Case Study

Regulatory CMC compliance reduced workload by 20-25%

Challenge

High additional workload due to expansion in product portfolio

- More than 150 different formulations, resulting in more than 1200 national registration documentations worldwide.

Solution

Large pool of experts ensuring high flexibility depending on workload

- Provided profound knowledge of Quality dossier and GMP requirements.
- Had long-standing experience in CTD Module 3 preparation.
- Have wide range of language skills avoiding time and external resources for translations.
- Offered attractive pricing models due to availability of near-shore resources.

Outcome

20-25% reduction in workload

- PharmaLex performed compliance checks between national registration documentation and GMP documentation to ensure risk reduction and guarantee business continuity.
- PharmaLex prepared transfer activities from contract manufacturing organizations to client's manufacturing sites.
- PharmaLex supported the update of Module 3 CTD documentation and provision of additional variation documentation.