

Exhibit 1005

Dwayne Polzer

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LinkedIn

Executive Summary

Experienced Quality Manager with a proven track record of maintaining Quality Systems Regulation compliance while bringing new medical devices to market. Self-starter and team player with extensive background in mechanical and biomedical engineering and design with excellent written and verbal communication skills.

Professional Experience

PainTEQ - Tampa, FL

Contact: Dan Newman, dan.newman@painte.com

Director of Quality and R&D, Dec 2019 – Present

- Lead development, implementation, and application of Quality Management System
- Lead all Biomedical Engineering efforts
- Represent PainTEQ's interests to partner manufacturers in all aspects from R&D to post-production
- Tissue Bank Director
- Apply FDA 21 CFR 1270 and 1271 for human tissue and biologics
- Management Representative to the FDA
- Oversee Risk Management throughout all processes
- Train employees at all levels on utilization of quality systems procedures and documents
- Develop standard operating procedures and work instructions for all processes
- Oversee Purchasing and Supplier Qualification system
- Manage all Audits and Inspections, both internal and external
- Stay current with all applicable regulations and standards

VGI Medical - Largo, FL

Contact: Scott Ely; 727-519-3904, kscottely@gmail.com

Quality Manager, Jan 2018 – Nov 2019

- Quality Manager of the Quality Management System
- Apply FDA 21 CFR 820 and ISO 13485 to medical device design
- Management Representative to the FDA and Registrar
- Tissue Bank Director
- Designed and implemented all processes to bring manufacturing in-house
- Apply FDA 21 CFR 1270 and 1271 for human tissue and biologics products
- Work with contract manufacturers in all aspects from DFM to post-production
- Manage CAPA, Complaint, and Nonconformance systems
- Design and execute Verification and Validation activities
- Oversee Risk Management throughout all processes
- Manage all Audits and Inspections, both internal and external
- Maintain Document Controls throughout all departments and processes
- Manage Acceptance activities from Design Controls through Inspection
- Develop standard operating procedures and work instructions for all processes
- Oversee Purchasing and Supplier Qualification system
- Train employees at all levels on utilization of quality systems procedures and documents
- Maintain catalogue of recognized standards for R&D and validation activities
- Supervise several employees in daily quality activities
- Conduct Management Reviews in accordance with regulation
- Implement updates and improvements to Quality System commensurate with company objectives
- Maintain state and federal licenses and registrations
- Strategize comprehensive and swift responses to regulatory bodies, including 510(k) Additional Information Requests
- Stay current with all applicable regulations and standards

Quality and R&D Engineer, Dec 2016 – Jan 2018

- Part of a small team that developed and launched two spinal implants and delivery systems
- Validated spinal implants and surgical instruments utilizing cadaver labs
- Contributed to Quality procedures and instructions for device and human tissue
- Conducted Failure Mode and Effects Analysis of medical devices
- Gathered Design Inputs to produce Design Outputs with 3D modeling software
- Conducted Design Verification and Validation
- Oversaw prototyping, including 3D printing and working with machine shops

R&D and Logistics Engineer, April 2010 – April 2011, Dec 2014 – Dec 2016

- Designed, implemented, and maintained inventory tracking system for devices and HCT/P
- Performed mock surgical procedures within a laboratory environment for R&D and QC
- Developed hardware and software for testing devices
- Maintained knowledge of applicable regulatory and intellectual property requirements
- Conducted grant and patent research, writing, and submissions

Specialty Pharma Education Center & Specialty Pharma Journal - Tampa, FL

Contact: Ryan Anderson; 813-310-6892, ryananderson0618@gmail.com

Associate Director, April 2011 – July 2012

- Developed and managed continuing education programs for health professionals
- Conducted successful grant writing, submission, and follow up
- Project manager for hardware, software, website, and marketing materials development
- Maintained knowledge of regulatory requirements for educational programs and marketing
- Responsible for solving technical and personnel issues using innovative thinking and methods
- Represented corporate and client concerns at trade shows, and engaged potential clients
- Developed customer and resource database
- Conducted SWOT, PEST, GAP, and related market analyses
- Responded to IT issues to enact appropriate, timely solutions

University of South Florida, Tampa, FL

Contact: Dr. Bill Lee, 813-974-2136, wlee2@usf.edu

Graduate Researcher, January 2002 - December 2008

- Developed robotic gripper that automatically adjusted grip force when an object began to slip from grasp (two-person team)
- Developed driving simulator for adaptive driving devices training in a true-to-life environment with 120-degree display and full-function limited range of motion controls
- Coordinated with other team members and departments to execute cross-disciplinary objectives according to a project plan developed with committee of professors
- Researched and designed innovative methods, tools, and machines to assist persons with disabilities in various environments

Education

University of South Florida, Tampa, FL Fall 2004 – Fall 2008

M.S. Program – Biomedical Engineering

Graduate Advisor: Dr. Bill Lee, PhD. wlee2@usf.edu

Graduated: December 2008, GPA: 3.7

University of South Florida, Tampa, FL Summer 2006 – Fall 2007

M.S. Program – Entrepreneurship in Applied Technologies

Graduate Advisor: Dr. Michael Fountain, PhD. fountain@usf.edu

Graduated: December 2007, GPA: 3.9

University of South Florida, Tampa, FL Fall 1999 – Spring 2004

Bachelor of Science: Mechanical Engineering

Graduated: May 2004, GPA: 3.5

Skills

Management: Effective manager of one to twenty employees in diverse settings, as well as several projects in parallel

Applied: Internal and external auditing, quality inspection, design reviews, supplier management, design validation, technical writing

Computer: SolidWorks CAD, Microsoft Office Suite, QuickBooks

Interpersonal: Excellent verbal and written communication, team building, training, conflict resolution

Certifications

Certified Biomedical Auditor by ASQ

AAMI “The Quality System Regulation 21 CFR 820 and ANSI/AAMI/ISO 13485: Navigating Regulatory Requirements” certificate

Currently pursuing Certified Quality Engineer ASQ credential

Publications

Polzer D, Burke R. “Introducing Slip-Sensitive Reflex and Proposal for Use in a Semi-Automated Tree Finger Gripper.” University of South Florida Honors Thesis; December 2003; Tampa FL

Honors and Achievements

Kaufman Entrepreneur Fellowship: Selected to perform an entrepreneurial research project for a local biomedical company

Tau Beta Pi: Chosen for the distinction to be member of the foremost engineering honors society

Best Undergraduate Display: Awarded at the 2003 USF engineering EXPO for the presentation of an assistive driving simulator

Honors Symposium: Selected to present Honors Thesis at the USF Research Symposium

USF Honors College Scholar: 1999 - 2004

Florida Academic Scholar: 1999 - 2004