Case Study

Flexible eCTD publishing support

Challenge

Global innovator company looking for flexible support and ability to meet tight deadlines

- Global innovator company and European generics arm requiring UK local affiliate support.
- Covering MAAs and post-approval submissions.
- More than 250 MAs
- Typically 25 – 30 eCTD sequences required per week across the portfolio.

Solution

Flexible contractual framework allows hours to be used for standard publishing support or strategic advice

- Provided a team of trained publishers who are appraised in the client's ways of working and the latest eCTD intelligence.
- Client provided completed dossier components and receive back a validated completed sequence.
- PharmaLex took a proactive approach to discussing and rectifying historical publishing issues to prevent future problems.
- PharmaLex made submissions on the client's behalf when required.

Outcome

Successfully published a wide variety of submission packages in eCTD format

- Ability to work to tight deadlines and last-minute updates to documents.
- Lifecycle management strategic advice is provided e.g. baseline requirements
- A number of historical issues with eCTD management have been rectified.
- Support with submissions through relevant electronic portals is provided when the client experiences capacity constraints.