Case Study

Regulatory Operations IND transition to eCTD

Challenge

Transitioning a Gene Therapy Paper IND to eCTD

- Small-sized pharma company in EU
- Mapping from a paper IND to eCTD with an exceptional investigational drug to the application backbone
- Multiple dossiers previously submitted in paper format
- Education, training & guidance regarding eCTD submissions in the US
  - eCTD Template Training
  - Formatting Training
  - Pre-publishing & QC
  - Compilation & Dispatch

Solution

PharmaLex network of resources and experience utilized to guide the client to success

- CMC subject matter expertise for gene therapy was provided to effectively map eCTD locations of legacy documents
- Anchor eCTD submissions were established and dispatched through the FDA electronic submissions gateway to begin the eCTD submission management
- Experienced regulatory operations managers guided the client regarding the nature of lifecycle operators and eCTD granularity
- Technical support was provided for eCTD templates

Outcome

Applications were successfully transitioned to eCTD format with the agency

- Specialized expertise according to their unique technology was provided
- Experienced regulatory operations managers specifically assigned to support the client in transition as well as for ongoing lifecycle maintenance of application dossiers
- Client successful in application compliance with current technological submissions standards of eCTD