

Nyla M. Kennard

nyla.kennard@yahoo.com

SUMMARY

Dynamic, creative, detail-oriented **Quality Manager** experienced in the medical device industry. Proven track record of developing, implementing and improving business processes. Diverse background in medical technology, quality, customer service and manufacturing operations. Excellent leadership, teamwork, collaborative and problem solving skills with the ability to influence and drive for results.

- Lean Six Sigma
- Quality Engineering
- Human Error Reduction and Investigation
- Process Improvement Best Practices
- Corrective and Preventive Action
- Audit Compliance

PROFESSIONAL EXPERIENCE

Consultant

DESARA Group

2009- Current

- Provide consulting services geared towards achieving competitiveness, certifications, and compliance to international standards and regulations through structured courses, on-site workshops and focused coaching sessions.

Abbott Laboratories (Diagnostics Division) Irving, Texas

1989-2008

Quality Manager

2007-2008

- Selected to lead Lean Six Sigma (LSS) Blackbelt Corrective Action Preventive Action (CAPA) Project with projected savings of \$500,000 by reducing redundancy and complexity of CAPA process.
- Reviewed and completed Gap Assessment for 4 current procedures against new CAPA process.
- Managed verification and assessments of 25 employees during the Dartford, England site pilot of global CAPA Learning Unit.
- Reviewed and approved over 1000 Supplier Corrective Action Reports, Nonconformance Events and Failure Analysis Investigation reports.
- Assigned to a task team, which reduced backlog of 2500 aged Nonconformance Events to 700 within a 3 month period.
- Coordinated Corrective Action Board (CAB) resources, processes, database records and meetings in response to an FDA audit observation.
- Developed and trained employees on CAB processes and Nonconformance database(s), improving consistency amongst over 100 investigators in their ability to write Failure Analysis Investigation reports and Corrective Actions.
- Streamlined CAB process by developing and maintaining investigation tracking tool for CAB, Quality and Manufacturing Engineers and Failure Analysis investigators.

Senior Business Process Improvement Analyst

2006-2007

- Completed Abbott training and certification in Lean Six Sigma, which resulted in assignment as Lean Six Sigma project leader for Highly Serviced Instrument reduction projected to save over \$500,000.
- Streamlined Customer Service by coordinating revisions for over 30 business processes.
- Implemented Best in Class business practices for Field Service and Customer Support based on surveys, observations and management input.
- Developed and trained Field Service organization to on-line manual, technical escalation process and Quick Reference Guide.

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Field Service Administration Manager

2003-2006

- Received Vice President's award for successful launch of new Field Service Database for over 200 Field Service employees, meeting all deadlines.
- Represented Field Service for audits, quality system document reviewer and approver.
- Coordinated field resources to support Abbott's accounts in aftermath of Hurricane Katrina and Rita.

Customer Service Team Manager

2001-2003

- Managed 16-20 Technical Support, Order Entry and Contracting Advocates to give focused support to Key accounts for multiple sales territories.
- Collaborated with service and sales to resolve issue and concerns from customers to stabilize and grow Abbott's diagnostic business.
- Performed call review, individual job standards analysis, growth and personal development.

Quality Records Supervisor

2000-2001

- Supervised the activities of 8 Production Support Associates for the Instrument Manufacturing Operations.
- Coordinated the construction of a secure Manufacturing Review Board (MRB) cage for non-conforming product.
- Selected to represent Quality on the Site Project Performance Factors team which resulted in streamlined performance review process for non-exempt employees.

Quality Engineer

1997-2000

- Provided Quality Engineering manufacturing support to ensure compliance with FDA/GMP/ISO regulations.
- Collaborated with Manufacturing and Design Engineers for 8 Cost Reduction projects, resulting in savings of over \$1 million dollars.
- Conducted product stock sweeps and interacted with suppliers to resolve manufacturability issues.

Customer Systems Engineer

1992-1997

- Co-led international ISO 9002 project, developing a standardized Quality Manual and procedures for the United Kingdom, Belgium, Spain and Sweden resulting in successful ISO 9002 certifications.
- Provided worldwide field service support and development of training materials and service manuals.

Customer Support Systems Specialist

1989-1992

- Resolved customer complaints and provided classroom and on-site customer training.

Medical Technologist

1982-1989

- Performed laboratory testing in Hematology Labs at University of Iowa Hospitals, Iowa City, Ia.
- Performed laboratory testing in Hematology and Chemistry Labs at Mercy Hospital, Des Moines, Ia.

EDUCATION

B.S. General Science, Medical Technology

University of Iowa, Iowa City, IA

A.A.S. Electronics Engineering Technology

National Education Center, Des Moines, IA

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CERTIFICATIONS/AWARDS

ISO Lead Assessor certification
American Society of Quality Engineering CQE certification
Lean Six Sigma training and certification through the George Group
Human Error Reduction, Investigation and Diagnostic certification by Talsico®
American Society of Clinical Pathology, Medical Technology certification
STC Lone Star Chapter Distinguished Technical Communications Award
Competent Toastmaster, Toastmaster's International

COMMUNITY INVOLVEMENT

Grapevine High School Speech Contest Judge, Grapevine, Texas
Irving School District Science Fair Judge, Irving, Texas
Task Coordinator Capital Campaign, First United Methodist Church, Coppell, Texas