



MICHAEL ANDERSON

MANUFACTURING COMPLIANCE SPECIALIST

CONTACT

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SKILLS

- GMP compliance
- FDA regulations
- Quality assurance
- Training and development
- Risk management
- CAPA processes

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN CHEMICAL ENGINEERING, UNIVERSITY OF CALIFORNIA, BERKELEY

ACHIEVEMENTS

- Developed a compliance training program that resulted in a 40% decrease in compliance violations.
- Recognized for leading a quality improvement project that enhanced operational efficiency by 20%.
- Received the Compliance Excellence Award for outstanding performance in quality management.

PROFILE

Results-driven Manufacturing Compliance Engineer with over 8 years of extensive experience in the pharmaceutical manufacturing sector. Skilled in developing and implementing compliance protocols that align with FDA regulations and GMP standards. Proven ability to lead cross-functional teams to achieve compliance goals while fostering a culture of quality and safety. Strong communicator with a passion for mentoring junior engineers and promoting best practices in compliance and quality assurance.

EXPERIENCE

MANUFACTURING COMPLIANCE SPECIALIST

PharmaMakers Corp.

2016 - Present

- Conducted compliance audits in accordance with FDA regulations and GMP requirements.
- Designed and executed training programs for staff on compliance policies and procedures.
- Collaborated with production teams to ensure adherence to quality standards during manufacturing.
- Utilized risk assessment techniques to identify compliance vulnerabilities in processes.
- Developed compliance documentation and maintained accurate records for regulatory review.
- Participated in CAPA investigations to address compliance failures and implement corrective actions.

QUALITY COMPLIANCE ENGINEER

BioHealth Solutions

2014 - 2016

- Facilitated audits and inspections by regulatory agencies, achieving zero non-conformances.
- Implemented a compliance management system that streamlined documentation processes.
- Advised management on compliance risks and mitigation strategies.
- Led internal training initiatives for quality assurance personnel on regulatory compliance.
- Utilized data analytics to monitor compliance metrics and report findings to senior leadership.
- Engaged with external stakeholders to ensure ongoing compliance with evolving regulations.