

Regulatory CMC Compliance reduced workload by 20-25%

Support in compliance checks and following activities

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

- Profound knowledge of Quality dossier and GMP requirements
- Long-standing experience in CTD Module 3 preparation
- Wide range of language skills avoiding time and external resources for translations
- Attractive pricing models due to availability of near-shore resources

Outcome



Client's resources now focused on strategic activities with distinct reduction of workload by 20-25%

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