

QUALITY ASSURANCE MAIN RESPONSIBILITIES

Create and execute quality strategies and plans for the QMS, ranging for simple to high complexity.

Provide a high level of expertise and experience to the Team, while serving as a project member or team member. Holds signature responsibility for designated areas.

Represent the company in interaction and negotiations with regulatory agencies regarding quality requirements and strategies. Organizes and manages meetings with regulators, including agendas and training/preparation of company personnel attending the meeting.

Leads the quality strategy for the company globally.

Leads the ISO 9001.13485 based quality programs globally to ensure effective implementation of quality systems, continuous improvement efforts, and promotion of a quality/compliance culture.

Provides leadership in product quality problem solving resolution efforts across the organization.

Act as the primary authority for compliance actions such as product or service corrective actions or recalls.

Serve as chair of the Quality Management Team meeting to facilitate review and decision making based on the operation of quality systems and quality metrics.

As needed, provide leadership on quality and regulatory affairs matters during mergers and acquisitions.

Liaise with peers in other operating companies to share experience and best practices.

Act as the primary authority for internal quality compliance matter.

Monitor FDA, EU and ISO laws and regulations, and provide their interpretation to company leadership. Provides comments to management for inclusion in responses to FDA and other agency legislation/regulatory/guidance.

Serve as team expert for material review board, product labeling as they relate to registration and commercialization of medical devices.

Suggest opportunities for improvement that have a significant impact (cost, cycle time, quality, etc.) and assists in developing or executing an implementation plan.

Perform other related duties and required and/or assigned.

Apply at: career@apbiocode.com