What you need to know for **Submissions in Switzerland**

Updates

Switzerland's regulatory authority **Swissmedic** started with submissions for pharmaceuticals in **eCTD format in 2009**. Since 2020 Swissmedic is using eCTD M1 version 1.5. Additionally, Swissmedic is also accepting **eDok format and paper submissions**.

A Swiss specialty in eCTD is the "galenic form", an old term for the pharmaceutical form of the pharmaceutical product. In Switzerland, there needs to be a M1 folder for each "galenic form". Product life cycles with more than one galenic form contain a common folder in Module 1.

An **overview of the documents that need to be submitted** for different regulatory activities is **available.**

Paper submissions are still possible, also Paper submission with eDok copy (Swissmedic's application submission format), paper version + electronic version (see Swissmedic website), but eCTD is encouraged. Other electronic submissions, **e. g. NeeS, will be rejected.**

Submissions can be uploaded via **Swissmedic's eGov portal or submitted on CD/DVD.**

Drug Master File

- The **eCTD DMF dossier is a stand-alone dossier** and is independent of the marketing authorization eCTD dossier. Therefore, the DMF (DMF Holder, substance name) and the Drug Product (Authorisation Holder, tradename) consists of two individual eCTD life cycles.
- It is possible to **submit the marketing authorization application as eCTD and the DMF/ASMF** dossier as a paper dossier and vice versa.
- The **DMF/ASMF can be a hybrid submission**, which means that the restricted part is submitted in paper, whereas the open part is submitted in eCTD format as part of Module 3.
- **M1 Galenic Form is "common"**.
- **Envelope Elements:**
  - Swissmedic DMF number (if known)
  - DMF Holder
  - Galenic form name is common
  - Marketing Authorisation Number is n/a
- **Submission description:** the corresponding version of the DMF should be described in the element, e.g.: AP & RP Version 3.00 / description.

Clinical Trial Application

- **Sponsor needs location/agency in Switzerland.**
- Submission on **CD/DVD and Paper,** including cover letter and application form.
- **eDoc Folder Structure on CD/DVD** since 01.01.2022 to reduce paper usage:
  - **Submit CD/DVD and form «Confirmation electronic submission»** to allow Swissmedic to review the submission from CD/DVD.
  - Form **«Confirmation electronic submission» needs to be submitted each time** with follow-up submissions on CD/DVD.

EXTEDO
eRegulatory Affairs

EXTEDO's Regulatory Solutions for Switzerland:

- eCTDmanager: eCTD compilation and publishing for Swiss submissions.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.

ASPHALION
Knowledge from experience

Asphalion can give you support in the following areas:

- eCTD compilation and publishing for Swiss submissions
- Document formatting
- Non-eCTD compilation and publishing
- Transition from non-eCTD to the mandatory eCTD format
- Submission to the agency according to the latest version of Swiss validation rules

For further information, please contact: info@asphalion.com | info@extedo.com