Support for a Well Established Use dossier in the European Union

BlueReg (BR) was involved in the elaboration of a well-established use (WEU) dossier for an orphan drug in a life threatening and debilitating condition for the European Medicines Agency (EMA). BR initiated a systematic review of the literature on clinical aspects to support the WEU justification and updated it in line with regulatory requirements. BR also structured the non-clinical and clinical overview sections of this Common Technical Document (CTD). A regulatory risk / mitigation assessment was conducted for each WEU eligibility criteria in view of an EMA pre submission meeting.