Case Study

Parallel NDA/MAA eCTD Submission

Challenge

3 dossiers (an NDA and 2 MAA) for initial application for DP for prevention of pregnancy

- Dossiers for EMA and FDA with differences in the requirements
- Support for the client (one US NDA and one EU MAA) and their third-party collaboration partner (one additional EU MAA)
- Differences in the administrative part of the dossiers and following updates of M1 and M2 documents
- Short notice changes before the planned submission dates due to difficult alignment between affected parties

Solution

Follow-the-sun approach for EU and UD Regulatory Op. resources including defined communication and alignment

- Definition of an early-stage dossier preparation strategy and alignment with all stakeholders
- Effective preparation and re-use strategy for all common files and dossier parts to minimize the publishing time and multiplication of work
- Stricter requirements for technical validation had been applied for all common files in order to be applicable for FDA and re-used for EMA
- Coordinated and organized co-work between European and US teams of PharmaLex
- Guaranteed 24hrs support for the client with maximum provision and assurance for meeting the timelines (“follow-the-sun approach”)

Outcome

Successfully submitted applications to EMA and FDA without delays or rejections

- Submitted on time and passed technical validation
- Expert support with knowledge covering both EU and US regions
- Structured teamwork between EU and US to meet timelines and provide high quality dossiers
- Utilization of most cost-effective resources, while offering a flexible support model even for last minute changes