Michele Orosco

Clinical Research Professional

ABOUT ME

With 20+ years in biotech and medical devices, I offer strategic planning and practical solutions for clinical trials from First in Human (FIH) to commercialization. I work independently, uphold strong ethics, and maintain a professional, approachable manner.

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EDUCATION

BA in Organizational & Speech

San Francisco State University – Communication

July 2002 - August 2005

Masters in Clinical Research

May 2023 - Present

Certificate: Good Monitoring Practices

October 2007

Certificate: RAPS Regulatory

November 2019

SKILLS

- Clinical Trial Project Management
- Regulatory Submissions and Compliance
- Site Selection, Initiation, and Monitoring
- Vendor and CRO Oversight
- Protocol Development and Implementation
- Risk Assessment and Mitigation
- Quality Assurance and GCP Compliance

ACHIEVEMENTS

- Participated in FDA inspection and FDA Advisory Meeting
- Developed a full Clinical Quality System
- Mother of three

WORK EXPERIENCE

T.E.N. Research — Carmel Valley, CA

Consultant — May 2022 – Present

- Provide guidance to clients regarding clinical research strategy and planning
- Develop clinical protocols and investigational plans
- Conduct clinical site selection, qualification, initiation, and monitoring
- Oversee vendors such as CROs, committees, and core laboratories
- Perform literature reviews and pre-clinical research

Clin-Assist LLC, Santa Rosa, CA — Santa Rosa, CA

Final: Director of Clinical Affairs
Hired: Assistant/Clinical Coordinator — February 2005 – May 2022

- Oversaw Clinical Affairs, Quality Assurance, Document Control, and Data Management
- Managed multiple clinical trials in various therapeutic areas
- Performed Regulatory submissions
- Oversaw site management and monitoring from start to close
- Developed Clinical Operations infrastructure and Quality Management System (QMS)

MedQIA LLC — Los Angeles, CA

Clinical Trial Manager (CTM) — April 2012 – April 2015

- Managed global clinical project teams.
- Identified team goals and ensured objectives were met.
- Assisted in development and direction of Quality Management System (QMS)
- Responsible for overall project and site management
- Oversaw project activities, ensured compliance with Clinical Operations/CRO processes and procedures and addressed non-compliance issues

Earlier career roles available upon request July 2002 - August 2005