

Leïla Belbekri
Contractor Clinical Quality Auditor - Quality System Manager
Study Start Up Associate
France

Education

High school Saint Dominique, Pau (France)
Bachelor of Science Degree
Major: Chemistry

Ecole Nationale supérieure Chimie, Toulouse (France)
Diploma in advanced studies
Major: Biochemistry

Summary

- Over 10 years of experience working in clinical research with over 6 years of experience as Project Manager
- Over 3 years of experience working as freelancer clinical quality auditor, quality system manager for drug store, study start up associate.
- Professional Skills: Audit in clinical studies, knowledge ISO 9000, ISO 9001:2008, ISO 14001:2004, Knowledge of regulatory submission (EC and CA) and contract management in France, Belgium and Switzerland,
- Experience in Electronic Data Capture trials: Inform, EDC, Medidata, Rave
- Languages : French (verbal and written), English (verbal and written), Arabic (verbal and written)

Professional Experience

Optimum Clinical Research
July 2009 - Present

Freelancer Clinical Quality Auditor - Quality System Manager - Study Start Up Associate

I worked as quality auditor for one CRO, and I realized audit in French sites.

I'm consultant for several drug stores, to implement their quality system using ISO 9001/QMS Pharma manual.

I work as study start up associate for CRO, biotech company or institutional sponsors.

Responsibilities:

- *Auditing of 5 sites in France for one international study in Rheumatology. Clinical trial data and record audit to verify the compliance with sponsor SOP, study protocol, good clinical practice guidelines and French regulation. Audit report preparation.*
- *Responsible of internal audit of drug stores using ISO 9001:QMS pharma guidelines, delivering of audit analyse, advice in the redaction of internal procedures, ensuring that quality system implementation calendar is respected.*
- *Responsible of EC and CA submission; Preparation of ICF, protocol synopsis, Critical document collection, contract negotiation. Obtain Critical Document Package approval.*

Monitoring force

May 2004 to July 2009

Senior Project Manager

I was responsible for managing a clinical team of 5 CRAs across 2 North African countries.

Responsibilities:

- *Study start-up, monitoring, study close out*
- *CRA recruitment training and supervision, accompanied monitoring visits, presentation at investigator meetings, collation of study status reports and metrics, management of CTMS, site visit report review, preparation of study newsletters and study-specific procedures. Principal contact with sponsor, management of Budget and contractors. Find solution in order to improve patient recruitment; Regulatory submissions; Participation of investigator meetings; training staff for using eCRF.*

Chiesi

May 2001 to April 2004

Study coordinator

I was responsible for managing CRO, tasks included writing of descriptions, contracts, budget management.

Responsibilities:

- *Tasks included management of Budget and monitoring contractors. Regulatory submissions; writing of CRF and part of protocol (ICF), selection of site participation of investigator meetings.*

Chiltern International
January 1999 to April 2001

CRA

I was responsible for managing several clinical studies in France, Belgium and Switzerland.

Responsibilities:

- *France, Belgium and Switzerland (20 sites)*
- *Study start-up, monitoring, study close out*
- *Site qualification visits, critical document collection, contract negotiations, EC and CA submission, training staff for using CRF, Back up of Project manager.*

Training

LRQA
December 2012

ISO 9001:2008 ; ISO 14001:2004
Internal Quality Audit

QMS pharma
January 2013

Quality system for Drug stores
Using of ISO 9001/QMS