



Acucela Inc.
21720 23rd Dr. SE
Suite 120
Bothell, WA 98021
Tel: 425.527.3260
Fax: 425.527.3156

Acucela is a clinical-stage, privately held biotechnology company focused on developing new drug therapies for blinding eye diseases such as age-related macular degeneration (AMD), Stargardt disease, diabetic retinopathy and retinopathy of prematurity, as well as dry eye. The Company offers competitive compensation, a team-oriented environment, and career growth opportunities.

Manager Regulatory Affairs - A regular full time position is available immediately at Acucela Inc., in Bothell, Washington. Some of the primary responsibilities are:

- Proactively solicit regulatory submittals from other departments across the Company.
- Assure the proper management, retention, and version control of all applicable Regulatory Affairs and product documentation including master files and amendments.
- Ensure that all regulatory documents are prepared in accordance with regulatory guidelines and internal standards and SOPs.
- Identify areas for improvement within daily functions, internal procedures, and regulatory agency interaction.
- Interact with project team members to define submission logistics and scheduling; coordinate priorities for submissions.
- Maintain a high level of expertise through reading and participation at professional seminars and workshops.
- Coordinate and ensure effective and timely input into the planning, agreement and generation of required documentation, and the review and compilation of dossiers, as needed, for submission from project teams.

Qualifications and Requirements

- Bachelors degree in life sciences or analytical field required, advanced degree preferred.
- Minimum 5+ years of current regulatory affairs experience in biotech or pharmaceutical industry required.
- Demonstrated experience in IND and NDA filings.
- Knowledge of all relevant pharma regulatory procedures and reporting requirements
- Experience with document management of INDs, IND Amendments, FDA Briefing Packages, and NDAs.
- Experience with CTD and e-NDA/e-CTD preparation preferred.
- Strong background in writing and editing technical reports and investigations with demonstrated ability to interact with project teams.
- Strong communication (verbal, written, listening) and interpersonal skills with the ability to communicate across multiple disciplines successfully and accurately, both internally and externally.



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- Excellent knowledge of the English language with strong proofing and spelling skills, presentation skills, with attention to detail and accuracy.
 - Strong negotiation skills.
 - Energetic, self-motivated, organized individual who is accustomed to working in deadline-focused, high-pressure entrepreneurial environment.
 - Ability to manage multiple simultaneous products/projects.
 - Strategic, analytical thinker with strong business acumen.
 - Demonstrates consistent logic, rationality, and objectivity when identifying significant problems and opportunities.
 - Creative problem solver with the ability to establish systems and define standard practices.
 - Applicant must have current legal work authorization to work for any company in the United States

No phone calls please. Only those candidates chosen for interview will be contacted. Send resume to Acucela Inc., Attn: Recruiter via email to career@acucela.com, or via facsimile at 425.527.3156. Only direct applicants will be accepted, no recruiters please. Acucela Inc. is an EOE.