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 45 years old – 3 children in school

Quality Assurance, Auditor Senior Clinical Research

AREAS OF EXPERTISE

QUALITY-AUDIT

- Setting up and management of quality system
- Carrying out of internal and external GCP audits
- Client audits and inspections participation
- Setting up and management of PACA
- S.O.Ps training
- Management of quality indicators

REGULATORY

- Regulatory training: GCP, European regulatory...
- Regulatory standby
- Setting up of regulatory web tools
- Interface with regulatory authorities
- Regulatory support to project teams
- Preparation and rereading regulatory documents

MANAGEMENT

- Clinical trial follow-up in accordance with regulatory requirements, along with administrative aspects, budget and sponsor reporting, direct management of ARCs
- Regulatory process management
- Regulatory filing management
- Biobank management

MONITORING

- Trial initiation, monitoring and final visits
- Phone call monitoring
- Administrative and investigational products follow-up
- Reporting of monitoring visits

20-YEAR EXPERIENCE IN CLINICAL RESEARCH

COMMISSARIAT À L'ÉNERGIE ATOMIQUE FOR HEIDELBERG UNIVERSITY (GERMANY)

(MARCH – AUGUST) 2011

Cognitive clinical study on volunteers conducted at the NeuroSpin biomedical laboratory, Saclay

Interface on the site for the investigator based in Germany

- Study documents realization
- Volunteers follow-up with realization of cognitive tests

AGENCE NATIONALE DE RECHERCHE SUR LE SIDA ET LES HÉPATITES VIRALES, PARIS

2006 – 2010

Academic sponsor conducting fundamental research, human and social research, clinical research (drugs and other health products)

Official representative Quality Assurance Manager

- Setting up of the agency's quality manual: Standard Operating Procedures writing and validation ~ 30 POS whose Scientific Advisory Board, Independent Committee, Protocol, Informed consent form, pharmacovigilance, Proposal, CRF
- Carrying out of internal and external GCP audits on ANRS's French clinical sites and in developing countries, CRO audits, follow-up of PACAs
- Management of ANRS's quality indicators for measurement of clinical site quality in clinical trials
- Research and exploitation of national and international regulation on clinical research
- Individual or collective trainings to quality system, regulatory requirements (GCP, ...): ~ 80 clinical studies doctors
- Setting up of web tools concerning research on person: research typology, tools for clinical research
- Interactions with key players and internal operational managers or with clinical trial units
- Participation in working groups with regulatory authorities via academic institutions: draft law "Jardet"; CNIL, reviewing of MR-001 methodology
- Responsible of records keeping: bid management, regulatory requirement in collaboration with the French National Archives, finance and logistics management
- Management of ANRS's biobank: CNIL statement; authorisation to collect, store and transform human samples, authorisation to import/export human samples for research, finance and logistics management

THERAPHARM RECHERCHES (NOW RPS), BOULOGNE-BILLANCOURT

1991– 2006

Contract Research Organisation – management of clinical studies from Phase I (pharmacological center) to Phase IV – Biometrics

Quality Assurance Manager (7 years)

- Management of quality system: drafting and updating of procedures (~130 SOPs)
- Carrying out of GCP audits: internal (Phase I, II, III, IV studies: 12/year), structural audits, external audits (investigation sites, subcontractors) ; follow up of PACAs
- Participation in client audits and inspections by Afssaps

- Interactions with key players and operational managers (Project Leaders, Data Managers...)
- Initial and continuous training of staff to quality assurance, SOPs and regulatory requirements
- Research and exploitation of national and international legislative information concerning clinical research
- Management of regulatory process with French authorities (Afssaps, Direction Générale de la Santé, Conseil de l'Ordre des Médecins, DRASS....)
- Review of clinical reports

Project leader (4 years)

- Management of phase III clinical trials:
 - Rheumatology (osteoarthritis) - Management of 220 private and hospital sites (520 patients) over 6 years - management of 5 CRAs
 - Neurology (Parkinson) – Management of 22 hospital sites (160 patients) over 18 months - management of 2 CRAs
- Management of phase II clinical trials:
 - Neurology (Epilepsy), study without direct benefit – Management of 6 investigational sites (100 patients) over 2 years - management of 1 CRA
 - Neurology (Epilepsy), study with direct benefit – Management of 6 hospital sites (150 patients) over 10 months - management of 1 CRA
- Management of phase IV studies in infectious diseases - Management of 60 private and hospital sites (220 patients) over 2 months - Management of 2 CRAs
- Data Management follow up
- Selection and interlocutor of sub-contractors: biomedical laboratories, pharmaceutical organisations
- Selection, management and continuous training of approximately 10 CRAs

Clinical Research Associate (4 years)

- Monitoring of private and hospital sites, general practitioners or specialists
- Therapeutic areas: ENT, cardiology, dermatology, neurology, hepatology

INSTITUT PASTEUR, PARIS

1989 – 1990

Laboratory of molecular immuno-pharmacology headed by Professor STROBERG

- Research topic: “Study on adrenergic β_3 anti-receptor polyclonal antibodies”

QUALIFICATIONS

- 2010 IATA certification: “Base: acceptance of dangerous goods”- Validity 07/06/2012 - ATC (Paris)
- 2009 Diploma: “Research on person and applied ethics” - Enseignement Pasteurien (Paris)
- 2000 Training: “Quality management and clinical research process” - SUNNIKAN Consulting (Paris)
- 1993 Diploma: Inter-university diploma of clinical research associate (DIU-FARC) - Paris VI University
- 1991 Diploma: Personal Assistant - La Femme Secrétaire (Paris)
- 1990 Specialist diploma in immunology - (3th year after “Baccalauréat” high school diploma) - École Supérieure des Techniques de Biologie Appliquée (Paris)
- 1989 Advanced Vocational Diploma in Biological Analysis: BTS Analyses Biologiques (Paris)

PUBLICATIONS

- “Measurement of clinical site quality in clinical trial: experience of the French Agency for Research on AIDS and Viral Hepatitis” (ANRS), 2003 – 2006; (28th Annual Conference of the International Society for Clinical Biostatistics – 2007)
- “Évaluation de la qualité d'un réseau de centres investigateurs d'essais cliniques : expérience de l'Agence nationale de recherches sur le sida et les hépatites virales (ANRS) 2003-2006”, First French Conference of Clinical Epidemiology ADELFI - RFUEC
- <http://www.anrs.fr/Rubriques-transversales/Outils-pour-la-recherche>

ENGLISH

Working knowledge

SPANISH

Basic knowledge

OFFICE SOFTWARE

Word, Excel, PowerPoint
Internet, Thunderbird, Outlook, Lotus Notes

HOBBIES

Water gym
International travels
Reading: historical novels, detective novels, sagas

B DRIVING LICENCE