



Senior Regulatory Scientist

Minneapolis, Minnesota, USA

About us

Calyxt, Inc. is a consumer-centric, food- and agriculture-focused company. Calyxt is pioneering a paradigm shift to deliver healthier food ingredients, such as healthier oils and high fiber wheat, for consumers and crop traits that benefit the environment and reduce pesticide applications, such as disease tolerance, for farmers. Calyxt develops non-transgenic crops leveraging processes that occur in nature by combining its leading gene-editing technology and technical expertise with its innovative commercial strategy. Calyxt is located in Minneapolis-St. Paul, MN, and is listed on the Nasdaq market (ticker: CLXT).

For further information please visit our website: www.calyxt.com

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Job Summary

Calyxt is seeking a highly motivated and result-oriented Senior Regulatory Scientist to join our Regulatory organization. The successful candidate will have an opportunity to work in a team environment and interact with experts in molecular biology, gene editing, plant transformation, regulatory, commercial, breeding and supply chain. The individual will be responsible for developing Regulatory product strategies and coordinating Regulatory studies for Calyxt's rich product pipeline. This includes product safety studies, regulatory submissions, label claims to ensure compliance of Calyxt products at each Product Development phase. S/he will have a unique opportunity to work with cross-functional teams as Calyxt gene edited products progress through the R&D pipeline, comply with regulatory requirements, and are brought to commercialization.

Key Responsibilities:

- Lead the development of nutrition and ingredient label declarations that are required per US FDA regulations and help to ensure accuracy of the regulatory information in Calyxt's databases.
- Support Calyxt's Identity-Preserved Process and ensure continuous improvement with engagement from key stakeholders.
- Work in collaboration with the R&D, Breeding, and Commercial teams to ensure Regulatory compliance for activities related to seed quality and storage, product Phase advancement and defining Regulatory paths to market.

- Write regulatory submissions for US authorities, or other global authorities as needed, to ensure Calyxt's products comply with local requirements while enabling timely product launches.
- Drive improvements and standardization across the phases of product development in order to ensure high quality standards while maintaining optimal speed to market and efficient use of resources.
- Participate in implementation and maintenance of product stewardship program across product develop phases so as to ensure regulatory compliance and product sustainability.
- Travel up to 20% both domestic and international.

Required Qualifications:

- Minimum of a Master of Science degree (preferably PhD degree) in a biological science, plant science or related field (Bachelor degree with 15 years of applicable experience will also be considered).
- Minimum of 5-7 years food or related industry experience, corporate or government regulatory experience in food labeling or solid background in nutrition related field.
- Good understanding of US Food and Drug Administration labeling regulations to assure the accuracy of ingredient statements, nutrition facts, allergen declarations and claims. Ability to monitor, interpret and ensure compliance with US regulations.
- Solid organizational and time management skills to ensure successful and timely documentation and completion of projects.
- Demonstrated leadership in developing regulatory strategies and obtaining timely product advancement.
- Good understanding or hands-on experience with R&D technologies in agricultural biotechnology and/or food industry.
- Excellent verbal and written communication skills and the ability to work in a team environment to achieve project goals.
- Ability and willingness to be hands-on as well as sense of urgency.

Preferred qualifications/experience:

- Experience in non-GMO product certifications.
- Stewardship experience.
- Product development experience.

Contact: Please send resume and motivation letter to CLX_SRS_2019-01@calyxt.com