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SKILLS

- ISO 13485
- Quality Control
- Compliance Auditing
- Documentation Management
- Risk Analysis
- Training Development

EDUCATION

BACHELOR OF SCIENCE IN CLINICAL LABORATORY SCIENCE, UNIVERSITY OF MICHIGAN

LANGUAGE

- English
- Spanish
- German

ACHIEVEMENTS

- Increased product compliance rates by 20% through improved quality control processes.
- Recognized for outstanding performance during regulatory audits.
- Led a project that enhanced training programs for quality assurance staff.

Michael Anderson

QUALITY ASSURANCE SPECIALIST

Highly skilled Biomedical Quality Specialist with over 7 years of experience in the diagnostics field. Demonstrated expertise in quality control and assurance processes for in-vitro diagnostic products. Recognized for developing and implementing effective quality systems that ensure product compliance with industry standards. Strong analytical skills and attention to detail contribute to successful quality audits and inspections.

EXPERIENCE

QUALITY ASSURANCE SPECIALIST

Diagnostic Innovations Inc.

2016 - Present

- Conducted quality audits and assessments to ensure compliance with ISO 13485 and FDA regulations.
- Developed and reviewed quality documentation, including SOPs and validation protocols.
- Collaborated with product development teams to integrate quality considerations into the design process.
- Implemented corrective actions in response to quality issues, improving product reliability.
- Monitored quality indicators and prepared reports for management review.
- Trained staff on quality assurance practices and regulatory requirements.

QUALITY CONTROL TECHNICIAN

InVitro Diagnostics

2014 - 2016

- Performed routine quality control testing on diagnostic kits and reagents.
- Assisted in the validation of new products and processes to ensure compliance with quality standards.
- Maintained accurate records of test results and quality control processes.
- Participated in cross-functional teams to address quality issues and implement improvements.
- Supported regulatory inspections by providing necessary documentation and reports.
- Monitored production processes to ensure adherence to quality specifications.