DLRC Ltd are currently looking to expand our RegOps team. We are an exciting, forward thinking regulatory affairs consultancy situated in Letchworth Garden City, Hertfordshire just 30 miles north of Central London with excellent travel links. If you are an experienced eCTD Publisher with 1-2 years' minimum experience and are keen to be a part of a growing team working on both European and US submissions, this role will provide you with the opportunity to work on Initial MAAs, NDAs, INDs and ongoing Maintenance submissions.

The successful candidate will be responsible for the daily operational activities for regulatory submissions and archives in accordance with agency requirements and company standards.

ESSENTIAL FUNCTIONS

The Regulatory Publisher is responsible for planning, electronically formatting and compiling regulatory submissions to achieve client deliverables and ensure quality, accuracy, and submission readiness. This includes:
- Applying full hyperlinking and bookmarking, performing quality control checking and being responsible for troubleshooting any publishing related activities and performing document level publishing tasks.
- Ensuring consistency, completeness and adherence in accordance with Regulatory agency guidance and specifications, whilst also complying with internal procedures.
- Providing guidance on good documentation and lifecycle management.
- The ability to manage and prioritize multiple tasks in a fast-paced environment whilst maintaining submission timelines.
- Staying current with new eCTD guidance and Global Health Authorities Submission Requirements.
- Preparing and formatting a variety of routine and non-routine Word and PDF documents
- Collaborating with project managers/leads to discuss preparation and submission timelines

REQUIRED KNOWLEDGE AND ABILITIES

- Bachelor's Degree or commensurate experience
- Minimum of 1-2 years' experience with electronic regulatory submission, associated publishing tools, templates.
- Strong technical aptitude, preferably with extensive exposure to Microsoft Word, Adobe Acrobat and the use of DXC Toolbox (ISI Toolbox)
- The ability to work with minimal direction and the flexibility to work productively and collaboratively within an environment with evolving priorities and deadlines
- Knowledge of the regulations and processes that govern content, maintenance and submission of controlled documents required by regulatory authorities.
- Excellent communication skills, both verbal and written.
- Exceptional attention to detail as well as organizational skills, including the ability to prioritize and multitask.