# Support for the Marketing Authorisation Application (MAA) through the centralised procedure in Europe

A small biotechnology company entrusted BlueReg (BR) to prepare and coordinate their MAA for registration in europe through the centralised procedure (CP) including full regulatory and scientific writing support.

* Marketing authorisation application

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# Challenges

This project consisted in support for MAA in Europe, with the following constraints:

- First MAA for the client
- Tight timelines for dossier preparation and submission
- Scientific challenges due to BR's involvement at the last stage of development in order to prepare and submit a dossier according to the applicable regulatory requirements.

## BlueReg support

BR created a dedicated team of consultants with individual expertise allowing to meet the regulatory requirements and client's expectations:

### A senior project lead

- Acted as main contact point to the client.
- Ensured coordination of activities between the client and BR consultants.

### A regulatory team composed of consultants with expertise in MAA

- Provided advices to the client on all steps and interactions with the European Medicines Agency (EMA) from eligibility to the CP until end of procedure.
- Worked closely with the scientific writing team to ensure regulatory guidelines were taken into account and any deviations from these guidelines fully justified in the CTD dossier.
- Provided operational support by coordinating the CTD preparation and ensuring respect of deadlines.
- Publishing in eCTD.

### A scientific writing team composed of consultants with expertise on CMC, non-clinical and clinical areas provided the following support

- Performing a gap analysis on the CMC, nonclinical and clinical package in preparation of MAA,
- Close work with client's manufacturing site ensuring all Quality requirements were correctly fulfilled.
- Strategic input, i.e. assessment, utilisation and positioning of available data, for preparation of quality, non-clinical and clinical Modules of CTD dossier and responses to Agency's questions
- Authored and/or reviewed non-clinical and clinical summaries and overviews (Module 2), as well as all CMC Modules (Quality Overall Summary and Module 3), and responses to Agency's questions.

The team of consultants composed at the start of the project remained constant during the project to ensure consistency throughout the project and optimise the expertise gained on the specific product under development. This contributed highly to the success of the project and increased the client's trust throughout the project.

## Achievements

- Submission of initial dossier and responses to questions according to agreed timelines in compliance with Regulatory requirements laid down by the EMA.
- Client's acknowledgement of BR scientific expertise (eg. major objections raised during procedure identified at the start of project during gap analysis).
- Creation of strong relationship with the client, BR becoming their preferred partner for any regulatory and scientific writing activities.