Effective Regulatory Strategy for Post-authorisation activities

Challenge:	Solution:	How we excelled:
➢ Client needed to amend a shelf-life parameter in the approved specifications (m3.2.P.5.1) ➢ The limit had been tightened during the initial Marketing Authorisation Application (MAA) assessment, based on pilot scale batches, however once commercial scale batches were launched it became challenging to meet this limit for multiple valid reasons ➢ This change had to be applied **to both EU and UK licences** in a manner that would maintain continued supply of the product to critical patients	➢ ERA reviewed the complete data, presented in Module 3, submitted during the MAA ➢ ERA also reviewed the data of current commercial batches as well as the ongoing stability data ➢ ERA prepared a robust justification document for the Client, based on the available data, clarifying the points that were not considered during the initial tightening of the limit ➢ ERA submitted this justification and effectively demonstrated that this change should not be considered as a widening of the approved limit ➢ ERA evaluated what information the assessor would need to make their decision and made sure it was included in the variation package (to avoid validation queries or delayed approval due to Request(s) for Supplementary Information) ➢ ERA obtained a positive outcome with no validation issues and received EMA approval within 30 calendar days ➢ ERA then worked closely with the MHRA and obtained a positive outcome for the same change to the UK National Marketing Authorisation (MA), via IRP route, within 5 business days	➢ ERA team are very knowledgeable and experienced in the understanding of the information provided in Module 3 and in the effective application of Variation guidance for post-authorisation changes ➢ This level of knowledge and expertise facilitated the efficient application of EMA and UK Guidance documents when preparing this application ➢ ERA have a wealth of knowledge & experience as a result of working with the various NCAs and could provide the client with a solution that achieved their desired outcome

Outcome: Approval of important change, without NCA queries, in a timely manner