Instructions for filling the E-Doc folder structure

The following points should be given special attention:

- An application form must always be submitted.
- The application form must be in the 01FM folder.
- Scanned documents must comply with the OCR standard, i.e. the text must be searchable as text. Please ask your IT department.
- There must be exactly 1 file in the 01FM folder (the application form).
- Folders that do not contain documents
  - must be deleted
  - must not contain any information sheets with the statement "this folder is empty" or similar information

E-Doc Structure:

Here you can see the folder numbers, the subject of the folder in the heading bar, as well as the detailed instructions on how to fill the folders:

00F	**Forms**
Instruction: **No documents** on this folder level	
00F-01FM	**Submission Form**
Instruction: It is mandatory that the following document is filed here: **- Application form** - This folder may only contain 1 document and only the application form that defines/controls the submission. - This form must be **available as a saved PDF (no scan!).** - No "Other forms" may be stored here. Please store "Other forms" in folder 02FO. Rationale: Failure to comply with the instruction will result in a "Formal Deficiency". - When printing the application form, not all fields are fully visible, therefore a scan will not show all the information. - The system will automatically read the application form in the future, therefore only 1 form may be in the 01FM folder and this form must be the application form.	
00F-02FO	**Other Forms**
Instruction: The following documents can be filed here: - Other forms e.g. corrections to the CTA form others It is mandatory that the following document is filed here. - **Scan of the page with the original wet-ink signature of the form (last page).** • Please note that the printed paper form with the original wet-ink signature page must be submitted on paper.	
01CL	**Cover letters**
Instruction: The following documents can be filed here: - Cover letter - Other information documents that cannot be filed in any other folder - Response to conditions including related documents - Response to Formal Deficiencies including related documents - Response to Further Information Request including related documents	
02EC	**Ethics Commitees**
Instruction: The following documents can be filed here: - Correspondence, forms and decisions concerning the Ethics Committee. - Other documents concerning the Ethics Committee(s)	
03RA	**Regulatory Authorities**
Instruction: The following documents can be filed here:	

- Study permits from other authorities
- Relevant correspondence **with other authorities**
- “Ground for non-acceptance” from other authorities

04P Protocol

Instruction:
The following documents can be filed here:
- If necessary, superordinate information on folders 41_TP, 42_MP and 43_SSA

41_TP

Instruction:
The following documents can be filed here:
- *** Study protocol** (track change and clean version)
- *** Amendments to study protocol**
- Other documents related to the study protocol
- Signature pages of the study protocol

*** Documents must have a version and date.**

42_MP

Instruction:
The following documents can be stored here:
- *** Master protocol** for studies with complex design (track change and clean version)
- *** Amendments to the master protocol**
- Other documents concerning the master protocol
- Signature pages of the master protocol

*** Documents must have a version and date.**

43_SSA

Instruction:
The following documents can be stored here:
- *** Switzerland specific appendix** (track change and clean version)
- *** Amendments to Switzerland specific appendix**
- Other documents related to Switzerland specific appendix
- Signature pages of the Switzerland-specific appendix

*** Documents must have a version and date.**

05S Safety

Instruction:
The following documents can be stored here:
- If necessary, superordinate information on folder 51_IB and 52_SmPC

51_IB

Instruction:
If you submit IBs for different IMPs at the same time, please create a separate folder here for each IMP. The folder name is ideally the substance name.

The following documents can be filed here:
- *** Investigator's Brochure (IB)** (track change and clean version).
- *** Addenda to IBs**
- Other documents related to IBs

*** Documents must have a version and date.**

52_SmPC

Instruction:
If you submit SmPCs or SmPCs for different IMPs at the same time, please create a separate folder for each IMP. The folder name is ideally the substance name.

The following documents can be filed here:
- *** SmPCs** (Summary of Product Characteristics)
- *** Information for healthcare professionals (Fachinformation)**
- Other documents concerning SmPCs or FIs

*** Documents must have a version and date**

06G GMP Dokumentation

Instruction:

1. If you submit **GMP documents for different IMPs** at the same time, please create here a **separate folder for each IMP**. The folder name is ideally the substance name.

2. For each IMP, the **GMP documents must be filed separately** for "Drug Substance" (61GMP_DS), "Drug Product" (62GMP_DP), "Packaging/Labelling" (63GMP_PL) and "Batch certification/Release" (64GMP_rel).
This means that a manufacturing authorisation which applies to several manufacturing steps must be filed several times:
Example:
QP declaration covers the 4 manufacturers for 1) "Drug Substance" synthesis, 2) "Drug Substance" testing, 3) "Drug Product "galenic manufacturing, 4) packaging.
Filing:
This document must be filed as follows:
Folder 61GMP_DS: 1x
Folder 62GMP_DP: 1x
Folder 63GMP_PL: 1x

The following documents can be stored here:
- If necessary, superordinate information on folders 61GMP_DS, 62GMP_DP, 63GMP_PL and 64GMP_rel.

61GMP_DS

Instruction:
The following documents can be stored here:
- GMP documentation for "Drug Substance" production

62GMP_DP

Instruction:
The following documents can be stored here:
- GMP documentation for "Drug Product" manufacture

63GMP_PL

Instruction:
The following documents can be stored here:
- GMP documentation for packaging and labelling

64GMP_rel

Instruction:
The following documents can be stored here:
- GMP documentation for release / batch certification

07Q Quality

Instruction:
The three substructures given correspond to the 3 most common types of submission.
- Please file your documentation in the appropriate folder.
- If you submit quality documents for different IMPs at the same time, please create a separate folder here for each IMP.
- If possible, use the predefined structure of the subfolders.
- Delete folders of the structure that are not filled.

The following documents can be stored here:
- If necessary, superordinate information on folders 71_sIMPD, 72_one_doc and 73_3m

71_sIMPD

Instruction:
If you submit **quality documents for different IMPs at the same time**, please create a separate folder here for each IMP. The folder name is ideally the substance name.

Simplified IMPDs (sIMPDs) can be submitted if the quality documentation - or part of it - has already been reviewed by an authority as part of a marketing authorisation procedure. In the sIMPD, chapters may be reduced or refer completely to the marketing authorisation documentation.

The following documents can be filed here:

Two types of sIMPDs are accepted:

1. **For clinical study batches:**
Four separate documents describing deviations from the market product.

Folder filling:

11_sIMPD_TOC:	*** Document directory:** This directory must be updated and submitted with each amendment on quality.
12_sIMPD_comp_tab:	*** Difference table.** Presentation of the deviations from the approved documentation in each chapter or the comment identical to the market product.
13_sIMPD_ds:	*** Drug Substance Part:** Only the deviations
14_sIMPD_dp:	*** Drug Product Part:** Only the deviations

2. For modified market goods:

Folder filling:

*** sIMPD** :

A single document. It usually does not contain a "Drug Substance" chapter.
The chapter "Drug Product" contains all chapters and describes in detail the origin, modification, manufacturer, testing and release of the product.

*** Documents must have a version and a date.**

72_one_doc

Instruction:
If you submit **quality documents for different IMPs at the same time**, please create a separate folder here for each IMP. The folder name is ideally the substance name.

IMPDs that contain all chapters in one document and which clearly show a single version with date can be filed here. If the version and date are not clearly visible on the document, a table of contents for the document must be filed in the corresponding folder, which contains a version and date. This index must be updated and submitted with each quality amendment.

Folder filling	*** Table of contents**
21_ TOC:	This list must be updated and submitted with each amendment on quality.
21_Q_doc:	**Quality document:** all chapters in one document

or:

Folder filling

*** Quality document:** all chapters in one document

The following documents can be filed here:
- *** Cleaned versions**
- *** Track change versions**

*** Documents must have a version and a date.**

73_3m

Instruction:
If you submit **quality documents for different IMPs at the same time**, please create a separate folder here for each IMP. The folder name is ideally the substance name.

This folder structure corresponds to the eCTD structure and the eCTD nomenclature and allows to submit all chapters separately.
- A *** contents directory** must be stored in the folder 31_TOC.
- In the folder 32_body data you store the *** documents** accordingly as long as the structure specifies the corresponding folders.
- Delete the empty folders

The following documents can be filed here:
- *** Cleaned versions**
- *** Track change versions**

*** Documents must have a version and a date.**

08L Label

Instruction:
If you submit **labels for different IMPs at the same time**, please create a separate folder here for each IMP. The folder name is ideally the substance name.

The following documents can be filed here:
- - Study labels

9PM Pharmacy Manual

Instruction:
The following documents can be filed here:
- *** Pharmacy manual**
- Other documents concerning Pharmacy manuals

*** Documents must have a version and date.**

10ASR Annual Safety Report / DSUR

Instruction:
If you submit **ASRs/DSURs for different IMPs at the same time**, please create a separate folder here for each IMP. The folder name is ideally the substance name.

The following documents can be filed here:
- *** Annual Safety Report**
- *** DSUR**
- Other documents concerning ASR and DSUR

*** Documents must have a version and a date.**

11USM Urgent safety measures

Instruction:
The following documents can be filed here:
- All information on the Urgent Safety Measure, except for affected core documents.

Core documents are protocol, IB etc. and must be filed in the corresponding folder.

12RAD

Instruction:
The following documents can be filed here:
- Documents concerning radiopharmaceuticals except for the Core Document concerned.

Core documents are protocol, IB etc. and must be filed in the corresponding folder.

13SUSAR

Instruction:
The following documents can be filed here:
- CIOMS Forms
- Other documents concerning SUSAR documentation

14FSR Final Clinical Study Report

Instruction:
The following documents can be filed here:
- *** Final Clinical Study Report**

*** Documents must have a version and date.**

15ISR Interim Reports

Instruction:
The following documents can be filed here:
- Interim reports

16DIL Dear Investigator Letter(s)

Instruction:
The following documents can be filed here:
- Communication letters to investigators

17PIP Pediatric Investigational Plan

Instruction:
The following documents can be filed here:
- Documents concerning the Pediatric Investigational Plan

18SA Scientific Advice(s)

Instruction:
The following documents can be filed here:
- Documents concerning scientific advice from different authorities.

19TOX Toxicology Reprots (preclinical)

Instruction:
Only for First in Human Studies or if explicitly requested by the Swissmedic-assessor.

The following documents can be filed here:
- *** Toxicology reports**
- Other Documents relating to toxicology reports

*** Documents must have a version and date.**

20TA Temporary Authorisation for Use Projects (TA)

Instruction:
Documents concerning Temporary Authorisation for the Use of Medicinal Products pursuant to Article 9b Paragraph 1 HMG (abbreviated: TA)

The following documents can be filed here:
- All documents for the submission of TA projects including core documents.
- Core documents for TA are IB IMPD etc. and must also be filed here.

21MEP Medical Device

Instruction:
The document names must allow conclusions to be drawn about the content of the document.

The following documents can be stored here:
- All documents that apply exclusively to the medical device.
- - Documents that apply to both the medicinal product and the medical device must be filed in the respective other folder (**and only once**).