RMO, Inc. (Rocky Mountain Orthodontics) is an internationally known manufacturer of orthodontic appliances headquartered in Denver, CO. We are a privately-owned company and have been in business over 80 years! We currently have an opening for a Regulatory Affairs Engineer in our Denver office.

GENERAL PURPOSE / SUMMARY OF POSITION:

Under direction of the VP of Eng/QA/Reg/SC, coordinates critical activities to support QMS compliance with ISO 13485, Council Directive 93/42/EEC, MDSAP, MHLW Ministerial Ordinance 169, and FDA QSR requirements. Responsible for establishing and leading the internal audit program of the quality management system. Develops audit protocols and checklists. Lead Auditor responsibilities. Acts as a consultant in quality systems requirements.

Owns product registration activities both domestically and internationally. Maintains applicable establishment registrations and coordinates with international dealers/distributors and their associated regulatory authorities to ensure RMO's product and market compliance.

Ensures corporate compliance to all required Federal, State, Local and International Regulations and Laws. Prepares all required documentation, application, and renewal of regulatory licenses, certificates, and permits for domestic and foreign entities.

Other Responsibilities / Duties:

- Coordinate efforts associated with the preparation of regulatory documents or submissions, including establishment registration, product registration, and certificates to foreign governments.
- Coordinate, prepare, or review regulatory submissions for domestic or international projects.
- Identify relevant guidance documents, international standards, or consensus standards and provide interpretive assistance.
- Interpret regulatory rules or rule changes and ensure that they are communicated through corporate policies and procedures.
- Maintain current knowledge base of existing and emerging regulations, standards, or guidance documents.
- Recommend changes to company procedures in response to changes in regulations or standards.
- Prepare or maintain technical files and MDR's as necessary to obtain and sustain product approval, registration, and licenses.
- Lead and coordinate internal and/or external audits
- Prepare or direct the preparation of additional information or responses as requested by regulatory agencies.
- Escort government inspectors during inspections and provide post-inspection follow-up information as requested.
- Participates in project teams as assigned and provides guidance on regulatory matters related to document requirements, regulatory submissions and maintenance.
- Other duties as assigned.

JOB QUALIFICATIONS:

Education or Formal Training:

- Bachelors/Associates degree or equivalent work experience.
- Lead Auditor training or certification.

Knowledge, Skills and Ability:

- Excellent written and verbal communication skills required.
- Proven ability of working in a cross functional team environment.
- Must possess working knowledge of ISO 13485, CE, MDD standards
- Knowledge of Federal, State, Local, and International Regulations and Laws for Medical Device Manufacturers.

Experience:

- Minimum of 5 years of experience in a Regulatory Affairs role in a Medical Device environment.
- Must have prior CAPA and Internal Audit experience
- Must have prior product registration and export compliance experience
- Experience/knowledge of EU MDD/MDR preferred

RMO, Inc. offers a competitive salary and benefits package including:

- Medical, dental and vision insurance
- 401k with company match
- Life, personal accident, short-term and long-term disability insurance
- Benefits Plus/ Flexible Spending Accounts
- PTO upon hire
- Costco membership
- Free downtown parking

Please send your resume including **salary requirements** to sbauer@rmortho.com or fax to the HR Dept. at 303-592-8223. For more information about our company, please visit our website at www.rmortho.com. **Resumes without salary requirements may not be considered**.