SHARON NAZIMEK
Director, Regulatory Operations and Submissions

Sharon is a Director of Regulatory Operations and Submissions at Advyzom. Sharon is responsible for the compilation and publishing of Health Authority submissions, conversion of Word documents to eCTD compliant PDF's, bookmarking, and hyperlinking within a document or across a submission. Sharon's knowledge and technical capabilities include Microsoft SharePoint, ISI Toolbox, Adobe Acrobat, Lorenz DocuBridge, Microsoft Office, StartingPoint Templates, Lifecycle management and FDA Electronic Submissions Gateway (ESG). Her extensive technical capabilities also included publishing tools such as Liquent InSight Publisher/Viewer, Accenture ViewPoint, eCTD Reviewer, Global Submit, Documentum/First Doc and Veeva Vault.

Sharon has a proven record in delivering submissions on time and under strict deadlines. Additionally, she can provide pre-submission document publishing, including working directly with clients. Sharon is highly focused on client's services in meeting their needs and timelines, offering frequent communication and close collaboration.

Sharon Nazimek has over 25 years of combined Regulatory Report/Submission Publishing in the pharmaceutical industry. She provided Submission publishing services as a consultant to Advyzom before joining the company as an employee. Prior to Advyzom, Sharon worked as a Senior Submission Publishing Specialist in Regulatory Operations for Mallinckrodt Pharmaceuticals, Daiichi Sankyo, and Hoffmann-La Roche/Genentech. She performed and oversaw preparation of submissions to the FDA in both electronic and paper formats and submitted Daiichi's first cross-referenced initial IND meeting a critical milestone for the company.