

Curriculum Vitae – GCP Auditor

Fatima HAMDANE

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WORK EXPERIENCE

2009 – onwards

Quality Management Associate and Auditor at HCR France & HCR Benelux

- QM System design and set-up for Pharmaceutical companies
- Study audits of sites as lead auditor and co-auditor
- Study audits with special focus (Pharmacovigilance, regulatory affairs, laboratory etc.)
- System Management (DIN EN ISO 9001 Standard)
- Management of Corrective and Preventative actions & implementation
- Training of employees and maintenance of training documentation
- Suppliers selection and qualification process
- Redaction of SOPs pertaining to Quality Management and to Clinical Operations

2007 – 2009

Clinical Research Associate at HCR France

- Managed selection, initiation of investigational sites
- Monitored multi-centre clinical trials, Phase III: Neurology, Phase IV, Gynaecology, Phase III: Infectious diseases, Phase II: Oncology.
- Organised investigator meeting
- Submission to Regulatory authority and to Ethics Committee in France
- Contribution to Informed consent form development
- Created study-specific procedures
- Managed national, multi-centre clinical research projects, Phase IV
- Supervising of in-house staff

QUALIFICATION

2009-2010

Quality Auditor (Pharmaceutical Industry)

University René Descartes, Paris, France

2007

Clinical Research Associate

CLINACT, Sèvres, France

2004-2005

Master in Biomedical Engineering

Faculty of Medicine, University Saints-Pères, Paris, France

2000-2004

Bachelor in Chemistry

University of Science and Technology, Paris XII, France

POST-GRADUATE TRAINING

Mar 2010	QA event for FDA inspection preparedness HCR, Levallois-Perret, France
Dec 2009	Current and future challenges in quality assurance SOFAQ, Paris
Oct 2009	ICH-GCP refresher ECCRT, Paris
Nov 2008	Audit/Inspection preparedness ECCRT, Brussels
Apr 2008	Introduction to GCP auditing in clinical research ECCRT, Levallois-Perret, France
Nov 2007	Introduction to GCP and regulatory requirements in France HCR, Levallois-Perret, France
2005	Graduate thesis: Study of the physical and chemical properties of phenols in stabilizing perfumes International Flavors & Fragrances, SAS, Bois-Colombes, France
2004	Graduate thesis: Chemical synthesis of HIV inhibiting proteases for the use in biomedical applications Faculty of Pharmacy, Paris XI, Chatenay-Malabry, France

LANGUAGES

French (native speaker) – English (Fluent)

MEMBERSHIPS

SOFAQ (French Association of Quality Assurance) – 1 meeting per year
BPC News (Association of GCP experts) – 1 meeting every 2 months

HOBBIES

Travels, cultural visits (museums, famous sites...), cinema (adventure, humour, fantastic movies), cooking, reading