

Theresa Dalla Riva

Vice President and Head of Regulatory Operations and Submissions

Theresa Dalla Riva is Vice President and Head of Regulatory Operations and Submission at Advyzom. Theresa was instrumental in implementing the electronic publishing services at Advyzom. In addition to managing the Regulatory Operations staff, Theresa spends a significant amount of her time on day to day project work for Advyzom clients. Theresa also serves as a project manager for IND and NDA/MAA applications.

Theresa and her team have the capability, flexibility and customer service spirit to meet our client's diverse set of needs. Advyzom has an approved FDA gateway and uses validated software to perform on behalf of clients IND, NDA/BLA, and pharmacovigilance for submissions to FDA, as well as submitting advertisement and promotional materials to the Office of Prescription and Drug Promotion (OPDP). Additionally, the Operations and Submissions team is experienced in publishing documents and submissions to EMA and Canada. Theresa ensures compliance with FDA e-CTD requirements and client archiving.

Theresa has over 28 years of experience in Regulatory Operations and Submissions. Prior to joining Advyzom, Theresa held management positions within Global Regulatory Operations at Daiichi-Sankyo Inc. and Hoffmann-LaRoche Inc./Genentech.

Theresa's technical capabilities include state of the art publishing tools such as, Accenture Quantum/ViewPoint, Liquent 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).