Contact

mara.mantegazza@psi-cro.com
+393807098464 (Mobile)
mara.mantegazza@gmail.com

www.linkedin.com/in/mara-mantegazza-275b6130 (LinkedIn)

Top Skills

Clinical Trials
Good Clinical Practice (GCP)
Clinical Research

Mara Mantegazza

Country Manager at PSI CRO Italy
Milan

Summary

Working in pharmaceutical industry is a chance and especially in CROs, to provide to our Clients the best service to get product on the market faster. This means serving patients by getting innovating products to them quicker.
In this objective, my current responsibilities are to improve the follow up of the trials by selecting the best CRAs, train & oversight them, in constant liaison with International teams.

My main skills and competencies are:
• High CRO knowledge
• ICH GCP
• Italian & EU regulations
• Leadership
• Oversight & risk evaluation
• Decision maker & Problem solving skills
• Performance evaluation & management
• Recruitment & talent acquisition
• Quality oriented

Experience

PSI CRO AG

11 years 7 months

Country Manager

January 2017 - Present (5 years)
Milan, Lombardy, Italy

Line Management of company Staff with Performance appraisal, Recruitment strategy
Country & Office Management with Budget preparation and management, Office premises management,
Oversight of any operation within the country
Resource Management and Training with Resource allocation and resource management,

Metrics and utilization oversight,
Manpower oversight (turnover, promotion, training...)
Communication with Executive Management and Department Heads on projects matters, Communication with investigators, authorities vendors on any country specific topic
Quality Control with development of country quality control strategy in collaboration with respective department
Business Development with feasibility strategy,
Sponsor and vendor contact
in collaboration with Business development and Project Management departments

Clinical Operations Manager
April 2013 - Present (8 years 9 months)
Via Aldo Moro, 47

• as Clinical Operations Manager:
o Set-up of Clinical Operations team
o Line management of monitoring and administrative roles; Allocation & Appraisal
o Oversight of quality systems, performance of quality control; recruitment;
• as acting Country Manager:
o Communication with clients, vendors, project teams on project and administrative & project matters;
o Participation in client and bid defense meetings
o Supervision of feasibility process
o Planning and implementing Country strategy;
o Periodic progress reporting of corporate and operations activities;
o Staff hiring and dismissal;
o Performance appraisal; & Staff training;
o Country budget set-up & management;
o Supervision and optimization of corporate and operations activities;
o Development of country-specific guidelines and QSDs;
o Quality assurance and quality control;
o Italian office set-up; & Supervision of management and maintenance of office premises;

Clinical Research Associate
June 2010 - March 2013 (2 years 10 months)

Clinical Research Associate Free Lance (7 sites)
Oncology area (2 studies/ 6 sites)
- Multiple Myelom,

Hodgkin - Lymphoma)

- Hematology (1 Study/5 sites)

On-site monitoring visits; remote monitoring; regular contact with site; regular TC and update to International management

Support in submission preparation and documentation review

Medpace

CRA

October 2010 - March 2013 (2 years 6 months)

Clinical Research Associate Free Lance

• Oncology area (1 Study/1 centre)

Activity

On-site monitoring visits; remote monitoring; regular contact with site; regular TC and update to International management

Support in submission preparation and documentation review

Quintiles

Clinical Research Associate

June 2008 - March 2013 (4 years 10 months)

Clinical Research Associate Free Lance- Monitoring

- Nephrology area
- Rheumatology area
- Oncology area

Foldrx Pharmaceuticals

Clinical Research Associate

September 2008 - April 2012 (3 years 8 months)

Clinical Research Associate Free Lance and regulatory procedure

- Rare disease
- Observational studies

Medpace

Regulatory Submission Coordinator

June 2009 - October 2009 (5 months)

Temporary consultancy contract as Regulatory Submission Coordinator for Italy

Sintesi Research

Project Manager

January 2006 - April 2009 (3 years 4 months)

International clinical trial on rare disease (Angioedema), gastrointestinal disease with the following skills

• CRA training and coordination;
• Contact with and reporting to Sponsor,
• monitoring and co-monitoring activities,
• audit preparation,
• documentation preparation and revision;
• TMF management; contact with providers (courier, Insurance company);
• contact with sites and local Partners (CRO and CRA freelance);

Medi Service S.r.l

Stage period

July 2005 - December 2005 (6 months)

Period of stage supporting PM for the following activities

• Support on monitoring activities in office and on site;
• supporting on preparation of EC submissions;
• support for TMF archiving and review.

Support for following studies:

• Observational study on Migraine (about 30 sites)
• Phase IV study on Migraine (about 5 sites in Italy)

Education

Università degli studi di Milano

Pharmaceutical Biotechnology · (1999 - 2005)