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Dear Sirs:

I am currently working as a "free-lancer" My experience and professional background has been focused on the **Regulatory Affairs/ Clinical Trials & Pharmacovigilance fields**, and medical writing fields and I have over 31 years of experience in regulatory affairs and pharmaceutical development, with specific experience in EU registrations, CMC regulatory requirements and multiple clinical aspects related to successful registration of drug products. I have also deep experience in life-cycle management and significant experience in generic development, as well as global clinical development. I am currently looking for a position that would align with my experience and professional background. I am available for home and/or office based jobs within a supportive working environment. I would welcome the opportunity to learn the latest innovative technologies (including PC tools) and challenges needed for new development roles. For further details, please see the information below and the attached CV (summary & extended version):

- ***STRONG SCIENTIFIC BACKGROUND TO ALLOW RELEASE, REVIEW AND ASSESSMENT OF SCIENTIFIC, TECHNICAL REGISTRATION FILES OR ISSUES, TO ANALYZE AND UNDERSTAND SCIENTIFIC AND REGULATORY LEGISLATIONS, AND TO PROVIDE SCIENTIFIC AND REGULATORY INPUT TO TECHNICAL TEAMS, WHEN REQUIRED (EU AND USA REGULATORY EXPERIENCE)***
- ***CAPABILITY TO REACH GOALS EFFICIENTLY***
- ***GOOD WRITING SKILLS, ABLE TO NEGOTIATE WITH INDIVIDUALS AND AT SAME TIME UNDERSTANDING DEPARTMENTAL CONSTRAINTS/PRESSURE (ACT WITH EMPATHY, BUILD NETWORK AND GOODWILL) WITHIN A HIGHLY COMPLEX ORGANIZATION (MATRIX STRUCTURE, MULTI-DISCIPLINARY AND MULTI-CULTURAL TEAMS)***
- ***GOOD INTERPERSONAL, COMMUNICATION AND MOTIVATIONAL SKILLS***
- ***GOOD ORGANIZATIONAL SKILLS, EFFECTIVE TIME MANAGEMENT AND ABILITY TO MANAGE MULTIPLE TASKS***
- ***CONTACTS NETWORK***
- ***IN-SITE AUDITS (including facilities)***
- ***AWARENESS OF POTENTIAL STAKEHOLDERS***
- ***LEADERSHIP SKILLS (PROACTIVE: Excelling in meeting solutions to challenges)***
- ***FULL RANGE OF SERVICES & THERAPEUTIC AREAS (Drugs, Generics, Medical Devices, Cosmetics, Disinfectants, OTCs, Biologicals, Alimentary Supplements - EFSA)***
- ***PROVEN EXPERIENCE IN EVERY DEVELOPMENTAL STAGE OF DRUG LIFECYCLES & LATEST INNOVATIONS***
- ***CONTINUOUS EDUCATION (Patents, Drugs, Legal Requirements in force and projected drafts)***
- ***TRAINING SKILLS***
- ***GLOBAL INTELLIGENCE PERSPECTIVE***
- ***BUSINESS INTELLIGENCE WITH PROVEN RESULTS***
- ***EMOTIONAL INTELLIGENCE & CULTURAL INTELLIGENCE***
- ***ENTREPRENEURSHIP & CORPORATE CITIZENSHIP (RSE)***
- ***ENTERPRISE RESOURCES PLANNING***
- **BIOTECH STAKEHOLDERS, REQUIREMENTS AND PRIVATE FUNDING**

- ***PROVEN EXPERIENCE IN EVERY DEVELOPMENTAL STAGE OF DRUG LIFECYCLES & LATEST INNOVATIONS***

Speed-up the MAA through effective selection of your drug registration/CTA procedure

Integrate CTD requirements from the start of your submissions

Gain faster response from the regulators through better negotiations

Compile and present the key information in your submission dossiers most efficiently

Maintain your license by performing post-approval obligations on time

Reduce; early or late stage, setbacks in the registration procedure by anticipating questions from regulators

Overview Summaries

EDUCATION

GOLD STANDARD EDUCATION AS A GLOBAL DRUG LIFECYCLE VIEWER

- **PHARMACY DEGREE (Complutense University, Madrid, Spain)**
- **MASTERS DEGREE IN RESEARCH & DEVELOPMENT OF NEW DRUGS (Navarre University, Pamplona, Spain)**

  PROVEN EXPERIENCE IN EVERY DEVELOPMENTAL STAGE INCLUDING GLOBAL DRUGS LIFECYCLE VIEW
  Personal Project at the Organic Chemistry Department:
  "Design Synthesis and Preliminary Pharmacology Evaluation of New Pyrimidoindole as Antihypertensive Agents"
- **POSTGRADUATE COURSE in Development European Procedures of Registration and Regulation of Drugs**
- **ESADE MBA ONLINE LEARNING**
- **GCP / GLP / GMP /GVP**

PROFESSIONAL BACKGROUND

SENIOR CONSULTANT – PRESENT

REGULATORY AFFAIRS

CONSULTANCY, PREPARATION & ADAPTATION of Dossiers
From NTA 98 to CTD (including Module 2).

Annual and 5-years renewals
Type I and II Variations. Transfer Applications.
Packaging Material
PSUR preparation
Installations approval (including Medical Devices)
Regulatory Authorities
Translations

Medical Writing: Clinical Study Reports, Clinical Study Protocols, Clinical Summaries in the CTD format, modules I to V of the CTD, Investigator Brochures, IMPDs/INDs, scientific publications
Cosmetic, Medical Devices Approvals

CLINICAL TRIALS

Clinical Trials Manager overseeing multiple clinical studies and CRO vendors, reporting on key study information performance metrics pertaining to time costs and quality deliverables e.g. study start-up metrics, enrollment data and data collection timelines. Provides operational input into study protocols, CRF; informed consent and amendments. Development of the core study documents, plans and processes. Proactively assesses potential risks to the study and proposes risks mitigation plans. Has routine interaction with key internal and external stakeholder communicating project status. Specifically tracks operational study timelines and monitors operational performance metrics through the life of the study. Helps to ensure team and external partner receive and document study specific training. Coordinates, prepares for and executes meetings, team meeting, investigator meetings and training.

CRA and CTL from study start-up until close out of the study
according to GCPs,GMPs, relevant guidelines, Directives
and local requirements.
(Site ID, Site Contracts, Investigator Meetings, CRF Design, IC,
Quality review of submission packages (EC and CTA),
Training, Interim and Final Visits Report,
Clinical Study Report)

Phases**: I; II; III, IV, Non-Interventional**

No. Of sites involved**: 10-14**

Therapeutic areas: **Digestive**

Dermatology

Transplantation

(Cardiac, Renal, Hepatic)

Antihypertensives

Antitumoral

AIDS

Antiparkinson

Anti-HCV

Biologics

ATMP

LANGUAGES

ENGLISH

GENERAL: Advanced-proficiency course at the British Institute
Spoken and written: FLUENT
Technical Texts TRANSLATIONS & READING: PROFICIENT
Both ways Translations

FRENCH

Spoken and written: Niveau B1-B2 at the Institut Français (“Français des affaires”)
TRANSLATIONS & READING: INTERMEDIATE

ITALIAN & PORTUGUESE

Technical Texts TRANSLATIONS & READING