

Senior Quality Release Manager

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Company: ByHeart, Inc.

Location: Australia

Category: other-general

Role Description

Reports To: Senior Director of Quality Assurance

Location: Remote , NYC, PA, OR, IA

Start Date: Immediate

The Senior Quality Release Manager will be responsible for managing release of ByHeart base and final product consistently across the organization at all manufacturing sites. This role will work closely with quality, operations, and regulatory to ensure timely and appropriate release of ByHeart product and to develop analytics to promote continuous improvement of right the first the first time and release process.

Role Responsibilities

Develop consistent process and tracking tools for review and release of ByHeart product to ensure visibility throughout the review and release process.

Ensure consistent and timely release of products per BlendHouse internal, customer, or regulatory requirements.

Manage the release and disposition status in the defined electronic inventory and quality management systems.

Directly manage site Quality Release teams to ensure effective application of processes and procedures.

Support review of Master Batch Records for completeness including but not limited to Critical

Control Points (CCP) records, production records, warehouse records, sanitation records, etc.

Implement systems and metrics to review current state and implement efficiency opportunities. Support sites in management of sample shipment, submission, and turnaround time to ensure on-time report of testing results.

Present nonconformances and items impacting quality or food safety to the ByHeart Corporate Food Safety Committee.

Work with cross-functional teams to define and monitor product sampling and analysis requirements to ensure food safety and quality criteria necessary for product release.

Review and support closure of any Event Reports for findings, discrepancies, or Out of Specification results discovered during batch review process. Work closely with Quality Assurance and Compliance teams for investigation. Work with owning departments to ensure timely closure of Event Reports for releasing.

Issue Certificate of Compliance or Certificate of Analysis as designated by customer guidelines or internal requirements.

Make improvements to the release process and provide necessary training regarding record keeping and procedure implementation.

Manage Batch Records filing for the site, all related contract manufacturing, packaging locations, ingredients, and customer related products.

Coordinate with contract partners and review paperwork.

Participate in investigations relating to non-conforming events (including product complaints) driving to root cause(s) and effective resolution (corrective actions).

Actively support and participate in the internal audit program and support, as needed, in regulatory inspections (e.g. FDA and / or third-party audits / certifications (e.g. SQF, Kosher, Organic).

Assist in completing documentation including but not limited to: Event Reporting, Corrective Actions, Change controls, Hold Reports, SOP's, and forms that meet Internal and Infant Formula Requirements.

Provide written report such as trending and aid in Event Reporting as required.

Comply with all policies and procedures of BlendHouse facilities and ByHeart.

Skills & Qualifications

To perform this job successfully, an individual must be able to perform each essential duty

independently and satisfactorily. Performance will be evaluated on an annual basis. It is essential that responsibilities are performed correctly and accurately. Duties must be executed in a timely manner. The requirements listed below are representative of the knowledge, skill and/or ability required.

Bachelor's degree required in food science, microbiology, toxicology, biological sciences, or related field, preferred.

Two to five years of experience in food processing or pharmaceutical environment (dairy, spray drying, or Infant Formula preferred). One to three years of management (supervisory or process related) experience.

Working knowledge of HACCP, Preventive Controls and SQF principles. HACCP and PCQI certifications are a plus

Familiarity with laboratory testing and reporting preferred

Ability to review processes and procedures, and utilize critical thinking and communication skills to relay opportunities for improvement, and coordinate execution of improvements and processes

Ability to generate reports and communicate key messages

Strategic and problem-solving mindset

Must be able to work independently in order to organize tasks and manage timelines and deliverables

Ability to manage problems involving several variables in standardized situations

Effectively communicates critical information regarding job responsibilities

Use of computer systems including but not limited to ERP System (Deacom), Microsoft Word, Microsoft Excel, PowerPoint, and Doc Control System (QT9)

The minimum annual salary for this position is \$120,000 and the maximum is \$150,000.

The salary range for performing this role outside of New York City will differ. Additionally, you will be eligible for a discretionary performance based annual cash bonus and to participate in our company's equity program, plus our robust medical, dental, vision, retirement, and other benefits.

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