

Customer Collaboration Project Manager

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Company: Sanofi

Location: Bogotá

Category: computer-and-mathematical

About the job

Our Team:

The Sample Operations department is responsible for all sample programs across the General Medicines (Diabetes & Cardiovascular) and Specialty Care Business Units.

This position is responsible for supporting the compliant operations and maintaining certain PDMA (Prescription Drug Marketing Act) activities. The sampling program operates under GMP's (Good Manufacturing Processes), SOP's (Standard Operation Procedures) and Work Instructions and this position will ensure the operations are meeting those requirements. With a large installation of remote sales professionals in the program base, compliance to SOPs, PDMA regulations and close collaboration with North America Quality (NAQ) is critical to the program success.

This role will partner with NAQ to ensure all appropriate regulatory documents are maintained as well as tracking any process deviations in order to ensure the Sanofi US sales field forces are meeting regulatory requirements. Additionally, the project manager will support training for the sales force, and vendor management for third party Sample Operations vendors.

Main responsibilities:

Partner with North America Quality, Legal and other stakeholders to ensure all Federal/PDMA, State, and local regulations are met.

Write, update, and follow program SOP's and work instructions.

Maintain and update the Sanofi Sample Compliance Manual and the ilearn Sample Compliance training curriculum and assessment.

Work with internal stakeholders to ensure the Sample Operations department is meeting all requirements of the Corporate Integrity Agreement (CIA).

Facilitate fulfilment of yearly FDA/Transparency reporting requirements.

Track/manage SOP Deviations/CAPAs that impact Sample Operations.

Liaison with Sanofi Customer Service to address sample related inquiries.

Immediately escalate reportable events to the internal FDA (Food and Drug Administration) contact

Monitor department mailbox and resolve inquiries.

Support the annual field re-certification activities.

Respond to field inquiries to promote good customer service and the overall success of the sample program.

Provide vendor management, business reviews, etc. with third party sample vendors.

Complete or oversee activities related to sample administration in the field.

Other department related assignments as required.

About you

Experience:

Soft skills : Proven ability to work transversally across departments and functions.

Forward-facing / Proactive

Good communication skills

Technical skills: Vendor management on day to day basis

Drafting of SOP (standard operating procedure) / Knowing processes

Quality or documentation or audit or regulatory or manufacturing experience

Pharmaceutical industry experience (nice to have)

Understanding of how Sales teams work (nice to have)

Knowledge of US healthcare system (nice to have)

Veeva CRM (nice to have)

Supply chain experience (nice to have)

Dealing with dataset (nice to have)

Education :

Languages: Fluent English

Pursue progress, discover extraordinary

Better is out there. Better medications, better outcomes, better science. But progress doesn't happen without people – people from different backgrounds, in different locations, doing different roles, all united by one thing: a desire to make miracles happen. So, let's be those people.

At Sanofi, we provide equal opportunities to all regardless of race, colour, ancestry, religion, sex, national origin, sexual orientation, age, citizenship, marital status, ability, gender identity or Veteran status.

Watch our and check out our Diversity Equity and Inclusion actions at !

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