

eCTD submissions for global DMF portfolio

Challenge



Client was lacking internal expertise during workload peaks

- Big multi-national chemical company.
- Client intended to switch all existing Drug Master Files (DMF – active substances as well as excipients) into eCTD format.
- Portfolio also included Veterinary Master Files, which require a specific electronic submission format.

Solution



Dossier compilation, publishing and validation performed on PharmaLex premises and systems

- Publishing and submission of large DMF updates was planned and kicked off with dedicated PharmaLex project.
- Publishing of small and medium-sized submissions on ad-hoc request (based on defined minimum timelines).
- PharmaLex offered support with:
 - eCTD publishing.
 - Electronic submission for DMF maintenance activities.
 - Consultancy for electronic submission management.

Outcome



Flexible handling of workload peaks

- Full access to pool of eCTD and eSubmission experts through PharmaLex.
- Technical transfer via Health Authority electronic submission gateways fully managed and maintained by PharmaLex.
- All system-related tasks are managed completely by PharmaLex, incl. system maintenance and validation and user training..
- Flexible solutions to new eSubmission requirements.