CASE STUDY

REGISTRATION

Support for a Hybrid Application in the European Union

BlueReg was involved in the review of a Hybrid Application for a medicinal product in Ophthalmology to be submitted to the European Medicines Agency (EMA).

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Challenges

This project aimed at providing regulatory and scientific writing support for a Hybrid Application for a medicinal product as per the Article 10(3) of Directive 2001/83/EC, with the following specificities:

- The Non Clinical and Clinical Overviews had been updated with published literature pertinent to the medicinal product in the broad therapeutic area (Ophthalmology).

- To ensure consistency between Module 3 and QOS.

- Very little published evidence relevant to the reference medicinal product.

BlueReg support

BlueReg put in place a team of highly experienced consultants with solid expertise in regulatory/ scientific writing to meet the client's needs and the project specificities.

A project manager:

- Acted as the main contact point with the client.

- Ensured project coordination between the client and BlueReg consultants, collected all necessary documentation, and ensured delivery of reviewed documents of high quality to the client as per agreed timelines.

Regulatory affairs and scientific writing consultants:

Regulatory actions:

- Review of the dossier Module 1 against regulatory requirements as per the Article 10(3) of Directive 2001/83/EC.

- Proposition of justifications for any missing information/data.

- Cross review of Module 1, Section 1.5.2 against the overviews (QOS, Non-Clinical and Clinical Overviews), to anticipate any potential major issues with the application.

Scientific Writing actions:

- Following Module 3 and QOS review, proposition of changes to have a "state of the art" Module 3 in term of writing and formatting. Assessment that ICH M4Q requirements had been fulfilled. Ensure consistency of Modules 2.3.S & 2.3.P overviews with Module 3.

- Review the Non-Clinical and Clinical Overviews updated following a systematic literature search for evidence relevant to the other products from the same drug class as the medicinal product and its reference in Ophthalmology.

- Review the documents in line with regulatory and scientific requirements for a Hybrid Application dossier being pursued by the client.

- Validation of the document structure required for such application.

Achievements

- With a team of consultants of complementing expertise, BlueReg ensured that this Hybrid Application was fully compliant with regulatory requirements as per the article 10(3) of Directive 2001/83/EC.

- The team validated the systematic literature search performed to provide sufficient and relevant non-clinical/clinical evidence for a Hybrid Application.

- The structure for the dossier overviews was as per EMA requirements, including the need to justify missing data.

- The team confirmed that Module 1.5.2 fully supported the legal basis and/or provided valid justification for missing data, to fulfil the regulatory requirements for a Hybrid Application.

- Potential outcomes and risks were highlighted to the client.

- The client recognised the high regulatory and scientific expertise of the BlueReg consultants and acknowledged the added value from the BlueReg support to their application.

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