DORIAN REGULATORY AFFAIRS BV

Dorian Regulatory Affairs BV is a small, flexible consultancy company, with extensive experience in the registration of conventional and biotechnological pharmaceutical products, particularly within Europe.

The company is located in the Netherlands and was founded early 1999 by Dorine Mulder, who started her career in regulatory affairs in 1983. Experience included more than 8 years as Director Regulatory Affairs at the European headquarters of a major biotechnology pharmaceutical company. Dorine Mulder has a Dutch Doktoraal degree (Drs.) in biochemistry as well as an English M.Sc. in toxicology.

During the years in industry, particular expertise has been gained in the fields of biotechnology, oncology, dermatology, ophthalmology and gastrointestinal diseases. Products have been registered in the EU through national procedures, the mutual recognition and decentralised procedure as well as the centralised procedure, while national procedures outside Europe have also been concluded successfully. Professional contacts have been established with national authorities as well as regulators at the EMA.

As a small company with extensive practical industry experience, services can be tailored to meet customers' specific needs and timelines. Dorian Regulatory Affairs BV can be your partner in optimising the registration package and strategy, and can assist in obtaining (or maintaining) a marketing authorisation at the earliest possible time.

The services that Dorian Regulatory Affairs BV offers include:

- Strategic regulatory advice
- Preparation of marketing authorisation and variation applications, including liaison with regulatory authorities and the preparation of responses to authorities' questions
- Preparation of consolidated dossiers incorporating responses and variations
- Preparation of Orphan Drug Designation Applications and liaison with the EMA
- Arranging SME status with the EMA, also for companies not established in the EU
- Evaluation of pharmaceutical, preclinical and clinical data for in-licensing purposes
- Regulatory intelligence services
- Preparation of Module 2 overviews and summaries
- Preparation of SmPC's, package inserts and labelling
- Co-ordination of requests for scientific advice (EMA and national authorities)
- Preparation of paediatric investigation plans (PIP)

Through a network of colleague consultants, who are active in related fields such as medical writing, GMP, toxicology and eCTD publishing, addi tional services that may be needed to successfully develop and register a product can also be arranged.

Clients range from small start-up to large wel l-established companies, and any size in-between. The products these companies have in their portfolios are biotechnological as well as conventional products, and projects vary from a few days' special assignments to large long-term projects. Products vary from orphan drugs to potential blockbuster products. About a third of the clients are situated in the US, a third in the Netherlands, with clients in the rest of the European Union making up de final third. For the non-European clients in particular, Dorian Regulatory Affairs can act as your European regulatory affairs department, including being the contact point for the authorities.

If you require additional information or would like to discuss your specific needs, please contact Dorine Mulder at Dorian Regulatory Affairs BV at one of the numbers shown below or visit our website at www.dorian.nl.

Dorian Regulatory Affairs BV

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Useful information

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