EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Karima Adamo

WORK EXPERIENCE

September 2019- Present

Epidemyology Assessor

ANSM (France)

Evaluation of Post Autorisation Safety Studies Protocols and Reports

September 2016-August 2019

President/Manager

FORTHEIN SASU (France)

find and execute consultancy contracts with CROs.

October 2012-December 2014

Director of Clinical development

Enterome (France)

Clinical studies in the field of inflammatory bowel diseases

- Responsible for the international implementation of projects in accordance with regulations (United States, France, Switzerland, Belgium)
- Responsible for submissions to health authorities and ethics committees
- Responsible for writing clinical operating standards
- Responsible for archiving and maintaining study documents
- Responsible for the selection of service providers
- Responsible for the clinical operations budget
- Responsible for writing study protocols and documents
- Line management

November 2011-September 2012

Clinical Project Manager

Guerbet (France)

Management of international phase III clinical study end activities, pivotal study for obtaining Marketing Authorization in the United States:

- Coordination and management of service providers
- Responsible for the medical review of data, monitoring and resolution of questions relating to study data until the database is frozen
- Review and adaptation of existing documents and development of new information supports intended for the various stakeholders
- Training of investigators, clinical research associates and medical representatives

May 2007-August 2009

Clinical Project manager

Ipsen (France)

International phase III study in endocrinology 13 countries (Europe and Turkey)

- Develop protocol and documents relating to the study
- Feasibility study
- Selection of centers and implementation of investigator contracts
- Selection of service providers, setting up of specifications and negotiation of contracts
- Preparation of submission files to health authorities and ethics committees of the countries involved in the study
- Responses to health authorities and ethics committees
- Establishment of study procedures
- Implementation of the investigators meeting
- Management of therapeutic units

- Management of clinical research associates and validation of on-site data control reports

EDUCATION AND TRAINING

October 1993-August 1998

PhD Pharmacology/Molecular Biophysics

Central School of Paris (France)

Volume regulation in cardiomyocytes

ADDITIONAL INFORMATION

Expertise

Post Autorisation Safety Study

Impact research

Publications

Projects

Memberships

Other Relevant Information