Michael Anderson

CLINICAL REGULATORY AFFAIRS MANAGER

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Strategic Clinical Regulatory Affairs Manager with a robust background in the development and commercialization of pharmaceutical products. Expertise in managing regulatory submissions for various therapeutic areas, with a strong emphasis on oncology and rare diseases. Proven ability to lead teams in the preparation of high-quality regulatory documents that facilitate swift approval processes.

SKILLS

- Oncology Regulations
- Rare Diseases
- Regulatory Submissions
- Clinical Trials
- Risk Management
- Team Leadership

EDUCATION

MASTER OF SCIENCE IN REGULATORY AFFAIRS, UNIVERSITY OF CALIFORNIA, SAN DIEGO

LANGUAGE

- English
- Spanish
- German

ACHIEVEMENTS

- Successfully accelerated the approval process for a breakthrough oncology drug.
- Awarded 'Top Performer' for contributions to regulatory submissions.
- Implemented new regulatory tracking systems that improved submission accuracy by 30%.

EXPERIENCE

CLINICAL REGULATORY AFFAIRS MANAGER

OncoPharma Inc.

2016 - Present

- Directed regulatory submissions for oncology products, ensuring compliance with FDA and EMA regulations.
- Managed cross-functional teams in the preparation of IND and NDA submissions.
- Developed regulatory strategies to facilitate timely clinical trial approvals.
- Engaged with regulatory authorities to discuss clinical trial designs and data requirements.
- Reviewed and approved clinical study protocols and informed consent documents.
- Provided regulatory training and mentorship to junior team members.

REGULATORY AFFAIRS ASSOCIATE

RareMed Solutions

2014 - 2016

- Supported regulatory submissions for rare disease therapeutics.
- Maintained up-to-date knowledge of regulatory changes affecting product lines.
- Collaborated with clinical teams to ensure compliance with trial protocols.
- Assisted in the development of regulatory documents and submissions.
- Conducted research on global regulatory requirements.
- Participated in cross-functional meetings to provide regulatory insights.