

Coordination and Regulatory support across Europe for an innovative product/orphan drug

The Vice-President Global Regulatory Affairs of a US based company developing an important innovative product (orphan drug) contacted BlueReg to seek regulatory support to discuss the different stages of development in Europe.

Our Client Objectives:

- Understand the pathway towards approval in the proposed market and target therapeutic indication.
- Anticipate potential discussion highlights with regulators and take advantage of pathways according to product type/category (ATMPs, ODD).
- Prepare a robust regulatory dossier that details application in order to optimize chance of approval and success.
- Alignment of EU with US strategy (streamline & capitalize, minimize change & cost).