



# MICHAEL ANDERSON

## REGULATORY AFFAIRS DIRECTOR

### PROFILE

Dynamic Regulatory Affairs Director with extensive experience in the biotechnology sector, specializing in the development and execution of regulatory strategies for innovative therapies. Recognized for the ability to navigate complex regulatory landscapes and deliver results in high-stakes environments. Expertise in leading teams through the regulatory submission process, ensuring compliance with local and international regulations.

### EXPERIENCE

#### REGULATORY AFFAIRS DIRECTOR

##### Innovative Biologics Inc.

2016 - Present

- Directed regulatory strategy for multiple biologics, achieving successful market entry.
- Mentored a team of regulatory professionals, enhancing departmental capabilities.
- Streamlined submission processes, resulting in a 25% reduction in time to market.
- Engaged with regulatory agencies to negotiate product approval pathways.
- Ensured compliance with GxP regulations across all operational areas.
- Led risk management initiatives to identify and mitigate regulatory challenges.

#### REGULATORY AFFAIRS CONSULTANT

##### Regulatory Insights LLC

2014 - 2016

- Provided regulatory guidance to biotech startups on product development strategies.
- Assisted clients in preparing and submitting IND applications to the FDA.
- Conducted gap analysis to identify compliance issues and recommend solutions.
- Facilitated workshops on regulatory requirements and best practices.
- Advised on labeling regulations and marketing compliance.
- Developed regulatory intelligence reports for clients to inform strategic planning.

### CONTACT

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- San Francisco, CA

### SKILLS

- Biologics regulation
- Team leadership
- Negotiation
- Quality assurance
- Market access strategy
- Compliance analysis

### LANGUAGES

- English
- Spanish
- French

### EDUCATION

MASTER OF BUSINESS  
ADMINISTRATION, HARVARD BUSINESS  
SCHOOL

### ACHIEVEMENTS

- Instrumental in obtaining FDA approval for a novel biologic therapy ahead of schedule.
- Recipient of the 'Regulatory Excellence Award' for outstanding contributions to the industry.
- Authored a comprehensive regulatory framework adopted by multiple startups.