Jae Seo
Director, Regulatory Operations and Submissions

Jae Seo is a Director of Regulatory Operations and Submissions at Advyzom. Jae provides leadership and support by directly handling submissions to the FDA. He has a proven track record in delivering projects with strict deadlines on time. Additionally, he can provide pre-submission document publishing while working with clients and their submission vendors. Jae has the skill set to efficiently manage multiple projects in a matrix Global environment and interacts effectively with executives, regulatory agencies, vendors, and staff. He is responsible for the planning and preparation of regulatory submissions and supports formatting, organization, and structuring of major submissions in eCTD format and submitting advertisement and promotional materials to the Office of Prescription and Drug Promotion (OPDP).

Jae has over 15 years of experience in Regulatory Operations and Submissions. Prior to joining Advyzom, Jae held positions within Global Regulatory Operations at Array BioPharma as Senior Manager of Regulatory Operations managing submissions and lifecycle maintenance for IND and NDA/sNDAs. He also worked in Regulatory Operations at The Medicines Company wherein he managed the implementation and validation of Veeva Vault RIM, eCTD docuBridge and Starting Point regulatory authoring templates. Previous to The Medicines Company, Jae worked at Gilead Sciences and CSC (formerly Image Solutions Inc.).

Jae has outstanding working knowledge of document management systems, publishing software, and technical capabilities which include Documentum/First Doc, CoreDossier/EZSubs, Veeva Vault RIMs, SharePoint, Lorenz docuBridge, ISI eCTDXpress, Quantum Publishing, Global Submit eCTD Validator, Adobe Acrobat Pro 7, 9, & 10, ISI Toolbox, Liquent/Accenture Templates, Microsoft Office Suite 2007/2010/2013, Filezilla FTP Transfer, and Electronic Submissions Gateway (ESG).