

MICHAEL ANDERSON

Clinical Operations Manager

- San Francisco, CA
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Dedicated biotechnology operations manager with a focus on clinical operations and regulatory compliance within the pharmaceutical industry. Extensive experience in managing clinical trials and ensuring adherence to Good Clinical Practice (GCP) guidelines. Proven ability to lead teams in the execution of clinical studies, from protocol development to final reporting. Skilled in stakeholder engagement and managing relationships with regulatory agencies, ensuring successful submissions and approvals.

WORK EXPERIENCE

Clinical Operations Manager | Clinical BioResearch

Jan 2022 – Present

- Managed clinical trials for a portfolio of biopharmaceutical products.
- Ensured compliance with GCP guidelines and regulatory standards.
- Coordinated with investigators and sites for study execution.
- Developed study protocols and informed consent documents.
- Monitored trial progress and data integrity throughout the study lifecycle.
- Prepared regulatory submissions, achieving timely approvals.

Regulatory Affairs Specialist | PharmaRegulatory Services

Jul 2019 – Dec 2021

- Prepared and submitted regulatory documents for clinical trials.
- Monitored changes in regulations to ensure compliance.
- Collaborated with cross-functional teams to align regulatory strategies.
- Conducted training sessions on regulatory requirements for staff.
- Assisted in the development of quality assurance protocols.
- Participated in regulatory inspections, ensuring compliance.

SKILLS

clinical operations

regulatory compliance

clinical trials

stakeholder engagement

project management

quality assurance

EDUCATION

Bachelor of Science in Pharmaceutical Sciences

2015 – 2019

University of North Carolina

ACHIEVEMENTS

- Successfully managed the launch of three clinical products with positive patient outcomes.
- Recognized for outstanding contributions to regulatory submissions, achieving a 100% approval rate.
- Awarded 'Best Clinical Manager' for excellence in trial management.

LANGUAGES

English

Spanish

French