



# MICHAEL ANDERSON

## Regulatory Affairs Specialist

Dedicated Biotechnology Specialist with a focus on regulatory affairs and quality assurance within the biotech industry. Expertise in navigating complex regulatory frameworks to ensure compliance throughout the product lifecycle. Proven track record in developing and implementing quality management systems that meet international standards. A strategic thinker with strong analytical skills, adept at identifying potential compliance issues and developing proactive solutions.

### CONTACT

- (555) 234-5678
- michael.anderson@email.com
- San Francisco, CA

### EDUCATION

**M.S. in Regulatory Science**  
University of Southern California  
2014

### SKILLS

- regulatory affairs
- quality assurance
- compliance management
- project leadership
- risk assessment
- training and development

### LANGUAGES

- English
- Spanish
- French

### WORK EXPERIENCE

#### Regulatory Affairs Specialist

2020-2023

Pfizer

- Managed regulatory submissions for new biopharmaceutical products.
- Collaborated with R&D to ensure compliance with regulatory requirements.
- Developed and maintained quality management systems in accordance with ISO standards.
- Conducted internal audits to assess compliance with regulatory guidelines.
- Provided training on regulatory standards to cross-functional teams.
- Presented compliance findings to senior management and stakeholders.

#### Quality Assurance Manager

2019-2020

Bristol-Myers Squibb

- Led quality assurance initiatives to ensure product safety and efficacy.
- Managed a team of quality assurance professionals in compliance activities.
- Developed training programs for staff on quality assurance practices.
- Conducted risk assessments and developed mitigation strategies.
- Oversaw regulatory inspections and audits, achieving zero non-conformities.
- Collaborated with manufacturing teams to implement quality improvement strategies.

### ACHIEVEMENTS

- Successfully led regulatory submissions that resulted in the approval of 3 new drugs.
- Recipient of the 'Quality Excellence Award' for outstanding performance in quality management.
- Developed a compliance training program adopted company-wide.