

Sr. ePublisher – provide contract electronic publishing support to U.S. biopharmaceutical companies for U.S., Canadian and European regulatory submissions. Have publishing experience with the electronic and paper CTD submissions, as well as “hybrid” formats.

Publishing Experience

Sr. Contract Publisher and Manager, **PACE eSUBMISSIONS, LLC**

DENDREON CORPORATION: Assisted with publishing Module 3 of a hybrid BLA for CBER in CTD format using Omnicia’s OmnieFile publishing software. Completed submission ahead of schedule.

DEY, L.P.: 6/2005 & 12/05 - 5/2006: Assisted with publishing and quality review of a CDER eCTD NDA submission and related CSRs.

TERCICA, INC.: 7/2004 – 8/2004; 1/2005 – 2/2005; 10 - 12/2005; 6 – 8/2006: Assisted with publishing of Increlex NDA for CDER in eCTD format using CoreDossier & Submission Accelerator software, assisted with publishing of CTD MAA for Europe in paper and electronic formats, managed EU submission of 120-day response. Helped train support staff in use of various publishing software.

AMGEN CORPORATION: 8/2002 – 1/2003 AND VARIOUS TIMES SINCE: Managed publishing and QA of 4 Enbrel sBLAs (3 completed ahead of schedule), numerous site doc and periodic reports for the FDA, and a sNDS for Canada. Created publication timelines and trained temporary staff in the use of CoreDossier. Assisted publishing of hybrid eCTDs and miscellaneous submissions for CBER & CDER.

ELAN PHARMACEUTICALS, INC.: SUMMER 2003, 2/2004 – 5/2004: Assisted in developing demo for EU paper CTD; wrote test scripts for editing and printing CoreDossier publications from European office, published multiple nonclinical reports and CSRs, and managed Module 2 for EU NDA in CTD format.

CHIRON CORPORATION: 1/2002: Project lead for filing e-IND (electronically and in paper) for CBER. Guided staff in troubleshooting their first use of CoreDossier and Documentum for electronic publishing. Strong team effort led to success in meeting extremely tight deadline.

3/2002: Assisted with electronic filing of amendment to e-IND and trained staff in use of CoreDossier.
12/2004 – 1/2005 AND VARIOUS TIMES SINCE: Published IND for FDA and assisted with various ROW (rest-of-world) regulatory filings. Operated Docutech printer for printing paper filings. Covered daily publishing duties for “Rest of World” submissions while staff publishers were on vacation.

IMMUNEX CORPORATION: 3/2001 - 7/2002: Published many small and medium sized periodic reports, annual reports, site docs and study reports using CoreDossier. Developed Word TOC and extraction tree templates, optimized Acrobat distillation properties for color images, “cleaned” scanned documents for use in filings, collaborated with technical writers to minimize processing effort needed to create consistent formatting and worked with Liquent’s tech support to resolve numerous software issues.

Publisher, **IMMUNEX CORPORATION**, Submissions Technology, via Lab Temps, Bellevue, WA 3/1999 – 12/1999: Assisted with validation testing of CoreDossier. Supported publishing of company’s first large paper and fully electronic sBLAs to CBER. Assisted with creation of the writer’s style guide and template.

Skills

Strong analytical skills, detail-oriented, reliable, calm under pressure and resourceful.

Project Manager:

- ❖ Expedite production of submissions with detailed planning and multi-tasking
- ❖ Create and maintain cooperative working relationships for great team efforts
- ❖ Troubleshoot to find “work-arounds” to software bugs and resource limitations
- ❖ Organize communications and data for clear understanding

Software Used in Publishing:

- ❖ CoreDossier (certified Expert)
- ❖ Microsoft’s Office
- ❖ ISI’s Toolbox
- ❖ Lipient’s Subm. Accelerator
- ❖ Adobe Acrobat
- ❖ Omnicia’s OmnieFile
- ❖ Lipient’s Ultralink
- ❖ Documentum
- ❖ Datafarm’s ezQA
- ❖ Global Submit’s Reviewer
- ❖ OpenText’s Livelihood
- ❖ ART’s PDF Linker

Education & Software Training

- ❖ DIA’s Regulatory Affairs courses on The IND and The CTD/NDA Phase
- ❖ Arbortext’s Understanding SGML, XML & Epic Editor
- ❖ BS in Chemical Engineering, University of Washington, Seattle, WA