Regulatory publishing support on request

Challenge

Client lacking resources for EU publishing activities

- Global generic company needed support for EU publishing activities for parts of its product portfolio.
- All EU eSubmission activities (eCTD, NeeS) were transferred to PharmaLex.
- Scope of PharmaLex responsibilities:
  - Direct correspondence and interactions with Regulatory Affairs functions.
  - Collection of related documentation.
  - All dossier as well as submission activities.

Solution

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

- Defined and agreed process between PharmaLex and client.
- Provided direct access to responsible PharmaLex publisher(s).
- Publishing and submission of big dossiers planned and kicked off with dedicated PharmaLex key contact.
- Publishing of small and medium-sized submissions on ad-hoc request (based on defined minimum timelines).
- Archival copy of all sequences provided to client.

Outcome

Full access to pool of eCTD / NeeS experts at PharmaLex with minimal lead time

- Flexible handling of workload peaks.
- All system-related tasks are managed completely by PharmaLex, including system maintenance and validation and user training.