

Every day, Kelly Scientific Resources (KSR) connects scientific professionals with opportunities to advance their careers. KSR is the first and largest scientific staffing company in the world, and we currently have an exciting **direct hire full-time Senior Regulatory Affairs Associate** position available in the **Fort Collins, Colorado** area.

By working with Kelly Scientific Resources, you will receive:

- Competitive pay
- Eligibility to a comprehensive benefits package
- Access to the Kelly Science Learning Center
- The opportunity to gain experience and references at one of the world's foremost pharmaceutical companies
- And more!

Purpose and Scope

Under minimal supervision, perform all functions pertaining to domestic and international regulatory submissions including review of documentation, preparation of documents for electronic or paper filing, compilation of submissions, and review/approval of final submissions.

Essential Duties & Responsibilities

- Serve as regulatory representative on project teams. Offer regulatory opinions with consultation from senior regulatory management.
- Coordinate with personnel from other departments to obtain data/documentation for submissions and maintain timelines.
- With supervision from Regulatory Manager, act as liaison with regulatory agencies.
- Review draft investigational and commercial labeling artwork.
- Assist Regulatory Manager as requested.
- Perform regulatory research tasks as requested.
- Assist in or maintain product applications (INDs, NDAs, ANDAs).
- Maintain electronic document management system as required.
- Conform to regulatory department standards.
- Prepare and assist in preparation of domestic and international regulatory submissions.
- Provide training and guidance to other staff members when needed.
- Provide review of informed consents and protocols.
- Maintain up-to-date knowledge of current guidance and regulations.
- Perform various other duties as assigned.

Knowledge, Skills & Abilities

- Demonstrated knowledge of MS Office, Adobe Framemaker and Adobe Reader/Writer.
- Excellent writing and organizational skills.
- Ability to work independently.
- Ability to coordinate information from various internal and external disciplines.
- Ability to understand regulatory and technical concepts and requirements.
- Ability to perform multiple tasks on several projects.
- Ability to prepare written summaries of technical data suitable for inclusion in regulatory submissions.
- Ability to understand, and comply with domestic and international regulatory requirements.

- Ability to follow specific directions and to request instructions for complex tasks.

Education & Experience

- Bachelor's degree in related field.
- Four or more years experience in the pharmaceutical/biologic industry with knowledge of preparing and submitting regulatory dossiers/applications to regulatory agencies.

Benefits & Compensation

- 65 – 85 K per year plus benefits
- Competitive health care package
- GREAT vacation and paid time off
- Relocation assistance provided

Kelly Scientific Resources® has grown into a \$270 million global business as the scientific business unit of Kelly Services. We provide clinical research and scientific staffing to pharmaceutical, biotechnology, medical device and contract research organizations across the US. Kelly Services is an Equal Opportunity Employer.

To be immediately considered for this position, please e-mail morofme@kellyservices.com or call 1-877-269-5401!