ERIN BOLGER

DIRECTOR, REGULATORY OPERATIONS AND SUBMISSIONS

Erin Bolger is a Director of Regulatory Operations and Submissions at Advyzom. Erin 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 which includes, but is not limited to, information amendments, protocol amendments, IND safety reports, annual reports, NDA/MAA, summary documents.

Erin worked as a Regulatory Operations Specialist/Project Coordinator at Radius Health Inc. with responsibilities in identification and tracking of submission components, preparing, organizing, and publishing submissions to Health Authorities for multiple drug applications, prioritizing workload, and quality and timely filing of documents. She was the key point of contact for Veeva Submissions Vault Users to support the full use of the Regulatory Information Management (RIM) system. She created and maintained regulated documents and data in the RIM system. Erin was responsible for assembling and submission of promotional materials to the Office of Prescription Drug Promotion (OPDP) utilizing Veeva PromoMats.

Erin graduated from James Madison University with a BS in Biology. She has a proficient working knowledge of document management systems, publishing software, and technical capabilities which include Veeva RIM Vault, Veeva PromoMats, Veeva Quality Vault, ISI toolbox, SharePoint, Lorenz docuBridge, Adobe Acrobat Pro, Lifecycle Management, Liquent/Accenture templates, Microsoft Office Suite 2007/2010/2013, Copyright Clearance Center and Electronic Submissions Gateway (ESG).