Contatta

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Competenze principali

English
Sperimentazioni cliniche
ICH-GCP

Languages

Inglese (Full Professional)
Spagnolo (Elementary)
Italiano (Native or Bilingual)

Andrea Carbone

CRA Manager II presso Medpace
Milano

Riepilogo

Master Degree in Pharmacy and Second Level Postgraduate Master in "Research and Preclinical and clinical drug development" at the University Milano-Bicocca.
Currently working as CRA Manager II at Medpace. Through both my academic and work experience I have developed expertise in project and people management, communication and cross-functional collaboration.

Esperienza

Medpace
6 anni 4 mesi

CRA Manager II
luglio 2021 - Present (5 mesi)
Milano, Italia

Responsible for overall training, management and development of CRAs and/or Clinical Monitoring Interns.

Key accomplishments and responsibilities:

- Line management of Clinical Research Associates (CRA) in specified country/region(s);
- Recruitment, training, development and allocation of CRAs in country/region(s);
- Manage turnover and retention of CRAs to meet company objective;
- Act as a resource and assist with training for entry-level CRA managers;
- Assist Clinical Trial Managers (CTM) with achieving project objectives in regards to CRA performance standards and monitoring consistency and compliance;
- Assist CTMs in trouble shooting and serve as a resource for issue resolution;
- May serve as a main contact for the country/region including feasibility; and
- May serve as a lead CRA as needed.

CRA Manager

giugno 2019 - giugno 2021 (2 anni 1 mese)
Milano, Italia

Clinical Research Associate - Experienced II
aprile 2018 - maggio 2019 (1 anno 2 mesi)
Milano, Italia

Key accomplishments and responsibilities:

- Comprehensive knowledge of practices and procedures relating to all clinical monitoring visit
types, including practical application of this knowledge;
- Demonstrated ability to act as a Lead CRA;
- Act as a resource for new CRAs and ability to facilitate training and serve as a mentor for
new CRAs; and
- Implements new ideas/solutions, without prompting, within their authority.

Therapeutic Areas: Hematology, Oncology (Solid tumors, Bladder Cancer), Cardiology, Rare disease, Diabetes, Immunology/Infectious Diseases, Nefrology/Urology,Medical Devices, Gene Therapy.

Clinical Research Associate - Experienced I
ottobre 2016 - marzo 2018 (1 anno 6 mesi)
Milano, Italia

Clinical Research Associate II
agosto 2015 - settembre 2016 (1 anno 2 mesi)
Milano, Italia

SPRIM Advanced Life Sciences
Clinical Research Associate
maggio 2015 - luglio 2015 (3 mesi)

Key responsibilities and accomplishments:

- Evaluation of study processes, identification and resolution of potential issues
- Monitors the progress of the clinical trials
- Ensures sponsor and investigator obligations are being met and are compliant with applicable local regulatory requirements and ICH-GCP guidelines

- Assesses the qualification of potential investigative sites, initiates clinical trials at investigative sites, instructs site personnel on the proper conduct of clinical trials, and close clinical trials at investigative sites
- Reviews and verifies accuracy of clinical trial data collected, either onsite or remotely
- Provides regular site status information to team members, trial management, and updates trial management tools
- Completes monitoring activity documents as required
- Performs essential document site file reconciliation
- Performs source document verification and query resolution
- Assesses IP accountability, dispensation, and compliance at the investigative sites
- Verifies Serious Adverse Event (SAE) reporting according to trial specifications and ICH-GCP guidelines
- Communicates with investigative sites

PRA Health Sciences
Clinical Research Associate I Trainee
settembre 2014 - marzo 2015 (7 mesi)
Milano, Italia

Key accomplishments and responsibilities:

Implements and monitors clinical trials to ensure sponsor and investigator obligations are being met and are compliant with applicable local regulatory requirements and ICH-GCP guidelines
• Assesses the qualification of potential investigative sites, initiates clinical trials at investigative sites, instructs site personnel on the proper conduct of clinical trials, and close clinical trials at investigative sites
• Reviews and verifies accuracy of clinical trial data collected, either onsite or remotely
• Provides regular site status information to team members, trial management, and updates trial management tools
• Completes monitoring activity documents as required by PRA SOPs or other contractual obligations
• Works closely with other clinical team members to facilitate timely resolution of trial and/or clinical issues
• Escalates site and trial related issues per PRA SOPs, until identified issues are resolved or closed
• Performs essential document site file reconciliation
• Performs source document verification and query resolution

• Assesses IP accountability, dispensation, and compliance at the investigative sites
• Verifies Serious Adverse Event (SAE) reporting according to trial specifications and ICH-GCP guidelines
• Communicates with investigative sites
• Ensures all required training is completed and documented
• Facilitates audits and audit resolution

Roche Pharmaceuticals
pRED Neuroscience Intern
luglio 2013 - settembre 2013 (3 mesi)

The mission of Dr. Luca Gobbi laboratory is to investigate the Chemistry-Biology interface designing new PET imaging ligands to support on going drug discovery programs.

University of Naples Federico II
Laboratory Intern
aprile 2012 - marzo 2013 (1 anno)
Università degli Studi di Napoli "Federico II", Faculty of Pharmacy, Naples, IT.

Internship in the Medicinal and Toxicological Chemistry department, in the process of preparing an original research thesis.

Farmacia Florio dei dottori Ettore e Patrizia Florio s.n.c.
Pharmacist Trainee
maggio 2012 - luglio 2012 (3 mesi)

Farmacia Florio dei dottori Ettore e Patrizia Florio s.n.c.
Pharmacist Trainee
novembre 2011 - febbraio 2012 (4 mesi)

Formazione

Università degli Studi di Milano-Bicocca
Master di II livello, Second Level Postgraduate Master Student in Research and pre-clinical and clinical drug development · (2014 - 2015)

Università degli Studi di Napoli 'Federico II'
Doctor of Pharmacy (PharmD), Facoltà di Farmacia · (2007 - 2013)