

Global CMC responsibility during portfolio integration

Challenge



Tight contractual agreed timeframe and multiple data migrations and process adaptations

- Portfolio acquired by client for which CMC maintenance already handled by PharmaLex >8 years before acquisition.
- PharmaLex with same functional role in new company but different scope of work.
- Compliance with changing client processes due to data migration.
- Portfolio with > 80 INNs (chemicals, herbals, biologics) authorized worldwide.

Solution



Transparency of timeframes and individual project planning

- Provided flexible staffing solutions (new tasks versus maintaining historical knowledge).
- Used strong business-driven prioritization.
- Conducted regular team internal Q&A on changing process and system environment following initial client training.
- Continued use of process history and portfolio knowledge files during transition.
- Ensured continuous communication with client to follow-up on activities.

Outcome



Data migration completed in parallel to ongoing CMC maintenance activities

- CMC maintenance progressing according to planning in parallel of data migration.
- Successful performance of gap analysis and outline of remediation measurements according to client's standards and expectations.
- Process improvements implemented by client.