MICHAEL
ANDERSON

Regulatory Affairs Specialist

- San Francisco, CA
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Dedicated Regulatory Affairs Specialist with a profound understanding of the biotechnology sector, focused on ensuring compliance and facilitating product approvals. Demonstrates a high level of proficiency in preparing regulatory submissions and engaging with regulatory bodies. Recognized for an analytical approach to regulatory challenges and a commitment to maintaining the highest standards of compliance.

WORK EXPERIENCE

Regulatory Affairs Specialist | NextGen Biotech   Jan 2022 – Present

- Prepared and submitted regulatory filings for investigational new drugs.
- Reviewed product documentation for compliance with regulatory standards.
- Collaborated with clinical teams to ensure alignment on regulatory requirements.
- Maintained up-to-date regulatory documentation and tracking systems.
- Conducted training on regulatory compliance for internal stakeholders.
- Engaged with regulatory agencies to address inquiries and provide documentation.

Regulatory Affairs Assistant | BioPharma Innovations   Jul 2019 – Dec 2021

- Assisted in the preparation of regulatory submissions for clinical trials.
- Conducted research on regulatory guidelines and requirements.
- Supported the regulatory team during audits and inspections.
- Maintained regulatory documentation and files.
- Participated in team meetings to discuss regulatory strategies.
- Provided administrative support to the regulatory affairs department.

SKILLS

Regulatory submissions | Compliance | Cross-functional collaboration | Documentation | Training | Research

EDUCATION

Bachelor of Science in Regulatory Affairs   2015 – 2019
University of Southern California

ACHIEVEMENTS

- Achieved a 40% reduction in submission preparation time through process improvements.
- Recognized for exceptional performance in regulatory compliance initiatives.
- Contributed to a successful product launch that exceeded sales expectations.

LANGUAGES

English | Spanish | French