

Lakshmi Gulabchand

Principal Quality Engineer at Hollister Incorporated

Summary

Areas of expertise: Six Sigma Failure mode and effects analysis ISO 9000 APQP TS 16949 Change Management Supplier Development Auditing Design of Experiments ISO 13485 Program Management ISO 14971 Resource Optimization cGMP

Specialties

Certifications: American Society of Quality: Certified Quality Engineer (CQE) American Society of Quality: Certified Reliability Engineer (CRE) American Society of Quality: Certified Quality Auditor (CQA) Six Sigma Black Belt

Experience

Principal Quality Engineer at Hollister Incorporated

April 2012 - Present (3 years 9 months)

Senior Quality Engineer at Hollister Incorporated

April 2007 - March 2012 (5 years)

Responsibilities: • Provide FDA required Design Control Support to New Product Development project teams to ensure appropriate application of design control • Conduct Risk Assessments per ISO 14971. • Provide consulting and training on advanced statistical methods (Design of experiments, Sampling Plans, Interrater Agreement etc.) to new product development, global operations, as needed for validation protocols. • Support and review Preproduction's and First Articles submissions from Hollister plants on all new products and significant changes to the existing products. • Support vendor audits as required. • Support quality management system with corporate facility as required per ISO 13485. • Manage and support internal audit program at the corporate facility. • Provide support on an ongoing basis to Start up Hollister INDIA facility on Operational Qualifications (OQ), and Performance Qualifications (PQ). • Conducted Failure Mode and Effects Analysis (FMEA) training to Hollister Worldwide facilities and developed One Worldwide Specification for FMEA by collaborating with all facilities. • Conduct Variable /Destructive Gage Repeatability & Reproducibility (GR&R) as needed while supporting projects.

Program Manager at SiemensVDO Automotive

January 2002 - March 2007 (5 years 3 months)

Responsibilities: • Responsible to develop robust welding process and release one worldwide welding specification for PISA Italy, and Newport News USA locations. • Optimized laser-welding parameters by running Design of Experiments. • Developed weld reaction plans which helped in standardizing the way to react to welding issues on production floor worldwide across all shifts. • Developed process limits

and implemented SPC Charts to monitor the welding processes. • Evaluated and improved sample size and frequencies of process inspections. • Improved visual masters for weld defects and implemented them with operator training. • Developed and implemented a cross-section lab to monitor weld quality of welding processes Position: Six-Sigma Black Belt for Quality Department 01/05-10/05 Responsibilities: Helped quality engineers with data analysis and recommend solutions to customer corrective actions. • Reduced scrap fallout from 0.33% to 0.09% (100K savings) caused due to non-uniform distribution of laser energy on thin orifice disc Position: Senior Quality Engineer, Injector Mfg 01/02-12/04 Responsibilities: • Interfaced with customers on all aspects of quality and responded with 5 phase or 8D or 7 step corrective actions as required for product line. Ensured that all corrective action/ preventative actions are implemented and closed. • Achieved Green Belt Certification and supported Black Belts on several projects as needed. Completed green belt project by reducing the cycle time of lift set operation by 0.25 seconds (100K savings) • Developed cleanliness specification to reduce failure of fuel injectors due to contamination issues. • Material Review board chairperson for disposition of Nonconforming materials. Ensure all nonconforming material reports are addressed and closed.

Quality Manager at MetoKote Corporation

October 1995 - January 2002 (6 years 4 months)

Responsible for development, implementation, & maintenance of plant level procedures, work instructions, & records to comply with QS 9000/TS16949 requirements. Develop Control Plans, Process Flow Diagrams, Process Failure Mode and Effects Analysis (PFMEA) for all the production lines. Responsible for PPAP submissions to all customers Maintain calibration program of all plant equipment current to meet QS9000/TS16949 requirements. Conduct GR&R studies. Interface with customers on all aspects of quality and respond with 5 phase or 8D corrective actions as required. Analyzed SPC data every month on all production lines and provide necessary guidelines as required for process improvement. Responsible for Chemical lab and Waste Water Treatment operations to ensure legal compliance to OSHA and EPA regulations.

Languages

Hindi

Telugu

Skills & Expertise

Six Sigma

CQE

CQA

ISO 13485

FMEA

ISO 14971

APQP

TS16949

cGMP

PPAP
Quality Systems
Quality Engineering
Design Control
FDA
Minitab
Quality Management
Validation
Continuous Improvement
ISO
Lean Manufacturing
Medical Devices
Quality System
GMP
Manufacturing
Quality Auditing
Supplier Quality
Root Cause Analysis
Quality Control
SPC
Quality Assurance
Process Improvement
Design of Experiments
R&D
V&V
Green Belt
DMAIC
Engineering
CAPA
Design for Manufacturing
Product Development
Iso 9000
Kaizen
Injection Molding
21 CFR
21 CFR Part 11
5S
Change Control
Calibration
ISO 9000

Education

University of Missouri-Columbia

Master of Science, Industrial Engineering, 1992 - 1995

Vasavi College of Engineering

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2 people have recommended Lakshmi

"Lak is a tremendously driven and talented professional who will add to the effectiveness of any team and any company with which he works. He has a variety of talents that reach from Operations and Manufacturing to Quality Management, Quality Engineering, and Six Sigma. Lak has expert knowledge and an enviable record of success in quality management systems, and quality/reliability engineering methods that support R&D, Engineering, and Manufacturing. Lak is also proficient in the application of several advanced statistical methods that go beyond those normally available from Quality Engineers and Six Sigma Black Belts. Lak is a proactive member of any team to which he is assigned, constantly seeking ways in which he can add value to the goals of the team and the organization. I highly recommend Lak, and would gladly work with him at any time."

— **Clifford L.**, managed Lakshmi at Hollister Incorporated

"I have known and worked with Lakshmi for more than 14 years and through out that time he has always demonstrated the most professional demeanor and ethical behavior of anyone I have ever met. His knowledge of the Quality disciplines and ability to help people understand and take ownership of the processes has been instrumental in establishing true cultural changes in every organization he has helped to achieve true bottom line results in their quality efforts. His ability to work with all level of the organization and to provide leadership in any organizations improvement efforts makes him a valuable asset to any Company seeking to stay competitive in a dynamic market place while building true customer loyalty. I am pleased and honored to recommend Lakshmi. I know with his strong work ethic, knowledge base, and people skills he will be successful in any challenge that comes his way."

— **Bob Pepple**, was with another company when working with Lakshmi at MetoKote Corporation

[Contact Lakshmi on LinkedIn](#)