

Exalon GmbH is a growing company based in Radolfzell at the Lake of Constance. As service provider specialized in electronic regulatory submissions we work with international customers from pharma and biotech industry as well as drug manufacturers. To expand our publishing group we are looking for a

## **Regulatory Submission Manager (eCTD Publishing)**

### **Responsibilities:**

- Management of regulatory submission projects for various clients and regulatory procedures
- Publishing of regulatory submissions in eCTD (electronic Common Technical Document) format for regions such as EU, CH, US, CA, AU
- Awareness/monitoring of the applicable regulatory guidelines and internal procedures
- Involvement in various quality control processes, incl. SOP authoring
- Formatting of Word documents and processing of PDF documents

### **Qualifications / Skills:**

- Degree in regulatory affairs, medical documentation or comparable technical / pharmaceutical qualification
- Experience with regulatory eCTD publishing and knowledge of regulatory affairs requirements, working experience with docuBridge (Lorenz) would be a plus
- Experience with Document Management Systems
- Proficiency with IT systems, especially MS Office programs (Word, Excel) and Adobe Acrobat
- Detail-oriented with the ability to check documents for accuracy as well as consistency
- Good communication skills (both oral and written - English / German)

### **Offer:**

- You will be part of a dynamic team involved to various interesting / international projects
- Opportunity for professional development and increasing responsibility
- Detailed training regarding systems and processes
- Home office possible, onsite presence for initial phase (depending on experience)

### **Contact:**

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- Please send your application electronically (including potential start date and salary requirement)