

FORESTIER Nadine

599, rue Voltaire – Bât.A2
F-01220 Divonne Les Bains
Phone :+33.6.84.79.91.99
e-mail:nadine.forestier@laposte.net

Clinical Quality Assurance Manager **with a background in Regulatory Affairs and Clinical Research**

RA Regulatory Affairs (+10 years)
CR Clinical Research (+9 years)
QA Quality Assurance, Clinical and Pharmacovigilance system (+2 years)

ISO 9001:2008 Lead Auditor (2012)
Pharmacovigilance auditor (RQA, 2013)
Advanced auditing skills (BSI, 2013)

INDUSTRIAL EXPERIENCE

July 2013

Switzerland

QA/RA/CR

Consultant activity

Medical Devices Class II and III, involve in meetings with notified body, advice and support the Quality Assurance, Regulatory Affairs and Clinical Research departments- Individual and team Coaching.

2011 – April 2013

Merck Serono S.A.

Geneva, Switzerland

QA

Quality Assurance Manager

Clinical and Pharmacovigilance system

Region: EU/Intercontinental

- Functional management of GCP local QA managers in affiliates (33):
 - Develop tools and provide trainings (ICH-GCP, GCLP, inspection, CRO, audits)
 - Support preparation, conduct and follow-up of regulatory inspection activities and audits
 - Develop minimum local clinical Quality Documents in 40 affiliates
 - Implement affiliate quality systems applicable to local and regional sponsored clinical trials (interventional, observational, PASS, PAES), local pharmacovigilance activities (SDEA, Business Partners), PSP, Call-centers
- Implement the annual quality management review report and PV audit/compliance status
- Support and participate to the management, conduct and follow-up of development system process (EU guidelines on Good Pharmacovigilance Practices, module VIII (PASS/PAES)/Patient Support Programs /Safety variations involving label changes)
- Involve in Medical Devices (class II) and Biotech products recalls
- Audits of site, vendor, TMF
- No critical findings in inspections or corporate QA audits of affiliates (GCP and PV system) in 2011/2012

2007 - 2010

RA

Merck Serono S.A.

Geneva, Switzerland

International Regulatory Affairs Specialist

Region: APAC & Intercontinental region: Australia, New-Zealand, China, Indonesia, South Korea, Philippines, Vietnam, North Western Africa, Middle East

- Life cycle management and project development of biotech products and medical devices (class II)
- Manage Algeria affiliate implementation
- Lead Raptiva worldwide withdrawal
- Support Korean ODD procedure submissions

2006 - 2007

CR

Merck Serono S.A.

Geneva, Switzerland

Clinical Project Manager

Region: All except US, Canada

- Responsible for 2 international phase II clinical trials, Atacicept in Rheumatoid Arthritis

2002 - 2006

RA

International Project Leader in Regulatory Affairs

Region: EU, France, Latin America, Middle-East, Near East, Indonesia, Vietnam

Pierre Fabre Medicament

Boulogne Billancourt, France

- Life cycle management and project development of pharmaceutical products
- Responsible for the development of a product in Cardiology in EU in DCP (felodipine, phase I)
- Participation as support in one MRP (transdermal patch)
- Creation of the mexican affiliate (8 months)
- Registration of Navelbine oral in Mexico (9 months) and Brazil (17 months)
- Responsible for the Central America re-organization and Latin America MA portfolio harmonization

1997-2002

CR

International Clinical Trial Manager

Region: All except US

Sanofi

Paris, France

- Responsible for international phases II, III and IV clinical trials in Oncology, Internal Medicine, CNS, Cardiology, Allergy and particularly an international phase III on Eloxatine (2200 patients)

1995 -1997

RA

Project Leader in Regulatory Affairs

Region: France

Sanofi

Paris, France

- Life cycle management of OTC pharmaceutical products and cosmetics.
- Responsible for advertising. Switch from Ethics to OTC MAs (Rhinathiol, Mitosyl)

1993 -1994

CR

Regional Clinical Research Associate

Region: France

GSK

Paris, France

- Responsible for national regional phases II and III clinical trials in various therapeutic areas (Oncology, Infectiology, CNS, Gastro-enterology..).

1992 -1993

RA

Regulatory Affairs Assistant

Region: France

GSK

Paris, France

- Create and implement a regulatory data-base. Submission and follow-up of national clinical trials

1991-1992

CR

Clinical Research Associate

Region: France

Sanofi

Antony, France

- Monitor a national phase I clinical trial in Oncology (Taxotere) and a national phase III in Infectiology (Pefloxacin)

HOSPITAL Experience

1987 - 1992 Hospital Resident (Pharmacy, Laboratories, Pharmacology, Pharmacovigilance) including one year as Award - Winning Resident

RESEARCH Experience

1991 Pharmacology of Nifedipine and its polarographic dosage

1989 Protein grafting of nanoparticulate vectors

LANGUAGES

French, Spanish: native speaker - English: fluent - German: read and write

POSTGRADUATE TRAINING

2005 D.E.S.U. in Human Resources, Coaching, Paris, France

1992 D.E.S.S. in Health Law, Paris, France

1992 CESAM-STARC (Certificate in Clinical Statistics), Paris, France

1991 D.E.S. in Specialized Pharmacy (Former Hospital Resident), Rennes, France

Hospital Pharmacist Gold Medal for a Clinical Research project with Sanofi

1989 D.E.A. in Molecular and Cellular Biology, Rennes, France

1986 Doctor of Pharmacy, Marseille, France

PERSONAL DETAILS

Nationality: French