



MICHAEL ANDERSON

LEAD QUALITY AUDITOR

PROFILE

Accomplished Quality Auditor with a robust background in the pharmaceutical industry, focusing on regulatory compliance and quality assurance. Expertise encompasses the development of quality management systems and conducting audits that ensure adherence to FDA regulations. Known for exceptional analytical skills and a detail-oriented approach that enables the identification of compliance gaps and the implementation of effective solutions.

EXPERIENCE

LEAD QUALITY AUDITOR

Pharma Solutions Corp.

2016 - Present

- Led audits of manufacturing processes, ensuring compliance with FDA regulations.
- Developed training programs for staff on quality assurance practices and regulatory requirements.
- Implemented corrective actions that resulted in a 40% reduction in non-compliance incidents.
- Collaborated with R&D teams to ensure quality standards were integrated into product development.
- Utilized risk management methodologies to assess and mitigate quality risks.
- Prepared comprehensive audit reports for regulatory submissions and internal reviews.

QUALITY ASSURANCE AUDITOR

BioHealth Industries

2014 - 2016

- Conducted internal audits to assess compliance with quality management standards.
- Developed quality metrics and key performance indicators for continuous monitoring.
- Facilitated training sessions on quality assurance and compliance for new employees.
- Participated in regulatory inspections, providing documentation and support.
- Performed gap analyses to identify areas for quality system improvements.
- Collaborated with suppliers to ensure adherence to quality specifications.

CONTACT

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SKILLS

- FDA Regulations
- Quality Management Systems
- Regulatory Compliance
- Risk Management
- Auditing
- Training and Development

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN
PHARMACEUTICAL SCIENCES,
UNIVERSITY OF HEALTH SCIENCES, 2012

ACHIEVEMENTS

- Achieved a 100% compliance rating during regulatory audits over three consecutive years.
- Implemented a quality improvement project that enhanced product safety, achieving a 20% decrease in adverse events.
- Received the Quality Leadership Award for excellence in quality management initiatives.