



Mike Stanley

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Professional Summary:

I possess a broad knowledge of the principles necessary to effectively evaluate and control product quality and to develop quality control systems. I am seeking a position that will foster my professional growth and utilize my skills and abilities to their fullest potential. I am a self-starter and do not require supervision. I am highly familiar with lean manufacturing, manufacturing flow, and product process improvements.

Software Experience:

AutoCad	Visual Basic for Applications (VBA)	Windchill
Adobe Creative Suite	SLIM (Stability Laboratory Information Management)	SAP
Microsoft Office Suite	HTML, CSS, JavaScript, Python	Minitab
Microsoft Power Bi	BMRAM (Asset Management)	Infinity

Key Skills:

Project Management	Change Control	OOS Investigation Reports
Personnel Management	Document Creation	NC Reports
Product Stability Coordination	21 CFR Part 820	CAPA Investigations
Calibration Coordination	ISO 13485	Validation Development
Safety Committee Member	Unlicensed First Responder	Technical Writing
ASQ Calibration Technician	Statistical Analysis	Quality Audits
Process Development	Process Improvement	Lean Manufacturing

Education:

University of North Texas
Bachelor of Science in Biology
Minors: Chemistry and Spanish

Professional References:

Provided upon request

Work Experience:	
Fresenius Medical Care (October 2015 – present)	
<i>The world's leading provider of products and services for people with chronic kidney failure.</i>	
Lead Inspector (October 2017 – present)	QS Technician II (October 2015 – October 2017)
<ul style="list-style-type: none"> • Supervised the day to day operations of the six member inspection team • DHR review and final product release • Acted as backup for the QS Laboratory and QS Document Control Supervisors • Implemented SPC Charts for supplier performance, operations, and QS Laboratory • Created and implemented a variety of process improvement spreadsheets with complex formulas and macros • Performed interviews for inspection and laboratory candidates • Carried out CAPA activities • Product stability coordinator • Performed periodic calibrations on a variety of equipment • Assisted on the implementation of an automated environmental monitoring system • Increased productivity by defining expectations, establishing mutual goals, and promoting teamwork • Automated KPI monitoring which drastically reduced non-value added workload • Utilized SAP to track and manage the flow of critical components and finished goods • Assisted in quality audits through a variety of roles 	<ul style="list-style-type: none"> • Daily activities included the testing of raw materials and finished product through chemistry and microbiology techniques • Worked cross-functionally with various departments onsite as well as Global R&D and various sites across the globe • Streamlined the flow of product through the QC process which dramatically increased efficiency • Improved work environment organization by utilizing 5S methods • Assumed the role of product stability coordinator • Conducted OOS and NC investigations in a timely and efficient manner • Created and revised documents on a regular basis • Improved new hire training • Revised stability program holistically to align with governing regulations • Implemented stability LIMS database • Created template for FDA grade stability reports • Assisted the implementation and validation of various instruments and equipment • Proficient with the following instrumentation: PE AAnalyst, Varian 240FS, PE FTIR, Autopol V+, Autopol VI, Endoscan, Metrohm Titrinos

Work Experience Continued:	
Medix Scientific	
<i>A leading staffing and workforce solutions organization.</i>	
QC Technician (January 2015 – October 2015)	
<ul style="list-style-type: none"> Daily activities included the testing of raw materials and finished product through chemistry and microbiology techniques Worked cross-functionally to resolve quality issues and increase the quality of product 	
University of North Texas	
Research Assistant (January 2014 – December 2014)	
<ul style="list-style-type: none"> Assisted in genetic engineering method development Utilized the following techniques: PCR, gel-electrophoresis, tissue culturing, bacterial transformation, cloning, plasmid development, and various other standard genomic methods 	
Fastenal	
Sortation / Quality Inspection (March 2013 – August 2014)	
<ul style="list-style-type: none"> Inspected incoming and outgoing product for damage while sorting it into the correct bins 	
Costco Wholesale	
Lead Sales Associate (January 2009 - August 2010)	Major Sales Associate (June 2008 - January 2009)
<ul style="list-style-type: none"> Led the major sales team by communicating goals, defining expectations, and promoting teamwork Assisted in controlling inventory and stock management 	<ul style="list-style-type: none"> Assisted members in purchasing major appliances, jewelry, and electronics Periodically stocked and faced product to provide members with a clean and organized warehouse
Academy Sports and Outdoors	
Customer Service Representative (May 2006 - June 2008)	Cashier (December 2005 - May 2006)
<ul style="list-style-type: none"> Ensured customer satisfaction and provided professional customer support Processed product returns and layaway 	<ul style="list-style-type: none"> Handled cash, credit and check transactions Maintained a clean work environment
Albertson's Grocery	
Cashier (June 2004 - December 2005)	Courtesy Clerk (October 2003 - June 2004)
<ul style="list-style-type: none"> Handled cash, credit and check transactions 	<ul style="list-style-type: none"> Provided customer service to shoppers