

## Quality Customer Service Manager

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Company: ByHeart, Inc.

Location: Australia

Category: office-and-administrative-support

### Role Description

The Quality Customer Service Manager is responsible for effectively managing all product complaints by ensuring investigations are conducted thoroughly and within required timelines and to regulatory requirements. This position works closely with internal and external Customer Service partners to maintain and improve the company's relationship with customers and consumers while meeting quality and regulatory compliance. This function provides leadership and direction in accordance with departmental and company goals and priorities to drive improvement.

Reports To: Senior Manager, Quality Compliance

Location: Remote

### Role Responsibilities

Accountable for managing and overseeing the Complaint Program throughout the ByHeart supply chain including the investigation process, root cause analysis through to the implementation of preventative measures as a result of production, complaints, and supplier events.

Ensures investigations are conducted thoroughly, within required timelines and to compliance requirements including ensuring the adequacy of root cause analysis and appropriateness of communication regarding the corrective & preventive action.

Responsible for managing all CAPA effectiveness checks associated with the Complaint Program.

Responsible for tracking and trending product complaints and adverse events, assessing for reportability, and escalation to Management as needed.

Develops and maintains complaint procedures.

Responsible for Quality programs:

Complaint Management (Trackwise System management/configuration, Triage, investigations, CAPA, Trending, Escalation, Customer Responses),

Quality Customer Service for external (Retail, DTC, Suppliers) and internal (Parent Experience, Pharmacovigilance, Branding, Legal, Medical) partners as the liaison for quality-related requests, certifications and customer communications.

Establish implementation plan for strategic objectives to enhance Complaint systems and compliance across ByHeart sites, incorporating integration of best practices.

Collaborate with other functional area goals and priorities by soliciting information from those functional groups for continuous improvement and innovation.

Make decisions based upon assessment of information from many sources including customers, manufacturing processes, QC testing, and other available information.

Provide strategic technical guidance and management support for quality functions minimizing workload, optimizing resources, streamlining existing systems, and contributing to continuous improvement opportunities.

## Skills & Qualifications

BS - 10 years or equivalent at minimum

Minimum of 5 years in regulatory industry

Process and system management experience

Detailed knowledge of Quality Management Systems and processes required

Knowledge of FDA requirements and understand how to develop applicable SOPs that are compliant to applicable regulations

Project management, administrative, and technical capabilities are required, as well as effective verbal and written communication skills

Provides well written investigation and technical summaries (meets defined quality standards)

for Senior Management.

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.

#J-18808-Ljbffr

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