Regulatory Affairs Services

PhytoLab

FLEXIBLE ECTD PROCESSING, PUBLISHING AND SUBMISSION – ASSISTANCE FOR YOUR MARKETING AUTHORISATION DOSSIERS

Background

The Common Technical Document (CTD) has been established as the standard format for all registration / marketing authorisation dossiers throughout the EU since 2003. Use of the eCTD format has also been mandatory for all regulatory activities within the framework of the national procedure since 1 January 2019. In spite of this, there are numerous dossiers for earlier marketing authorisations, which are not available in eCTD format at all, or only in part.

Strategic evaluation

In some cases, depending on the format of the dossier and the regulatory authority concerned, it may be necessary to submit an obligatory eCTD baseline submission in case of conversion of the dossier from hardcopy or NeeS format to eCTD. However, even if the regulatory authority does not impose such a mandatory requirement, it is advisable to convert Module 3, for example, into a consolidated format prior to upcoming regulatory activities such as pending variations, as this is the only format in which the life cycle of the dossier can be clearly mapped. This consolidated version of the dossier not only offers a means of ensuring that the dossier status approved by the authority is transparent and available at a glance, but also facilitates the planning and implementation of all future regulatory activities, especially with respect to variations to be submitted at short notice.
Incidentally, a baseline submission can still be carried out, even if individual sections of the dossier have already been submitted in eCTD format at an earlier point in time.

Processing, publishing and submission: flexible and reliable

Creation of a baseline version can give rise to capacity bottlenecks within a company, especially when everything has to be done quickly. We offer you a means of optimising your resources by offering uncomplicated assistance at short notice to reformat your NtA, NeeS and CTD data to produce eCTD sequences. You have the flexibility to decide whether you just need eCTD-ready files for electronic processing at your own premises, or whether you would prefer us to take the load off your shoulders completely by publishing and submitting the eCTD dossier on your behalf, via the CESP portal (Common European Submission Platform), for example.
Our all-inclusive eSubmission service enables you to plan upcoming regulatory activities with confidence and conduct them quickly and cost-effectively without incurring additional structure costs for hardware, software, technical support or staff to handle workload peaks.
Benefit from the many years of experience gathered by our regulatory affairs experts.

Our experts will be happy to advise you.

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