swissmedic

Information sheet
Instructions for filling the eDok_KLV folder structure

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Instructions for filling the eDok_KLV folder structure

General points

- An application form must always be submitted.
- Scanned documents must comply with the **OCR standard**, i.e. the text must be **searchable as text.** Please ask your IT department.
- 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

eDok_KLV Structure:

Here you can see the folder numbers, the subject of the folder in the heading bar, and the documents to be filed in the folders.

00F	**Forms**
Only Forms shall be filed in this folder • Application Form as a saved PDF (No scan! No digital signature!) • Scan of the page with the original wet-ink signature of the form (last page). • Other forms not described above	

01CL	**Cover letter**
The following documents can be filed here: • Cover letter • Other information documents that cannot be filed in any other folder	

02EC	**Ethics Commitees**
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**
The following documents can be filed here: • Lists of submission status of other authorities • Study approvals from other authorities • Relevant correspondence **with other authorities** • “Ground for non-acceptance” from other authorities	

04P	**Protocol**
Documents concerning the trial protocol can be filed here: If there are multiple protocol types (e.g. study protocol, master protocol, and/or a Switzerland Specific Appendix or similar), file them separately in the folders provided.	
41_TP	**Trial Protocol**
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 Master Protocol

The following documents can be filed 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 Switzerland Specific Appendix

The following documents can be stored here:

- *** Switzerland Specific Appendix** to the study protocol (track change and clean version)
- *** Amendments to the Switzerland Specific Appendix**
- Other documents concerning the Switzerland Specific Appendix
- Signature pages of the Switzerland Specific Appendix

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

05S Safety

The following documents can be stored here:

If Investigator's brochures (**IBs**) and Summary of Product Characteristics (**SmPCs**) / Information for healthcare professionals (Fachinformationen (**FIs**)) are submitted at the same time, distribute the information accordingly to the folders below

51_IB Investigator's Brochure

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 Summary of product characteristics

If you submit SmPCs/FIs 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)
- *** FIs** (Information for healthcare professionals, Fachinformation)
- Other documents concerning SmPCs or FIs

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

06G GMP Dokumentation

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 applicable, distribute the information to the folders 61GMP_DS, 62GMP_DP, 63GMP_PL and 64GMP_rel.

61GMP_DS

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

62GMP_DP

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

63GMP_PL

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

64GMP_rel

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

07Q Quality

The **three substructures** (71, 72, 73) below correspond to the 3 most common types of submission.
- Please file your documentation in the folder with the appropriate structure.
- 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.
- 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, distribute the information to the folders 71_sIMPD, 72_one_doc and 73_3m

71_sIMPD

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: *** Table of Content = Document directory:**
This directory must be updated and submitted with each amendment on quality (track change and clean version).
Sample:

Document Title	Company Code	Version	Date
Active substance name -comparative table (clinical vs. commercial prouduct)	xxxx	x.y	dd-mm-yyyy
Active substance name - Drug Substance part	xxxx	x.y	dd-mm-yyyy
Active substance name - Drug Product part	xxxx	x.y	dd-mm-yyyy

12_sIMPD_comp_tab: *** Comparative table.**

List the differences from the approved documentation in each chapter or write "*no difference*".

Sample:

Active substance name Version: x.y Date: dd-mm-yyyy

INTRODUCTION:

The purpose of this dossier is ....*Please give rationale*...

Table 1
Drug Products presented in the Clinical Product dossier

Drug Product Description
Abcdefghi film coated tablets 20 mg
.....
Swissmedic Authorization number of the Commercial Product: .....

Table 2
Overview of differences between the currently approved clinical product dossier and the commercial product dossier

eCTD Section	Clinical Product dossier vs. Commercial Product dossier	comment
S DRUG SUBSTANCE		
S.1 General Information	no differences	N.A.
S.1.1 Nomenclature	Explain differences in detail	N.A. or comment
S.1.2 Structure	Explain differences in detail	N.A. or comment
...	Explain differences in detail	N.A. or comment
S.4.1 Specification	Compared to the commercial product...	comment
S.4.5 Justification of Specification	Compared to the commercial product...	comment
...	...	...
...	...	...
P DRUG PRODUCT		
P.1 Description and Composition of the	Explain differences in detail	N.A. or comment
P.2 Pharmaceutical	Explain differences in detail	N.A. or comment

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. Usually it 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.

The following documents can be filed here:
- *** Cleaned versions**
- *** Track change versions** (for all updates)

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

72_one_doc

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 (an index) for the document, which contains a version and date, must be filed in the corresponding folder. This index must be updated and submitted with each quality amendment (track change and clean version).

Folder filling 21_ TOC:	*** Table of contents** This list must be updated and submitted with each amendment on quality. (track change and clean version)
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 (**for all updates**)**

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

73_3m

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. This list must be updated and submitted with each amendment on quality (track change and clean version).
- 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 (**for all updates**)**

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

08L Label

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

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

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

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

14FSR Final Clinical Study Report
The following documents can be filed here: • *** Final Clinical Study Report** *** Documents must have a version and date.**

15ISR Interim Reports
The following documents can be filed here: • Interim reports

16DIL Dear Investigator Letter(s)
The following documents can be filed here: - Communication letters to investigators

17PIP Pediatric Investigational Plan
The following documents can be filed here: • Documents concerning the Pediatric Investigational Plan

18SA Scientific Advice(s)
The following documents can be filed here: • Documents concerning scientific advice from different authorities.

19TOX Toxicology Reprots (preclinical)
Only for First in Human Studies or if explicitly requested by the Swissmedic-assessor. The following documents can be filed here: • * Toxicology reports • * PK(PD) modelling report • Other Documents relating to toxicology reports *** Documents must have a version and date.**

20TA Temporary Authorisation for Use Projects (TA)
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
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 (**only once**).

Change history

Version	Change	sig
1-3	New layout, no content adjustments to the previous version.	hem
1.2	Examples for sIMPDs included	gav
1.1	Correction of errors	plp
1.0	SAP submission process and eDok_KLV structure	gav