**MICHAEL O. ayeNi, MBA**

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**SUMMARY & KEY STREngths**

**Quality focused Project Manager** **with a broad knowledge of automated manufacturing processes.** **Experience with quality and process for profitability. Strong understanding of Six Sigma tools, Lean Manufacturing systems and capital cost saving projects.**

 **software skills, leadership training & CERTIFICATIONS**

* **SIX SIGMA GREEN-BELT: MSI Certified**
* SOFTWARE SKILLS: **Microsoft Off. (Excel, Access, Outlook), SAP, AutoCAD, Windchill, COMET**
* Statistical Quality Control – Control charts, SPC charts, Histograms, X-Bar charts
* **LEAN Manufacturing/Kaizen/Six Sigma – GE Corporate training program**
* ISO 13485 – Medical Device and Quality Systems
* **FDA Asceptic Training – Corporate Seminar, ZimmerBiomet**

**Education**

**Master of Business Administration (Specialization: MIS) 2016 – 2018,** North Central University, Scottsdale, AZ

**Bachelor of Science, Manufacturing Engineering 1994 – 1999,** Central State University, Wilberforce, OH

**Professional experience**

***Manufacturing Process Engineer – Philips Healthcare, Bothell, WA***

***02/2018 – Present (Short-term Contract to close CAPAs)***

* Update of dFMEAs by extraction of failure mode mitigation per Safety Risk Management files for CAPA completion
* Ensure Software validation and verification of Non-Product Service Software (NPSS) for CAPA completion
* Editing and updating of Master Validation Plans per SOPs, official documents and reviewer feedback
* Coordination of Process validation per quality system procedures and instructions
* Coordination of Installation and Operation qualifications per Quality Management System
* Participation in Risk Management FDA compliance based on total product lifecycle according to ISO 14971

***Quality Engineer – Zimmer- Biomet, Warsaw, IN***

***01/2017 – 01/2018 (One-year Contract to remediate files of all non-conformant products)***

* Dispositioning of all non-conformant products (NCRs) to meet remediation requirements
* Generation and preparation of Quality Engineering Change Requests (QECRs)
* Preparation of Gauge Rejection Notices (GRNs) requirements for quality management evaluation
* 21 CFR Part 820 Subpart G – Production and Process Controls
* Knowledge of ISO 14971 – Medical Device (patient based) Risk Management pFMEA
* **Asceptic coating validation through testing for foreign particles/contaminants**
* Using Test Method Validation(TMV) / Measurement System Analysis (MSA)
* **Evaluate sterility of Asceptic rooms on daily basis through PQ and OQ**
* Determination of disposition for major product holds per FDA standards

***Process Manager – Corning Inc., Winston-Salem, NC (WCP)***

***03/2016 – 09/2016 (Short-term Contract to remedy SAP failure which led to a plant shutdown)***

* **Monitoring and Facilitation of Fiber Optic Cable production process using COMET (Manufacturing Automation)**
* Coordinating production in Fiber coloring department using a fiber tracking algorithm
* Coordinating colored Fiber supply for Buffering process between 3 production lines
* Responsible for dispositioning appropriate corrective action for In-process defective Fiber stock
* **Application of Six Sigma LEAN techniques to improve the movement and utilization of Fiber**
* Coordination of production schedule for Buffering lines, Stranding lines, and Jacketing lines

***Interim Period (12/2015 – 02/2016): During this period I worked on acquiring my Six Sigma Green-Belt Certification and also did some LEAN Manufacturing improvements for a local manufacturer of plastic bags.***

***Quality Assurance Engineer-GE Energy, Mebane, NC***

***12/2014 – 11/2015 (Contract – Handoff to SAP Super user)***

* Accountable for manufacturing metrics that pertain to EHS, Quality, Service and Cost-out
* Develop and maintain **Quality Management System documents** such as manufacturing methods, technical documentation, and training documentation
* Extensive use of **SAP** in Return Material Authorization inventory management and corrective action
* **Support and facilitate investigations, root cause analysis (Using 6Ms, 5 Whys and corrective actions)**
* Developed and managed database for recalls using the SQL Server; maintained and developed backup and disaster recovery efforts
* **Implemented a CAPA system by investigation, action, and review of defective product cases**

***Quality Assurance Associate – Beckton Dickinson, Mebane, NC***

***12/2013 – 11/2014 (Contract till plant shut-down and relocation)***

* Responsible for investigating deviations to procedures and specifications
* Inspect incoming, in-process, and finished goods while utilizing basic GD&T Principles and/or ANSI Principles (where applicable) for compliance with established quality specifications
* Determine long-term and short-term corrective actions
* **Risk Assessment of product quality and safety based on 21 CFR 200 guidelines**
* **Daily update of material disposition status in SAP**
* Audit Device History Record for compliance to standards including deviations or protocols and analyzing inspection results vs. engineering specifications

***Manufacturing Team Leader (Automotive) – CPC Assembly Products, TE Connectivity, Greensboro NC***

***6/2010-11/2013 (Contract)***

* **Implement LEAN Six Sigma to optimize production and reduce waste**
* Perform quality checks per the quality inspection process (QIP)
* Collect data to generate control charts such as X-Bar charts, S-Charts, R-Charts and Histograms
* Perform visual inspection using microscope, perform inspection using comparator, Ram Optic, micrometer, calipers
* Process Inspection Rejection Reports (IRR’s), route paperwork, enter information into tracking system and process Authorization to Ship (ATS) paperwork
* **Perform Process Audits against ISO standards and local requirements for CAPA**

***Process Development Engineer (Automotive), Veyance Technologies Inc., Sun Prairie, WI***

***4/2006-5/2010***

* **Implemented process control systems that reduced start up waste by 15%**
* Responsible for product engineering during a plant downsizing project
* **Application of Six Sigma to initiate process improvements**
* Disposition and quarantine of defective products to avoid customer service and delivery issues
* **Performed deviation investigations by collaborating with manufacturing and quality**
* **Facilitate weekly deviation meeting and provide status updates of all investigations**

***Lean Manufacturing/Quality Engineer, GE Medical Technologies, Madison WI***

***3/2003-3/2006 (Contract)***

* Implement and refine manufacturing processes by applying continuous improvements and LEAN manufacturing principles to production processes
* **Support and facilitate investigations, root cause analysis and corrective actions**
* **Implemented a CAPA system by investigation, action, and review of defective product cases**
* **Risk Assessment of product quality and remediation of complaint files according to 21 CFR 198**
* **Development of Quality Checklists and updated SOPs for compliance to ISO**

**\*\*\*\*REFERENCES WILL BE PROVIDED UPON REQUEST\*\*\*\***