Case Study

Strategy and delivery of global biosimilar development program

Challenge

Needed expertise for biosimilar regulatory strategy and support with execution

- A company with small molecules background wanted to enter biosimilar field and although had recently recruited a skilled technical team, lacked the global regulatory approval experience.
- Support required for initial regulatory and development strategy for EU, US, Canada, Brazil and other regions of the world.
- In need of support to execute the strategy to obtain approval.

Solution

Defined development strategy and support execution of recommendations

- A project manager was assigned to lead the project and act as a single point of contact.
- A skilled multi-disciplinary (non-clinical, CMC and clinical) regulatory expert team with a background in global biosimilar requirements was defined and completed a gap analysis and development strategy document.
- Regional regulatory experts input into the document to ensure specific regional requirements were identified and the PharmaLex team worked with the client to support execution.

Outcome

Biosimilar approvals

- Project manager retained oversight of this complex program.
- Realistic budgets were agreed and delivered to the agreed timelines.
- Successful approval of biosimilar in multiple regions (other regions of the world ongoing according to defined strategy).