Expert CMC advices on quality dossier preparation in support of Compassionate Use Program in France and preparation of a Quality Investigational Medicinal Product dossier in e-CTD format.

In the context of PRIME, a European biotechnological company entrusted BlueReg CMC team with the task of bringing the available quality data package of a synthetic peptide to global registration prerequisites for the next steps of development (Compassionate use program in France, Phase III global program, registration in Europe and US) and to write the Quality part of the IMPD for early access submission in France.

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Challenges

One of the main challenges was the change of the drug substance (DS) and the drug product (DP) manufacturers following the completion of the Phase II clinical trial, in a context of accelerated filling allowed by a granted PRIME. In a tight timeline before the dossier submission of the French Early Access Program called ATU (Autorisation Temporaire d'Utilisation), the Quality package required a thorough CMC review and an action plan was established and followed to upgrade specifications, methods, elucidation of impurities, batch manufacturing and stability data for both DS and DP. Then the Quality package was updated to incorporate quality documentation related to the newly introduced DS and DP manufacturers.

BlueReg support

BlueReg was selected for its recognized CMC expertise, project management skills, knowledge in ATU requirements in France and registration requirements across Europe and Rest of the World (RoW).

A dedicated team of consultants was assigned to this project, which included well experienced CMC experts and senior CMC medical writers.

The team was accountable for the following activities:

Strategic activities

- Critical review of the available Q-IMPD with a gap analysis as deliverable and recommendations on the CMC development plan from Phase II to registration requirements in Europe and US.
- Acting as CMC expert and main contact point for the French medicines agency, ANSM.

Operational activities and Project Management

- CMC coordination of drug substance and drug product manufacturers' activities for the upgrade of their quality data package, considering the international context (US, Europe, Asia).
- Establishment of DS and DP specifications, design of stability studies, review of method validation protocols, review o f DS and DP process development documentation, design of process validation for lyophilization.
- Project management, risk and change management by BlueReg's project manager certified PMP® in close interaction with the Sponsor, suppliers and subcontractors, participating to operational and strategic meetings, monitoring the project timetable.

Scientific writing

- Positioning of available data in the quality package (IMPD).
- Review data consistency, integrity and flow.
- Writing of IMPD (pharmaceutical part) in an e-CTD format.

Achievements

- Achievement of CMC requirements set-up for ATU submission and for the next steps of development at drug substance and drug product manufacturers level in a 6-month timeframe.
- Submission of the ATU dossier including pharmaceutical IMPD in e-CTD format, in accordance with agreed timelines.
- Customer's recognition of Blue-Reg's CMC expertise and writing skills.