

## Summary of Changes to SG-HSA eCTD Specification Package from Version 1.0 to Version 1.1

### 1. Changes to Technical Requirements

|   | Change description | Details                                                                                                |
|---|--------------------|--------------------------------------------------------------------------------------------------------|
| 1 | Document Matrix    | Removed submission requirement of DMF acknowledgement email (1.5.1) and Application Forms (1.2.1)      |
| 2 | Granularity Annex  | Revised granularity annex to allow multiple files to be submitted under Application checklists (1.2.2) |

### 2. Changes to Validation Criteria

|   | Change description (Section)                           | Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Files/Folders (2.1.9)                                  | Added new validation criteria to check that first Sequence of a Submission has a Sequence Type Initial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2 | Node Extension exists for all Clinical Studies (3.4.8) | Revised to check that either study tagging file or node extension is used to group leaf elements in 5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5, and 5.3                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3 | Leaf operation attribute (3.5.2)                       | Clarified that only “new” operation should be used in the first Sequence of an Application                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 4 | Life Cycle Management (4.5)                            | <p>i) Updated 4.5.2 to clarify that only “new” operation should be used in the first Sequence of an Application</p> <p>ii) Removed 4.5.13 “Any subsequent leaf for all content provided in the Checklists (1.2.2) element must have 'new' operation attribute.”</p> <p>iii) Removed 4.5.14 “The Table of Summary of Changes (1.2.4) should have 'new' operation attribute.”</p> <p>iv) Removed 4.5.19 “Any subsequent leaf for all content provided in the Approved Foreign Labelling (1.3.5) element must have 'replace' operation attribute once it has been added initially with 'new'.”</p> |
| 5 | File existence (4.6)                                   | i) Removed 4.6.3 “All files provided in section 1.2.2 Checklists must be provided as a source file (.docx)” to allow submission of documents in file format in accordance with current Guidance on Therapeutic Product Registration in Singapore                                                                                                                                                                                                                                                                                                                                                |

|   |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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|   |                | <p>ii) Amended validation severity for 4.6.4 on submission requirement of source files for documents in selected sections with “new” operation from “Warning” to “Info”</p> <p>iii) Removed 4.6.5 and 4.6.6 on submission requirement for of source files for documents in selected sections with “replace” and “delete” operation</p> <p>iv) Amended 4.6.9 to allow multiple files to be submitted under Application checklists (1.2.2) in accordance with updated Granularity Annex</p> |
| 6 | Envelope (4.7) | Amended 4.7.7b to remove “DMF acknowledgement email (1.5.1)” to align with current regulatory document submission requirement                                                                                                                                                                                                                                                                                                                                                             |

### 3. Additional Changes to Specification Document

|   | Change description                                          | Details                                                                                                                                                                                                                                                                                                                                                                                   |
|---|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Validation Warnings                                         | <p>Applicants are required to include justifications in their cover letter for any validation warnings arising from the criteria outlined in Section 3 and Section 4 of SG-HSA Validation Criteria.</p> <p>Applicants should note submission with excessive and/or repeated warnings in other sections of the validation criteria may be rejected during screening and/or evaluation.</p> |
| 2 | Product Labels                                              | Submission of source file for product labels is revised to be optional.                                                                                                                                                                                                                                                                                                                   |
| 3 | Clarification on submission withdrawal/rejection procedures | <p>When a Submission is withdrawn or rejected, applicants are required submit a Submission Withdrawal Sequence to restore the content to an earlier version.</p> <p>Please refer to the specification for more details.</p>                                                                                                                                                               |
| 4 | Other administrative changes                                | Editorial updates are made to align with the updated technical requirement and validation criteria.                                                                                                                                                                                                                                                                                       |