

PILAR CORRALIZA

SUMMARY OF QUALIFICATIONS:

A Senior Consultant, Clinical Trials Manager and leading expert on Regulatory Affairs & Drug Development with over 31 years pharmaceutical experience. Provides a full range of services and therapeutic areas including drugs, generics, medical devices, cosmetics, disinfectants, OTCs, biological and alimentary supplements (EFSA), with proven experience in every developmental stage of drug lifecycles and the latest innovations. Exceptional competence in corporate quality control and effective stakeholder negotiator for CROs, Clinical Laboratories, Biotech requirements and Private Funding, as well as On-site Audits including facilities. Excellent leadership and communication skills with experience as an Associate Director of a CRO managing a department of five staff, maintaining optimum levels of performance and productivity.

HIGHLIGHTED EXPERIENCE:

SENIOR CONSULTANT, Freelance Clinical Trials & Regulatory Affairs Services 1999 –Present

Providing freelance consulting services in the areas of clinical trials and regulatory affairs services.

Satisfied Clients include global companies:

GSK, PFIZER, PROCTER & GAMBLE, SALVADOR CÓRDOBA, MDS PHARMA SERVICES, CHARLES RIVER, INGENIX PHARM. SERVICES, CELER PAWLOWSKI, CELER SOLUCIONES, ROCHE, GES GENÉRICOS; OPIS, QUALITECFARMA, EISAI., IMERETI, ITALFÁRMACO.

Regulatory Affairs:

- Consultancy, preparation and adaptation of dossiers from NTA 98 to CTD (including 2 Modules)
- Mutual recognition procedure application; centralized procedures; annual and five-year renewals
- Type I and II variations; transfer applications
- Packaging material and PSUR preparation; installations and cosmetic approval (including medical devices)
- Regulatory authorities
- Translations
- Medical writing: Clinical Study Reports, Clinical Study Protocols, Clinical Summaries in the CTD format, Investigator Brochures, IMPDs/INDs, scientific publications
- GDPs audits
- Promotional materials

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.

Clinical Trials Leader:

- CTL from study start-up through close out of the study according to GCPs, GMPs, relevant guidelines, directives and local requirements (site ID, site contracts, investigator meetings CRF design, protocol design, IC review).
- Quality review of submission packages (EC and CTA), training, interim and final visits report, clinical study report.
- Phases: II, III, IV, Non-Interventional.
- Number of sites involved: 10-14.
- Therapeutic areas: Digestive, Dermatology, Transplantation (Cardiac, Renal, Hepatic), Stem Cells in stroke
- Submitted CTA (IND) or translated protocols related to: Antihypertensives, Antitumoral-Oncology, AIDS, Antiparkinson, Anti-HCV, Pain, Respiratory, Biologics, Advanced Therapies, Cell therapies.
- Compassionate use

SELECTED EXPERIENCE:

SENIOR CONSULTANT - Freelance Clinical Trials & Regulatory Affairs Services Sep 1999-Present

- Providing Clinical Trials Management & Consultation for Regulatory adherence to a range of global biopharmaceutical services companies and multinational manufacturers. Senior Lecturer at the Master related to ATMP of Foundation ESAME.

REGULATORY AFFAIRS MANAGER & MANUFACTURER FACILITIES APPROVAL

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EDUCATION:

Masters - Development, European Procedures of Registration & Regulation of Drugs

Colegio Oficial Farmacéuticos
Madrid, Madrid, Spain 2015-2016

Masters - R&D of New Drugs

Navarra University Pamplona,
Spain 1989 -1991

Degree - Pharmacy (7/10 mark)

Complutense University, Madrid
Spain 1983-1989

YEARS IN THE INDUSTRY:

25+

SPECIALTIES:

- Project Management
- Product Development
- Clinical Development
- Regulatory Strategy Development
- Regulatory Drug Development
- CRO and Clinical Laboratory Audits
- Drug Development
- Global intelligence viewer
- Business intelligence with proven results
- Contacts Net
- Emotional & Cultural intelligence
- Continuous ongoing education (patents, drugs, legal requirements in force and projected drafts)

INDUSTRIES:

Biotechnology
Pharmaceutical

LANGUAGES:

Excellent multi lingual and technical translation skills

PILAR CORRALIZA

Imereti S.L. Feb-Dic 2020

Training, Consultation and preparation of the full Dossier for an ATMP Product. Manufacturer facilities approval.

Parexel International S.L. May-Oct 2016

- Consultation and clinical trials management on behalf of pharmaceutical clients to expedite drug approval processes

REGULATORY AFFAIRS TECHNICIAN - Roche Regulatory Affairs Department Feb-Mar 2015

- Reviewed packaging materials to ensure compliance

REGULATORY AFFAIRS TECHNICIAN - Química Sintética Regulatory Affairs Department Sep-Nov 2012

- Preparation, evaluation and revision of CEP, DMF and CMC DMF, CEP, CMC (USA requirements)

ASSOCIATE DIRECTOR - Pentafarma / Agora Farmacéutica (Local CRO) 1994 – 1999

- Operations management, leadership, full range of services and therapeutic areas, Clinical Trials & Regulatory Affairs

Earlier Career:

REG. AFFAIRS ASSISTANT & DMF MANAGEMENT - Chemo Ibérica, S.A. – Geinte S.A. 1993-1994

PHARMACIST - Gloria Diaz Lopez Pharmacy 1991-1992

SPECIALIZED TRAINING:

- New Royal Decrees related to Medical Devices (AEMPS : Spanish Agency Of Medicines & Medical Devices)
- Drugs Research in the National Health System (AEMPS)
- Analysis and Risk Management on Pharmacovigilance (ENS - National Health School)
- Tools for Emotional Intelligence (AEFI)
- ES2: 'GCP & Essential Guidelines' (Pharmaschool)
- Electronic Transmission of ICSR (AEMPS)
- Preparation of electronic dossiers under formats accepted by the AEMPS: NEES & e-CTD (AEFI)
- Pharmacovigilance: Theoretical and Practical Issues (2nd. Ed.) (Alcalá University)
- Authorization of activities of manufacturing, importation and distribution of Medical Devices (AEFI)
- Electronic Registration of medicinal products (AEMPS)
- Key aspects of the Marketing Authorization Dossier for declaration of healthy properties in Alimentary Supplements and Functional Food products (AEFI)
- Border Controls by Pharmaceutical Inspectors and the new computerized system SIFAEX (MSPSI)
- Electronic Case Report Forms eCRF: Inspections, Legal and Safety Requirements & Advantages (AMIFE)
- 5th Forum on the Information System of the NHS (MSPSI)
- Medical Liaison role in the present pharma environment (AMIFE)
- III Seminar AECIC on Paediatric Clinical Trials (Spanish Association of Clinical Research Companies)
- Data Protection Organic Law in relation to the Sanitary Sector: Practical Implementation (CEOE: Spanish Confederation Of Enterprises Organizations)
- Seminar on COMMISSION Regulation (EU) No 432/2012, establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (MSPSI)
- Private Funding of the BIOTECHNOLOGY (ALITER) – International Business School
- Regulatory Affairs in India & China (Generics & CTA in India – SFDA MAA and CTA in China) – (QUALITECFARMA)
- Updating in Clinical Research: New Royal Decree related to Clinical Trials and Investigative nets (AMIFE)
- 8th Monographic Workshop on Clinical Trials: Postmarket Non-Interventional Trials with human medicinal products. Clinical Research and Studies with Medical Devices (AEFI).
- III National Working Day on Biosimilars: Towards an Biosimilar Strategy in the National Health System (BIOSIM)
- II Course of Rare or less frequent Diseases for Health Managers and Hospital Pharmacists. Hospital Clínico San Carlos.
- Data Safety and Monitoring Board for Clinical Trials (The Global Health Network)
- Introduction to Data Management for Clinical Research Studies (The Global Health Network)
- Essential Elements of Ethics (The Global Health Network)
- GCLP: Facilities, equipment, materials and reagents (The Global Health Network)
- GCLP: Methods and system validation (The Global Health Network)

LANGUAGES cont:

ENGLISH

Spoken & Written: FLUENT

Translations & Reading:

PROFICIENT

Translations:

BOTH WAYS

Attending an advanced proficiency course at the British Institute

FRENCH

Spoken & Written: NIVEAU B1-B2

Institut Français

Translations & Reading:

INTERMEDIATE

Attending course "Français des affaires"

ITALIAN & PORTUGUESE

Translations & Reading:

INTERMEDIATE

SPANISH

Spoken and written: NATIVE

IT/ AUTOMATION:

Microsoft Office including:
Word, Excel & PowerPoint

- How to Conduct GCP Inspection and audits at the Clinical Investigator Site (The Global Health Network)
- ICH GCP E6 (R2) (The Global Health Network)
- The Study Protocol: Part I and II (The Global Health Network)
- Introduction to Informed Consent (The Global Health Network)
- Introduction to collecting and reporting adverse events in Clinical Research (The Global Health Network)
- Clinical Investigation with medical devices under new regulation (AEFI)
- 5th Edition Course on patents in the pharmaceutical industry: Protection of inventions and infraction of patents (AEFI)
- Functional foods: Are we what we eat? AEFI
- Module 3: CEP and ASMF variations (AEFI)
- Resolution on good reconstitution practices: A major contribution to the safety of patients (EDQM)
- Impurity Control in the European Pharmacopoeia (EDQM)
- Approaches for CEPs and the Ph.Eur. Strategy with regard to nitrosamine control: Current guidance and practical implementation (EDQM)
- 4th Workshop of promotion of drugs: Scientific activities and Service Contract with professionals (AEFI)
- Remote Audits (AEFI)
- Notification of food supplements in Europe and mutual recognition: How to apply for new statements of healthy properties (AEFI)
- Labelling of cosmetics with allegations of composition or sustainability (AEFI)
- Clinical Evaluation of Medical Devices according to EU MDR 2017/745 (AEFI)
- Judicial Expertise in the Pharmaceutical Industry (AEFI)
- Update in the promotion of medical devices targeted to general public and professionals (AEFI)
- Webinar CTIS: Are you prepared for the centralized submission? (SERMES)
- Registration of Economic Operators and Products (AEFI)