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).

BlueReg reviewed the Module 3 (Quality) as well as the Quality Overall Summary (QOS), Non-Clinical Overview and Clinical Overview, to determine if they contained sufficient relevant evidence to support a Hybrid Application. BlueReg also reviewed the legal basis for validation of the Hybrid Application status in Module 1 of the dossier.