

Parallel submission of multiple MAA's to the MHRA

Challenge:



- Client requested European Regulatory Affairs (ERA) to submit several UK National MA applications (MAA) to the MHRA within a very short timeline.
- ERA was given a deadline of 9 weeks to complete this work and upload the applications
- The scope of work included preparation of module 1 (including review of product information), preparation of Module 2.4 & 2.5 (with M4 and M5 Literature references), plus gap analysis of dossier (M3), eCTD compilation and upload via MHRA Portal

Solution:

- These MAA applications were divided up within the ERA team
- Relevant MHRA guidance documents were applied by ERA team
- ERA assessed the appropriate route of submission in the UK e.g. Purely National, IRP A or IRP B (Regulatory Strategy)
- ERA reviewed the documents provided (including product information) and performed gap analysis of dossier sections received
- ERA provided the client with a list of deficiencies identified and liaised with the client to fill as many gaps as possible, before submission took place
- ERA used its network of Clinical/Non-Clinical experts to compile Module 2.4 & 2.5 for the client
- ERA submitted the dossiers via the MHRA Portal on time
- ERA liaised with the Client & the MHRA to resolve any validation/requests for further Information (RFI) queries obtained during assessment

How we excelled:

- ERA team are adaptable and were able to manage this project as each member of the team has over 18 years' experience, each, in the pharmaceutical industry
- This level of knowledge and expertise facilitated the efficient application of MHRA Guidance documents when preparing applications for the UK
- ERA have effective teamwork and time management skills and could meet the tight turnaround time to the satisfaction of the client
- ERA have a wealth of knowledge & experience as a result of working with the MHRA and could provide the client with a full dossier review and submission service which resulted in positive outcomes

Outcome: Approval of 4 UK National MAA Applications within 10.5 months