

Stephen Oduya

DIRECTOR OF QUALITY

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SUMMARY

Director of Quality with 15 years in medical device and industrial manufacturing, leading quality assurance, compliance and supplier quality for 2 plants and 48 staff. Builds quality systems that pass FDA and ISO 13485 audits, applies Lean and Six Sigma to cut cost of quality, and has reduced field complaints 60% since 2021.

EXPERIENCE

Director of Quality

02/2021 - Present

Wasatch Medical Devices

Salt Lake City, UT

Maker of surgical instruments and disposables with 2 plants and 900 employees.

- Lead **48** quality engineers, auditors and inspectors across 2 plants and a supplier quality team.
- Own the quality management systems under ISO 13485 and FDA 21 CFR 820, with 2 FDA inspections and no 483s.
- Direct auditing programs that cover 120 suppliers and 30 internal audits a year.
- Apply Lean and Six Sigma to rework and complaint handling, cutting cost of poor quality by \$3.2M in 4 years.

Quality Manager

05/2015 - 01/2021

Bonneville Industrial Controls

Ogden, UT

ISO 9001 maker of industrial sensors and controls with 400 employees.

- Managed a 15-person quality team and the plant's ISO 9001 system through 6 clean recertifications.
- Rebuilt the corrective actions process, closing 90% of CAPAs on time versus 50% before.
- Led root cause analysis on a field failure affecting 8,000 units and closed it with a design change.
- Trained 40 supervisors on continuous improvement methodologies, including kaizen and 5S.

Senior Quality Engineer

06/2011 - 04/2015

Great Basin Precision

West Valley City, UT

- Ran supplier audits and PPAP reviews for 50 machined and molded part suppliers.
- Led 4 Six Sigma projects that saved \$900K in scrap, rework and warranty costs.
- Wrote IQ, OQ and PQ validation protocols for 12 new manufacturing processes.

SKILLS

<u>Quality Management Systems</u>	<u>Quality Assurance</u>	<u>Quality Systems</u>	<u>Lean</u>	<u>Six Sigma</u>
<u>Auditing</u>	<u>Root Cause Analysis</u>	<u>Corrective Actions</u>	<u>Continuous Improvement Methodologies</u>	
Leadership				

EDUCATION

Bachelor of Science

05/2011

University of Utah

Salt Lake City, UT

Mechanical Engineering

CERTIFICATES

Certified Manager of Quality/Organizational Excellence (CMQ/OE)

10/2017

American Society for Quality

Certified Six Sigma Black Belt (CSSBB)

06/2014

American Society for Quality

ISO 13485 Lead Auditor

09/2021

Exemplar Global