 | DESIGN CONCEPTS | The message standard should not prevent or restrict the ability to e-sign the message. |
| ICH106 | DESIGN CONCEPTS | The message standard should not prevent or restrict the ability to encrypt the message for secure transfer purposes |
| ICH107 | DESIGN CONCEPTS | The message standard must not require encryption |
| ICH108 | INTEGRITY | Integrity checks for all files included in the submission are required. |
| ICH109 | DESIGN CONCEPTS | The message should provide the ability to identify further specific usage of the file (e.g., SPL, SDTM, application format, packaging insert, CTN) beyond that defined by the CTD |

| | | |
|---|---|---|
| ICH110 | INTEGRITY | The ability to specify which algorithm is being used for file integrity checks is required. |
| ICH111 | TWO-WAY COMMUNICATION | It must be possible to identify the sender and receiver of a message. |
| ICH112 | TWO-WAY COMMUNICATION | It must be possible to relate any message to a particular message, regulated activity and/or application. |
| ICH113 | TWO-WAY COMMUNICATION | Every eCTD message must be uniquely identifiable. |
| ICH114 | DESIGN CONCEPTS | In principle, the number of xml files managing content should be kept to a minimum and use a consistent technical design approach even though the content models may differ regionally |
| ICH115 | ENVELOPE | The message standard must provide the ability to include information required for the processing (e.g., message standard version) and integrity (e.g., checksum) of the message |
| ICH116 | ENVELOPE | The message standard must provide a three-level hierarchy of application, regulatory activity and submission unit. |
| ICH117 | ENVELOPE | The message standard must provide information about the product. |
| ICH118 | ENVELOPE | The message standard must provide enough information to identify the sender. |
| ICH119 | ENVELOPE | The message standard must provide enough information to identify the recipient. |
| ICH120 | DESIGN CONCEPTS | The message standard must provide the ability for the sender or recipient to update previously submitted metadata |
| ICH121 | LIFECYCLE | The order/sequence of leaf elements within a CTD section must be able to be controlled |
| ICH122 | DOCUMENT REUSE | A file can be displayed in multiple sections of the CTD (preserving the leaf - file concept in the current eCTD specification) |

| | | |
|---|---|---|
| ICH123 | DOCUMENT REUSE | Maintain a similar file-leaf model as in the current eCTD in the eCTD NMV, with the following exception/changes:<br>a. The operation attribute value “append” be removed from the list of allowed values (leaving only new, replace and delete)<br>b. Allow a replace or delete leaf to modify more than one leaf in a previous sequence or sequences<br>c. Allow a single leaf to be “modified” by more than one leaf in later sequences (supports changes in granularity) |
| ICH124 | DOCUMENT REUSE | A file can be replaced in one existing eCTD section or context without impacting the use of the file in other eCTD sections or contexts |
| ICH125 | LIFECYCLE | Life cycle operations must occur within the same context as the existing (target) leaf |
| ICH126 | DESIGN CONCEPTS | There should be no restrictions on the characters used in controlled vocabularies |
| ICH127 | DESIGN CONCEPTS | There should be a basic ICH stylesheet for presentation purposes |
| ICH128 | DESIGN CONCEPTS | STF construct should be integrated into the message standard |
| ICH129 | STRUCTURE | Cardinality rules of the current eCTD Specification should be retained plus those cited in approved Change Requests (e.g., CR#1490/1500 - Module 3.2.A.3 will be made a repeating attribute in Version 3.2 of the specification based on excipient). |