Kathy Paul, B.S.
Director, Regulatory Operations and Submissions

Kathy Paul is a Director of Submissions and Operations at Advyzom. Kathy provides leadership and support by directly handling submissions to the FDA and meeting tight timelines. Kathy has strong experience in publishing all documents for IND/NDA/BLA and NDS applications. For Kathy, communication is the KEY to a successful submission.

Kathy has over 25 years of experience in Regulatory Submissions. Prior to joining Advyzom, Kathy held positions as a Regulatory Operations Specialist at Bristol-Myers Squibb/Celgene and Senior Document Publisher for Quintiles, Hoechst Marion Roussel and Marion Merrell Dow. Kathy has been a Global Lead Publisher for Submissions for EU, Swiss, Australia, New Zealand, Saudi Arabia and Bosnia/Herzegovina.

Kathy offers a wealth of knowledge in many types of submissions, IND's, NDA's, CSR's, CMC, Labeling, and Advertising. She excels in pre-publish activities. Kathy has experience using several publishing tools for eCTD Submissions such as Lorenz DocuBridge, Lorenz Validator, eCTDXPRESS, eCTD Manager, Liquent Insight Publisher, eSub-Livelink and CoreDossier . She also has technical experience using Microsoft Office Suite, Adobe Acrobat Professional, ISIToolBox Pharma and Electronic Submissions Gateway (ESG). Kathy has working knowledge using various DMS such as Sharepoint, Documentum (EDMS 98 and 4i).

Kathy earned her Bachelor of Science Degree in Education from Olivet Nazarene University and has taken postgraduate courses from California State University at Long Beach and Michigan State University.