

EU RA consultancy for marketing authorisation applications

Preparing and successfully filing a Marketing Authorisation Application (MAA) is a major achievement for which external staff are often required to cope with peak workloads. We offer you our expertise at an EU and national BENELUX level and extra hands to assist the team in this major exercise and guide them through the submission and approval process. We review submission components, help compiling the application and respond to questions. We are able to run your regulatory procedure, or support specific steps in the process (e.g. handle BENELUX translations during the CP linguistic process or manage the administrative closing during the national phase of MRP/DCP). We have experience with all types of MAAs and EU procedures (Centralised, Decentralised, Mutual Recognition, or National Procedures), including preparation and participation in pre-submission meetings, oral explanations or discussion meetings. We have also been involved in re-examination procedures and Referrals.

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