Cornelious Williams, Certified Six Sigma Black Belt

Core Competences

Six Sigma Tools: Brainstorming, Cause & Effect/Fishbone Diagram, Control Charts, Design of Experiment, Flow Charting, FMEA / Risk Assessment, Pareto, Process Mapping
Mechanical Design: Develop of Capital Equipment specifications, Design of Production Equipment for Class III Medical Device, Clinical Scale Solvent Casting Equipment
Materials Used: Stainless Steel, Aluminum, Teflon
Manufacturing Processes: Extrusion, Solvent Casting, Molding, Filling and Capping, Assembly
FDA: Validation, IQ/OQ/PQ
Management Skills: Managed Technicians assigned to projects, Project Timelines

Qualification Profile

Results-oriented, self-motivated Mechanical Design Engineer with a strong background in Design and Manufacturing Engineering focused on Technology Growth, Process Development, and Process Improvement in the medical device industry. Thirteen years encompassing design, prototyping, capital equipment specification development, and manufacturing. Strengths include analytical skills with the ability to communicate comfortably with all elements in a medical device manufacturing organization. Skills include Solidworks, Minitab and problem solving

Employment History

Immucor, Inc - *Validation Engineer* Norcross, GA Nov. 2008 – Mar. 2012

Process Validation and Mechanical Design Analysis

- Provided project definition and design analysis of new filling/capping lines
- Responsible for the validation of equipment used in the production of the Solid Phase product line with capital cost of $400K that produces sales in excess of $3 million annually
- Responsible for executing dye immersion and torque relaxation studies on vial components used in the filling process
- Executed Minitab generated DOE to establish process parameters for final packaging of solid phase products

Project Manager

- Managed facility qualifications coordinating outside vendor HVAC qualifications, protocol execution, turnover to production
- Lead Engineer on Elevated Investigation teams responsible for analyzing the mechanical function of the fill and capping process to determine the source of non-viable air action limit excursions and low volume fill complaints
- Managed project to source Environmental Chamber completing capital expenditure documentation and return on investment calculations
- Lead project to re-design procedures for the purchase of capital equipment

Process Developer

- Developed and implemented method to verify and document that facility improvement plans were carried out per the Immucor specifications
- Developed and implemented method to validate new filling and capping lines introduced to the manufacturing process

- Developed and implemented method to validate new components on all of the vial filling and capping lines at the Norcross, Georgia location

Technical Writer

- Wrote and managed the execution of protocols to determine if lot to lot variation exists for removal torque of filling/capping components
- Wrote and managed the execution of airflow visualization studies for controlled manufacturing areas

Team Participant

- Team member of Elevated Investigation for low fill volume complaints for vialed products
  - Contributed to the Define phase of the project
  - Assisted with Cause and Effect activity
  - Developed protocol for Bag study to aid in determining root cause of fill issues
- Team member of Elevated Investigation for particulates in vialed products
  - Assess incoming components for particulate presence
- SME of audit team for component supplier

Altea Therapeutics - *Mechanical Design Engineer* Atlanta, GA Sept. 2005 – Oct. 2008

- Assisted with the manufacture of transdermal patches that included producing the solvent suspension and processing of the transdermal films that contained either active API or placebo formulations

Manufacturing Designer

- Designed small scale equipment used in the manufacture of numerous cGMP batches of transdermal patches in class 100,000 clean room for indications such as diabetes and Parkinson's used in Phase I/II clinical trials
- Designed and built an array screening device for functional testing of two configurations of the electrical component of the PassPort™ Patch system
- Designed a retro-fit for an Ivek slide to accept either an applicator knife or a Meyer rod for solvent casting
- Designed an enclosure used to guard a robot used in the assembly of the PassPort™ Patch system

Process Developer

- Developed method to introduce nitrogen to packaging of drug film to extend shelf-life
- Conducted process development work to establish parameters for cGMP manufacturing
- Wrote development reports that document the steps taken to determine the appropriate conditions for cGMP manufacturing of products used in clinical trials

Porex Technologies - *Mechanical Design Engineer* Fairburn, GA Apr. 1999 - Sept. 2005

Project Manager/Designer/Product Developer

- Lead Design Engineer in the development of IQ/OQ/PQ validated PLC controlled gear motor driven continuous web manufacturing process for medical testing industry.
- Lead Product Development Engineer of continuous membrane for the medical testing industry that generates $220000 in annual sales.
- Lead Design Engineer of tooling and puller/cutter equipment used to convert continuous fiber into customer specified lengths.
- Lead Design Engineer of ultrasonic heated tooling equipment for flange forming to manufacture pool filtration media.

- Lead Product Development Engineer of filtration media for pools that resulted in annual sales of $300000.
- Lead Design Engineer of tooling and a semi-automated rotary table platen heated production tooling for polyurethane potting process for potable water filter production.
- Lead Design Engineer of injection molded stopple used in serum samplers for plastic blood collection tubes
- Lead Design Engineer of stepper motor driven ball screw linear actuator for pick and place device used in the production of medical devices for transport of tooling.
- Lead Design Engineer of IQ/OQ/PQ validated bellows damped molding process that reduced intra-tool part variation of class III medical devices.
- Lead Product Development Engineer of FDA regulated plasma blood product filtration device used in the removal of byproducts created as a result of pathogen inactivation and the manufacturing process that generates $75000 in annual sales.
- Lead Design Engineer of heat transfer system for extrusion process that increased underwater pellet production of medical device components by 300%.
- Lead Design Engineer of tooling for underwater pellet production of EVA used in the manufacture of class III medical devices.
- Lead Design Engineer of mold tooling for medical device production that reduced maintenance downtime by 95% by using the DMADV methodology.
- Lead Design Engineer of PLC controlled and pneumatically actuated production equipment that increased output of IQ/OQ/PQ validated FDA regulated class III medical devices from 80000 units to 200000 units annually by using the DMAIC methodology.
- Lead Product Development Engineer of FDA regulated platelet blood product filtration device used in the removal of byproducts created as a result of pathogen inactivation and the manufacturing process which included extrusion/pelletizing that generates $550000 in annual sales.

Process Developer

- Product Development Engineer filter for NSF regulated potable water industry that contains customer supplied powder media for reducing arsenic levels in water that generates $150000 in annual sales.

University of Cincinnati - *Graduate Research Engineer* Cincinnati, OH Sept. 1996 - Mar. 1999

- Lead investigator in electrochemical deposition of carbon fibers with polypyrrole interlayer doped with various sulfonic acid electrolytes. Responsibilities included preparation of pyrrole and electrolyte solutions, electrochemical deposition of pyrrole/electrolyte onto carbon fibers, analysis of deposition by FTIR, TGA, DSC, and SEM, fabrication multilayer composites by compression molding and characterization of mechanical properties of composites by inter-laminar shear strength, three-point flex test, flexural modulus testing and impact testing.

Continuing Education/Certification

- Clayton College and State University, PLC Basics
- ASME Basic Geometric Dimensioning and Tolerancing
- Draftech SolidWorks SolidBasics Part I
- Georgia Engineer-In-Training 20107

Education

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- 1999, Master of Science in Materials Science and Engineering, University of Cincinnati
- 1996, Bachelor of Science in Mechanical Engineering, North Carolina Agricultural and Technical State University
- 1995, Bachelor of Science in Mathematics, Jackson State University

Software
PLC Ladder Logic (RS500), AutoCAD Lt, I-DEAS

Hobbies
Classic General Motors vehicle restoration:

- Built and installed small block Chevy engine
- Installed suspension systems, body mounts, braking and steering systems