John L. Dancewicz

Regulatory Publishing Consultant

Core Competencies

- Life Cycle Management
- eCTD Formatting
- Technical Writing

Professional Summary

With over 13 years of experience in quality assurance and electronic document control, Mr. Dancewicz has supported a broad array of projects over the course of his career.

Mr. Dancewicz is responsible for planning, maintaining timelines and submitting eCTD submissions to Health Authorities (HA) assuring the quality and completeness of the submission. He reviews CMC documentation for consistency, quality, and compliance, and supports regulatory affairs to prepare eCTD submissions using industry templates while adhering to regulatory requirements.

Education

CMWP	Certified Medical Writing Professional	CfPIE
A.A.	Associate of Arts	Front Range Community College

Professional Experience

Design Space Inpharmatics, LLC **2019 - Present**

Regulatory Publishing Consultant

- Ensures that submission documentation meets all mandatory health authority and validation requirements,
- Compiles and publishes eCTD regulatory submissions to markets in accordance with current standards and processes,
- Coordinates regulatory operations and activities, including organizing, tracking and publishing of all regulatory submissions and related correspondence,
- Provides strategic, expedient, and efficient preparation of client submission deliverables and dossiers that met current local, regional and ICH/GMP regulatory and technical requirements.

International Regulatory Affairs Services, Inc. **2019-Present**

Regulatory Operations Consultant

- Ensured submission documentation met all mandatory health authority and validation requirements,
- Compiled and published eCTD regulatory submissions to markets in accordance with current standards and processes,
- Coordinated regulatory operations and activities, including organizing, tracking and publishing of all regulatory submissions and related correspondence,
- Provided strategic, expedient, and efficient preparation of client submission deliverables and dossiers that met current local, regional and ICH/GMP regulatory and technical requirements,
- Drafted Module 2 sections in support of Senior Regulatory staff.

Independent Consulting **2015-2019**

Web Design Consultant

- Collaborated closely with clients and web design businesses in choosing themes and developing page and site architecture,
- Integrated SEO techniques to optimize viewership,
- Maintained website functionality for clients over time with frequent plugin updates and maintenance,
- Extended functionality beyond WordPress tools with Javascript and HTML.

STAR Institute **2014**

Software Tester

- Supported development of large software systems utilized by the Department of Defense,
- Designed and ran various tests to verify integrity of rolling updates to software in development,
- Compiled analysis and error reports,
- Corrected errors and streamlined file structures,
- Provided IT support to team members.