

A person is running away from the camera on a dirt path that is covered with fallen autumn leaves. The path is lined with trees whose leaves are in various stages of autumn, ranging from green to yellow and brown. The scene is misty or foggy, creating a soft, atmospheric background. A large, semi-transparent green rectangular overlay covers the middle portion of the image, serving as a background for the text.

Regulatory affairs





Freshness

We never stop improving our activities; the secret of our success is our open-minded, fresh and positive attitude.

Successful Regulatory Documentation

We will be happy to provide you with our comprehensive, up-to-date expertise to meet all your regulatory needs.

Regulatory knowledge and strategy planning are crucial for your product's success. We are able to help you when your regulatory needs involve human and veterinary medicinal products, herbal medicines and medical devices.

With our thorough knowledge of current European regulations, guidelines, procedures and authorization requirements, we can help your product navigate through the following stages:

- *Marketing authorization*
- *Pharmacovigilance*
- *Pricing and reimbursement*
- *Pharmaceutical wholesale issues*
- *Clinical trial applications*
- *Quality assurance (GCP, GMP)*

Marketing authorization services are the final link in our total chain concept. We can provide pharmacovigilance services in both pre- and post-marketing settings. In addition to helping in submission of price applications/renewal applications, we can undertake health economic analysis to be conducted by outside experts.

Our regulatory services not only cover the Scandinavian and the Baltic countries, but extend to Western, Central and Eastern European countries through our regulatory network.

Fairness

We keep our promises.
You can trust us and rely
on our commitment to
co-operation.

Flexibility

We provide the highest
quality of work; we
are flexible, prompt,
and accurate with a
professional attitude.

Are you capable of making regulatory submissions in an eCTD format? - Medfiles is!

We are able to assist you in your electronic submissions.

Medfiles eCTD services

- Preparation of an eCTD application from your CTD format documents
- Reformatting of your non-CTD format (e.g. NtA) application into a CTD format and preparation of an eCTD
- Compilation of full dossiers/ individual modules / variations etc. in a CTD format and preparation of an eCTD
- Preparation of an eCTD from your NeeS
- Product life cycle management of your eCTD format submissions within the eCTD tool.

In its regulatory submissions Medfiles utilises one of the most comprehensive management softwares in the world - the LORENZ docuBridge®. Most of the current types of paper / electronic documentation of CTD / NeeS may be built / validated / published / managed / formatted / converted within the LORENZ docuBridge®.

Benefits

- Expertise in preparation of eCTD-format applications
- Reduce your investment and personnel costs for eCTD
- Medfiles fulfills your individual needs and provides seamless collaboration.

LIFE CYCLE MANAGEMENT

Electronic Submissions



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Medfiles fulfills your eCTD needs!



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If there is anything you would like to ask us, please, don't hesitate to contact us.

We keep our promises.

Excellence Combined With Speed

Our personnel pride themselves on their experience, commitment, competence and flexibility – they are the foundation of our acknowledged client-oriented service. Our personnel undergo continuous training to ensure that you will be guaranteed services of the highest quality.

Our aim is to enjoy a close, long-term partnership. By outsourcing your regulatory affairs to us, you will be able to focus on your core business, free-up human and fixed capital and simplify your internal administration.