



Chaitra Pandya

Project Manager

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☎ 9687677309

📅 6 years 0 month

Experienced professional with a demonstrated history of working in CRO. Skilled in clinical research, statistical Data Analysis, GCP and Regulatory Requirements. Strong Operations professional with a post graduate degree in Clinical Research

Profile Summary

- Impeccable success in managing operations involving resource planning, in-process inspection and coordination with internal departments & onshore stakeholders
- Steered the successful roll-out of process / transitions while defining scope, setting timelines, analyzing requirements, prioritizing tasks, identifying dependencies, evaluating risks as per preset budgets
- Expert in collaborating with top management & stakeholders for decision-making; ascertaining key business needs

Education

2010, Part Time

PG Diploma, ICRI, 76%

2004, Full Time

B.Pharm, Rajiv Gandhi Institute of Health Science, 65%

Work Experience

2016 - 2016

Project Manager

Cliantha Research

- To possess and implement proficient knowledge of Clinical Trial Directive, DIA TMF Reference Model and CTA/IND submission requirements for multiple countries/submission types.
- Have good knowledge in processes, ways of working and current guidelines for CTA/IND, and use this expertise to provide training, consultation and solutions within the team/ department as well as externally outside the department.
- Manage and accountable for the work of CTA/IND submission coordinators.
- Accountable to the development delivery functional lead for overall allocation of work plans, manage GRLs/TGs for overall CTA/IND study service request & allocation for agreed tasks and projects
- Ensures quality submission and compliance with regulatory guidelines and process as they apply to the role. Provides consultation and solutions being a subject matter expert in processes.
- Lead the creation and implementation of CTA/IND submission coordinator working practices and procedures aimed at simplifying processes and maintaining quality.
- Managing of development, refinement of the CTA/IND lifecycle strategy, timely content & delivery appropriate to each individual regulatory agency while maintaining compliance with company policy and procedures.
- Works with staff from other functions and capable of working to senior levels in development functions in provision

of advice, interpretation of relevant guidance's, researching topics and resolving issues.

- Required to liaise with LOC and Regulatory Agencies to resolve issues in relation to their accountabilities.
- Support submission team review and approval procedures.
- Maintain knowledge of relevant Regulatory Authority rules and GSK standards associated with submission format

2008 - 2010

Project Coordinator

Fisher Clinical Services

- To follow up, coordinate with Quality,labelling and Packaging verticles and create & maintain a dashboard for activities which summarizes key elements for decision making & best practice and deliverables to the client.
- Communication management across stakeholders w.r.t to administrative aspects of the projects through webcasts or any other modes of communication to share information.
- Internal and external stakeholder management.
- Accountable for timely planning and execution of projects, which are initiated by Team Lead Project Management based on identified and agreed strategic needs, to fulfil objectives on departmental and/or project level(s).
- To ensure the right visibility of the projects internally.
- To identify and map key stakeholders & makes the most of the information available to understand their needs and motivations.
- To temely communicate via relevant channels to ensure continued high buy-in and motivation from key stakeholders.

2007 - 2008

Marketing Executive

Institute of Clinical Research India (ICRI)

- Achieve allocated admission targets.
- Counseling Students and parents about our courses and competition exams landscape.
- Champion entire student cycle: Prospecting, Counseling, Admission, Orientation, Support.
- Interaction with students and parents on routine basis for giving them ICRI experience.
- Clarifying doubts of students and parents.
- Managing fee structure & fee software for different programs.
- Monitor class schedules to ensure smooth running of classes.
- Liaison with Head Office for upcoming programs, admission tests, schemes and other offers.
- Handling assigned administrative responsibilities.

2004 - 2006

Marketing Representative

Dr.Reddy's

Region: Hubli,Dharwad

- Establish, develop and maintain relationships with customers that can benefit from Dr Reddys products after assessing their needs, purchasing method, and frequency of contact preferences.
- Develop and execute plans to meet established sales goals and objectives while maintaining territory budget
- Complete planned customer visits to existing and prospective customers, provides information and support, calculates and quotes prices, takes orders, and closes sales
- Provides industry and product knowledge to customers on segment specific value propositions and helps customize the existing product portfolio to their needs with solution sales techniques
- Assist marketing and sales management in the development and implementation of new sales strategies, tactics and tools for new market opportunities
- Monitor performance against objectives and performs analysis on territory opportunities to develop customer and product forecasts
- Monitor market, customer and competitor trends and advise management on methods to improve company competitiveness
- Continuously develop self to understand customer needs, identify sales opportunities and effectively represent the company.
- Attend the conferences to make customer connects and develop competitive market intelligence.

Courses & Certifications

Clinical Data Management

Key Skills

Project management and client services

Stakeholders Management

Clinical Data Management

Language

English
Expert

Hindi
Expert

Gujrati
Expert

Personal Details

Date of Birth

19th September 1983

Gender

Female

Marital Status

Married

Address

C-5,1004,Waterlilly,Shantigram