**REGULATORY AFFAIRS ASSOCIATE**

**LOCATION** SAN RAFAEL, CALIFORNIA[**APPLY**](https://chk.tbe.taleo.net/chk06/ats/careers/requisition.jsp?org=BMRN&cws=1&rid=13602)

**DESCRIPTION**

BioMarin is the world leader in delivering therapeutics that provide meaningful advances to patients who live with serious and life-threatening rare genetic diseases. We target diseases that lack effective therapies and affect relatively small numbers of patients, many of whom are children. These conditions are often inherited, difficult to diagnose, progressively debilitating and have few, if any, treatment options. BioMarin will continue to focus on advancing therapies that are the first or best of their kind.

BioMarin’s Development Sciences group is responsible for everything from research and discovery to post-market clinical development. Development Sciences involves all bench and clinical research and the associated groups that support those endeavors. Our teams work on developing first-in-class and best-in-class therapeutics that provide meaningful advances to patients who live with rare diseases. Come join our team and make a meaningful impact on patients’ lives.

**SUMMARY**

The Regulatory Affairs Associate, with a focus on clinical and nonclinical aspects, will support the regulatory team in the development and implementation of global regulatory strategy worldwide for products serving patients with rare diseases and unmet medical needs. This individual will be responsible for assisting with the development and coordination of regulatory submissions, with input from cross-functional team members, to support regulatory filings, agency meetings, and overall program priorities.

**RESPONSIBILITIES**

* Responsible for coordinating cross-functional activities pertaining to regulatory function, including the development of meeting requests, timelines, and coordination of briefing documents intended for submission to regulatory authorities.
* Actively participate in regulatory sub-teams and lead meetings on defined topics with a clear objective.
* Proactively identify and communicate potential regulatory issues/risks and recommend solutions to Regulatory Affairs management.
* Maintain regulatory dossiers in compliance with global health authority requirements.
* Participate in the development of regulatory submissions for assigned products and regions.
* Interact with other global project team members to ensure the timely preparation and receipt of information required for regulatory submissions.
* Interact with internal and external partners as necessary to support product development.
* Conduct and analyze regulatory research to understand past precedence and the current competitive landscape.
* Educate internal stakeholders on implications of regulations.
* Provide preparation and planning support for meetings with US and ex-US regulatory agencies.
* Support the preparation of responses to questions and comments from regulatory agencies.

**EXPERIENCE**

**Required Skills:**

* Minimum 4 years of regulatory affairs experience or equivalent combination with advanced degree.
* Understanding of regulatory requirements, including ICH requirements and regional requirements for assigned territories. Experience with global regulatory dossiers desirable.
* Excellent writing skills.
* Strong communication (verbal, written, listening) and interpersonal skills with the ability to communicate cross-functionally in a collaborative manner.

**EDUCATION**

* Bachelor’s degree required. Prefer life sciences or related major.

**CONTACTS**

* Regulatory CMC, Regulatory PM, Regulatory Operations
* Clinical Science
* Clinical Operations
* Pharm/Tox, Immunology

We are an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, or any other characteristic protected by law.