

# NeeS to eCTD Service

## Simplify the process of migrating your NeeS submissions into eCTD format

With the ever-growing requirement for eCTD across Europe it is essential that your submission data is updated and available in the standard eCTD format. According to the EU roadmap, from January 2018, eCTD will be mandatory for all Mutual Recognition Procedure (MRP) and Decentralized Procedure (DCP) submissions, and from January 2019 all submission types within National Procedures (NP) will also be required in eCTD format – some countries even earlier this date, as Germany and Denmark.

### Benefits

- › Reduce the time and effort required to migrate NeeS formatted submissions to eCTD
- › Trusted guidance from industry and standards experts
- › Ensure data quality through detailed activity and adaption logs
- › Guarantee quality of final eCTD submission
- › All data is kept within EU borders during entire conversion process

## The most efficient way to migrate from NeeS to eCTD

If your submissions are currently only available in NeeS format, there is no time better than now to begin the transition process. EXTEDO's NeeS to eCTD conversion service provides you with the expertise and resources you need to convert your existing NeeS submissions into eCTD format. It saves you time and money, and allows your essential internal resources to continue with daily operational activities.

Our team of expert consultants will work with your business to uncover any existing NeeS submissions and plan your structured migration process. Through a partially automated sequence of steps we will then convert the existing submissions into the eCTD format. Throughout this process a detailed conversion report will be maintained, this outlines all activities undertaken and any adaptations made to the submission. Once the conversion is complete, our eCTD experts will perform a final review and technical validation of each submission to ensure that it complies with appropriate regional standards.



## EXTEDO's NeeS to eCTD conversion service includes the following elements:

- › Import of original EU NeeS dossiers
- › All activities and changes tracked and reported
- › High quality conversion supported by EXTEDO's industry-leading tools
- › Validation of final eCTD submission

Whether one or hundreds, if you still have submissions in NeeS format now is the time to get them converted to eCTD. EXTEDO is here to support you throughout that journey, so contact us now to find out how we make the process effortless.

For further information contact your local EXTEDO representative:



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### About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.