Regulatory and Clinical Affairs Main Responsibilities

Responsible for development of regulatory strategy and representation of Regulatory Affairs R&D project teams.

Communicate regulatory strategy to the senior management and other relevant functions.

Lead to assure successful planning and completion of regulatory activities.

Lead to set up and manage interactions with clinical sites to assure successful Clinical Studies.

Act as the primary authority for liaison with customers and regulatory authorities regarding quality matters, including hosting inspections and responding to observations.

Familiarity with product development, manufacturing, and supply chain cycles.

Develop regulator strategies, policies, guidelines, programs, procedures and investigative approaches and metrics to track compliance.

Develop, negotiate, and execute regulatory strategies (especially for US FDA).

Represent company interests with national government agencies, industry associations and/or other organizations in all regions (31 countries) for the purpose of ensuring compliance with legislation, regulations, and/or guidelines that impact the business in the clinical diagnostic market.

Design and implement appropriate metric to track performance and apply counter measures diagnostic tools to close any gap.

Establish and meet requirements for clinical diagnostic capability (CE, IVD, FDA, 510k etc.) in all functions including design, manufacturing, and service, and take on any other tasks as required.

Responsible for of global regulatory submissions as well as directing communications and interaction with US FDA and other regulatory agencies worldwide.

Responsible for product registration with regulatory agencies.

Recommend changes for labeling, manufacturing, marketing, and clinical protocol for regulatory compliance.

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