

AKSHAY DESHPANDE

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EDUCATION:

University of South Florida | Master of Science **Mechanical Engineering** | Class of 2018

Tampa, FL

SDM College of Engineering & Technology | Bachelor of Engineering **Mechanical Engineering** | Class of 2015

Dharwad, India

CAREER HIGHLIGHTS

- 5+ years of experience as a mechanical engineer with concerned realm specifically medical device quality assurance, quality management systems, auditing, supplier quality management, manufacturing, validation, and research.
- BSI Certified ISO 13485:2016 Lead Auditor
- OSHA - 30 Hours Certified for General Industry
- Lean Six Sigma Green Belt
- Management Representative with experience in developing Quality management system for Medical Device Company

PROFESSIONAL EXPERIENCE:

TECHFIT Digital Surgery

Daytona Beach, FL

Quality Engineering Manager

June 2019 – Present

- Developed, revised, and implemented relevant procedures pertaining to quality management systems and associated processes and procedures.
- Supervised 20 staff members to comply with ISO 13485:2016 & 21 CFR Part 820 QSR.
- Managed key performance indicators for product quality, identified safety issues and performance trends by performing statistical analysis and initiated actions for improvement.
- Experience with project management for project schedules, investment planning, budget, timeline, and other deliverables
- Demonstrated knowledge of advanced quality concepts, including PFMEA/DFMEA, risk management, Root cause investigations, CAPA, process control, continuous improvement, DoE, and six sigma concepts
- Experience with VSM, Kaizen, DMAIC, FMEA, FTA, RCA, MSA, SPC, Cp, Cpk, Cpm, Ppk, Hypothesis Testing, ANOVA, DOE.
- Established relationships with external suppliers for contract manufacturing, supplier quality and support
- Collaborate with a multi-disciplinary team for machining and cleaning validation (IQ/OQ/PQ) for the custom implant manufacturing process to ensure the compliance
- Experience with ISO 14971:2019, ISO14001:2015, ISO 13485:2016, GMP, ISO 9001, ohsas 18001/ISO 45001 and FDA, 21CFR820, EU MDR, MDSAP
- Managed company onboarding processes, interviewing, and selecting new personnel and cultivating teamwork and technical proficiency in training.
- Verified production process adherence to health and safety guidelines, OSHA regulations and legislation regulating production of medical devices.

B & M Precision

Ruskin, FL

Manufacturing Quality Engineer

June 2018 – May 2019

- Developed solutions to wide range of complex technical problems to meet organizational objectives and deadlines.
- Addressed and resolved technical concerns to comply with internal standards and regulatory requirements.
- Worked successfully with a diverse group of coworkers to accomplish goals and address issues related to our products and services.
- Served as technical resource for operations personnel, answering queries and advising production staff.
- Analyzed and optimized operations, providing input on standard procedures and policies to streamline throughput.
- Orchestrated tooling changeovers, setups, and repairs to minimize downtime and improve productivity.
- Review and update documents for the program, development activities, IQ/OQ/PQ & TMV validation/verification testing activities
- Participated with the team performing Risk Assessment, FMEA to identify root causes of problems and present possible solutions
- Used statistical tools such as Process Capability, Measurement System Analysis, and Statistical Process Control to assess and improve production processes. Supporting production operations to achieve production, maintenance, and quality KPIs.

TATA Marcopolo

Dharwad, India

Graduate Engineering Trainee

June 2015 – May 2016

- Oversaw transmission of engineering specifications, instructions, and processes guidelines to enhance administrative efficiency and eliminate unnecessary physical records.
- Reviewed corrections from senior engineers to learn and grow professionally.
- Coordinated with supplier representatives to organize schedules, review specifications, and meet quality goals.
- Worked closely with team members to deliver project requirements, develop solutions, and meet deadlines.
- Suggested design modifications with client's approval to develop Bill of Materials (BOM) as per requirements
- Conducted Root Cause Analysis, Continuous Improvement to improve efficiency/reduce overall cost of the product

**Aditya Birla Hindalco
Engineering Intern**

**Belgaum, India
June 2012 – December 2012**

- Collaborated with supervisors, leads and operator teams to develop a Process improvement plan by using Root cause analysis and VSM methodologies.
- Assisted lean team to carryout DMAIC on material flow and waste reduction in the alumina plant to achieve productivity gain of approximately 10%.
- Carefully monitored Statistical Process Control (SPC) of the end-product, reported quality issues to take corrective measures using the derived conclusions, hence increasing productivity, and reducing the process cost.
- Coordinated with vendor, created Request for quotation (RFQ), got approvals and purchased equipment's for automation of material unloading mechanism.
- Documented Standard Operating Procedure (SOP) for the new raw material unloading mechanism using MS Office to help new technicians on-board.

PROJECT EXPERIENCE:

QUALITY MANAGEMENT SYSTEM ISO 13485:2016 & 21 CFR 820

- Drafted and implemented action plan and achieved ISO 13485:2016 certification.
- Achieved certification with 0 non-conformances.

OSHA COMPLIANCE & SHARP

- Achieved OSHA compliance with a score of 2.97/3.
- Achieved SHARP (Safety & Health Achievement Recognition Program) Certification.

SKILLS:

- Microsoft Office
- Quality assurance experience
- Lean Six Sigma Green Belt
- OSHA, Environmental, Health & Safety, First Aid & CPR
- ISO 13485:2016, MDSAP, EU MDR, CE
- ISO 14971:2019, ISO/TR 80002-2:2017
- FDA 21 CFR Part 820 Quality Systems Regulation
- GAMP 5: Compliant GxP Computerized Systems

Knowledge of Standards: ISO 9001, ISO 13485:2016, ISO 14971:2019, FDA 21 CFR part 820, EU MDR 2017/745, OSHA, MDSAP, EU MDR

RESEARCH PAPERS PRESENTATIONS & PUBLICATIONS

- "DRIVING TOWARDS A GREENER TOMORROW"
Journal - International Research Journal of Humanities and Environmental Issues Vol. II, Issue 4, ISSN: 2277 – 9329
- "ALERT TODAY – ALIVE TOMORROW"
Conference – "International Symposium on Engineering and Technology" PUNE- January 2014
- SUSTAINABLE DEVELOPMENT: ROLES OF SOCIETIES GOVERNMENTS AND NGOS"
Journal - International Journal of Environmental Science: Development and Monitoring Vol. IV, Issue 2, 2013
ISSN: 2231– 1289
- "A BRIEF STUDY ON HYDROGEN INTERNAL COMBUSTION ENGINE"
Journal - International Conference on Advances in Engineering and Technology Vol. V, October 2014
ISBN: 978-81-908980-6-5
- "ECO-FRIENDLY DOINGS BRINGS ECO-FRIENDLY REWARDS"
Journal - SARC-ITR International Conference, Institute of Research and Journal Special Issue, ISSN: 978-93-82702-23-8