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Senior Associate, Medical Writing and Publications

Maria Pitler is a Senior Associate of Medical Writing and Publications at Advyzom. Maria has over 30 years of GLP and GCP QA/QC quality review, editing and audit experience in the pharmaceutical, veterinary pharmaceutical, and biotechnology industries to support due diligence and compliance. Maria is responsible for conducting proactive Quality Control reviews for risk reduction and assisting in the review of documents (e.g. Clinical Study Reports, Protocol, Protocol Amendments, ICF, IB, Briefing packages, Labels, eCTD Modules, TFLs, Safety narratives) for a variety of domestic and international regulatory submissions across various therapeutic areas. Maria has created and reviewed QC SOPs, work instructions and QC checklists to be used as quality and process tools for content QC.

Prior to coming to Advyzom, Maria worked as a Quality Manager at Bristol Myers Squibb and was responsible for the QC reviews of Phase 1 clinical trial documents and data.