

ERIN BOLGER, B.S.

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DIRECTOR, MEDICAL WRITING AND PUBLICATIONS

Erin Bolger is a Director of Medical Writing and Publications at Advyzom. Erin is responsible for leading team members in authoring and providing high quality documents for electronic submissions to health authorities. These documents include Clinical Study Reports, Clinical Protocols, Non-Clinical Summaries, Briefing Packages, Clinical Data Memos, Orphan Drug Designation, Investigator's Brochures, Fast Track Designation, and General Investigational Plan. She has a proven track record in delivering projects with strict deadlines. Additionally, she can work with document templates and provide pre-submission document publishing, which includes, but is not limited to, information amendments, protocol amendments, IND safety reports, annual reports, and 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, Lipient/Accenture templates, Microsoft Office Suite 2007/2010/2013, Copyright Clearance Center and Electronic Submissions Gateway (ESG).