GRISSEL FAURA TELLEZ

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PERSONAL PROFILE

I am an enthusiastic, hardworking and quick learning Biomedical researcher with a proactive demeanour. With extensive knowledge in both clinical and academic research, I'm able to quickly adapt to dynamic surroundings and work with scientists from different disciplines to solve new challenges. Currently, I am looking for new exciting opportunities in the Scientific/Healthcare research industry.

AREAS OF EXPERTISE

- Analytical mind
- ICH's GCP guidelines
- Presentation skills
- Literature research
- Scientific writing
- Networking
- Project management
- Clinical research
- Detail oriented

CAREER HISTORY

SSU & Regulatory Specialist II — 03/2017 – up to date

Syneos Health (Previously INC Research/inVentiv Health) – The Netherlands.

- Performs assigned activities within the regulatory Hub that support SSU activities as needed, from Site Start up to Close out, in all phases of clinical trials related to investigational drugs, biologicals and medical devices as required.
- Accountable to the PM/SSUL at the project level and line manager for deliverables during start-up or amendment management on allocated projects. At a project level, may act as SSUL for local studies.
- Provides expertise on regulatory submission requirements for post activation submissions/notifications.
- Responsible for the preparation of core package for amendments submissions and periodic notifications required by central and local, EC and RA, and other local regulatory authorities as needed within the country; as required by local requirements.
- Reviews essential document packages for site activation or amendment purposes, and may also be involved in essential document collection from site.
- Follows the project direction and expertise provided by the designated country start-up advisor.
- Forecasts submission/approval timelines and ensures they are compiled and undertaken in accordance with agreed timelines, allocated budgets, and required quality standards; if forecasted timelines are not reached: provides clear rationale for delays.

Project Specialist II — 11/2015 – 03/2017

INC Research – The Netherlands.

- Therapeutic area: Late Oncology.
- Supports Project Manager to ensure that the contracted services and expectations are in accordance with the executed contract and the Customer's expectations.
- Assures compliance with local regulations, Code of Federal Regulations/International Conference of Harmonization, Good Clinical Practices guidelines, and Company and Sponsor Standard Operating Procedures.
- Taking-initiative in supporting and coordinating with CRAs to address GCP issues and potential data queries.
- Proactively communicated to management new issues and potential solutions.
- Tracks project details, maintain internal systems and performing accurate and timely quality review of the Trial Master File (TMF) to ensure inspection readiness at all times.

PhD student — 02/2011 – 10/2015

Medical Biology Sciences: Groningen University & Southampton University –Netherlands & United Kingdom

- Therapeutic area: Immunology.
- Managed a joint/sandwich PhD with several project and collaborations demanding excellent organizational skills

and realistic objectives to achieve goals and targets on time. Also included management of budget.
- Strong communication/presentation skills (adapting content to the audience) presenting data clearly and confidently to both small and large groups in English.
- Scientific writing skills: wrote articles for international peer-reviewed journals.

Research Assistant 06/2010 – 01/2011

Genetics Clinic: Biomedicine Institute, Sahlgrenska academic, Goteborg University – Sweden.
- Therapeutic area: Oncology.
- Supporting scientific research group in their different projects, which involved working with various techniques: PCR, Western Blot, Cell Culture, Proliferation, and Cloning.

Clinical Research Associate IO 10/2008 – 08/2009

PPD: Contract Research Organization – Peru.
- Therapeutic area: Oncology and Thrombosis.
- Provided day to day administrative support to the PM/CRA, site team and contact point with Sponsor during start-up activities.
- Tracked and maintained central study files (including regulatory documents, enrolment, adverse events, investigator payment information, queries, INDs) for assigned projects and ensured accuracy and audit readiness.
- Supported with monitoring activities at sites during start-up activities to ensure compliance with the clinical trial protocol.
- Assisted investigator meeting.

Clinical Research Study Coordinator and Data Manager 02 – 09/2008

NGO: Inmensa.org -Investigaciones Médicas en Salud – Perú.
- Therapeutic area: HIV and HPV.
- Coordinated the execution of the clinical trial with CRO following the regulatory guidelines.
- Liaised with other departments (regulatory, pharmacy) to ensure trial, is carried out in accordance with the SOPs and Good Clinical Practice guidelines (ICH-GCP).
- Verify that the scientific integrity of the data collected, both, accurate and authenticated, including patients informed consent and data originating from the clinical investigation.
- Handle regulatory documentation from sites and maintain it complete and updated.
- Check the investigational product and laboratory kits, and maintain an updated inventory.
- Performed Quality Control on CRF/eCRF for data completeness, accuracy and regulatory reportability.

Clinical Research Associate Graduated – Entry Level 06/2007– 01/2008

GlaxoSmithKline Pharmaceutics– Peru.
- Therapeutic area: Vaccines and Epidemiology.
- Collected, maintained and reviewed all regulatory and administrative documents from site during site monitoring visits.
- Collected reported SAEs (Serious Adverse Events) and AEs information following the industry practices.
- Assisted in receipt, preparation, tracking and distribution of SUSARs.

KEY SKILLS AND COMPETENCIES

Professional
- Deep understanding of scientific medical research and literature research tools.
- Expertise in microscopy including immunohistochemistry, confocal and electron microscopy.

Personal
- Able to work well under pressure, prioritize workload to meet deadlines.
- Self-motivated with a positive attitude.
- High level of intellectual curiosity and passionate about conducting research.

ACADEMIC QUALIFICATIONS

Skövde University – Sweden

Master degree	Biomedical Sciences	2009 – 2010

Ricardo Palma University – Peru

Bachelor degree	Biological Sciences	2002 – 2006

OTHER QUALIFICATIONS

- **Spanish** (Native)
- **English** (Advanced)
- **Dutch** (A2/B1)
- **Portuguese** (Basic)
- **Computer skills:** extended knowledge of standard Ms Office, Outlook, GraphPad and SPSS.
- **Good Clinical Practice course:** by Asociación Nacional De Laboratorios Farmacéuticos – Perú.

SCIENTIFIC PUBLICATIONS & REFERENCES (Available on request)