

Renee Norton
Senior Director, Regulatory Operations and Submissions

Renee Norton is a Senior Director of Regulatory Operations and Submissions at Advyzom. Renee provides leadership and support by directly handling submissions to the FDA. She has a proven track record in delivering projects with strict deadlines on time. Additionally, she can provide pre-submission document publishing, including working with clients and their submission vendors. Renee is highly focused on client's services in meeting their needs and timelines, offering frequent communication and close collaboration, including on-site publishing support.

Renee has over 30 years of experience in Regulatory Operations and Submissions. Prior to joining Advyzom, Renee held positions within Global Regulatory Operations Groups at Celgene Inc., Elusys Therapeutics Inc. and Hoffmann-LaRoche Inc./Genentech.

Renee offers a wealth of knowledge in eCTD global submissions. She also has extensive experience developing training materials, SOPs and best practices to ensure the use of templates, processes and tools critical to compiling electronic submissions, as well as submitting advertisement and promotional materials to the Office of Prescription and Drug Promotion (OPDP). Renee's extensive technical capabilities include state of the art publishing tools such as, Accenture Quantum/ViewPoint, Lipient InSight Publisher/Viewer, eCTD Reviewer, Lorenz docuBridge, Global Submit, Documentum/First Doc, Adobe Acrobat 7, 9, 10 Pro, ISI ToolBox, Compose for PDF, Lifecycle Management, Word Templates, Microsoft Office Suite 2007/2010/2013, IpSwitch/Filezilla FTP Transfer, and Electronic Submissions Gateway (ESG).