Laura Jones

Director, Product Management -RIM, ArisGlobal

23 years of Information Systems third tier experience supporting a wide array of technologies concurrent with 22 years Pharmaceutical and Biotechnology Regulatory industry experience. Proficient in R&D technologies, such as CoreDossier, InSight Suite, ISI Publisher, and eCTD Xpress, eCTD Manager, docuBridge as well as various EDMS Administration and implementation activities related to submission and content management. Extensive knowledge of global agency guidance/ regulations with a specialty in electronic submissions and submission management such as IND, BLA, CTD, MAA, NDS, eBLA, eCTD, eIND, etc. Managed various System design and implementation projects for R&D systems as well as EDMS content management systems integration activities. Validation of quality systems for 21 CFR 11 and ISO 9600 series compliance including, but not limited to, CoreDossier, InSight, Xpress, ISI Publisher, eCTD Manager, Veeva Vaults, and Documentum. Awarded distinguished recognition award from FDA for Electronic Submissions Gateway (ESG) pilot test group participation.

Specialties: Extensive experience with publishing technologies and DMS Administration relating to Life Sciences document management and agency application submissions. Proficient in global Agency guidance/ regulations relating to submissions such as IND, BLA,CTD, MAA, NDS, eBLA, eCTD, eIND, etc.