



# MICHAEL ANDERSON

## REGULATORY AFFAIRS MANAGER

### CONTACT

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-  San Francisco, CA

### SKILLS

- Regulatory affairs
- Quality assurance
- Compliance audits
- Risk management
- Cross-functional collaboration
- Training development

### LANGUAGES

- English
- Spanish
- French

### EDUCATION

**BACHELOR OF SCIENCE IN BIOLOGY,  
UNIVERSITY OF FLORIDA, 2011**

### ACHIEVEMENTS

- Led a successful regulatory submission that resulted in a product launch ahead of schedule.
- Improved compliance audit scores by 25% through enhanced training initiatives.
- Recognized as Employee of the Year for outstanding contributions to regulatory compliance.

### PROFILE

Accomplished Biotechnology Compliance Manager with extensive experience in the pharmaceutical and biotechnology industries, focusing on regulatory compliance and quality assurance. Demonstrates an exceptional ability to navigate complex regulatory landscapes while ensuring that organizational practices adhere to industry standards. Recognized for strategic leadership in developing compliance initiatives that enhance operational efficiency and promote best practices.

### EXPERIENCE

#### REGULATORY AFFAIRS MANAGER

##### PharmaGenix

*2016 - Present*

- Managed regulatory submissions for new product approvals and modifications.
- Developed and implemented quality assurance protocols across clinical operations.
- Coordinated with regulatory agencies during product development phases.
- Conducted internal compliance audits and prepared reports for management.
- Trained staff on regulatory requirements and compliance best practices.
- Maintained up-to-date knowledge of regulatory changes affecting the industry.

#### QUALITY ASSURANCE SPECIALIST

##### GenBioTech

*2014 - 2016*

- Performed quality audits to ensure compliance with Good Manufacturing Practices (GMP).
- Assisted in the development of quality control processes for laboratory operations.
- Collaborated with cross-functional teams to address compliance issues.
- Reviewed documentation for regulatory submissions to ensure accuracy.
- Developed training materials for quality assurance procedures.
- Monitored compliance metrics and reported findings to management.