ANIA SZULC

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QUALITY / COMPLIANCE/ REGULATORY AFFAIRS PROFESSIONAL

"Anna strives to create a strong team environment with a solid work ethic and loyalty to the department and the company. She is a fair leader with high expectations who never settles for less."

Alejandra Betancourt, Phoenix Logistics, Inc.

Over 10 years of experience in Quality and Regulatory Management internationally and US in highly regulated environments • Systems Development Life Cycle (SDLC) • Innovation management • Corporate entrepreneurship •Development of Problem Solving culture • Initiative Leadership • Risk Analysis • Compliance/ Regulatory Affairs Director • Business Process Management/Analysis • Process Improvement Team Leader • Continuous Improvement Team Leader • Strategic Planning • Lean Manufacturing • Policy & Procedure Development • Product Development • FAI • RCCA • DFAR • ISO: 9001• AS9100 Rev C • Certified Lead Auditor ISO: 13485 • ISO: 14971• ISO/TS: 16949 5S • Kaizen • GMP• MIL-STD-1553 • 6 Sigma • 21CFR, part 820 • Training Development & Delivery • Mentoring • Internal and External Stakeholder Liaison • ERP/MRP development • SPC • PMP professional• FDA, DEA, EMEA and International Authorities •GMP Compliance• SAP • SaaS • Audits •Supplier Quality

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Summary of my profile:
I have over 10 year of experience directing Quality Management Systems in various industries. I am Quality and Regulatory Affairs leader who impacts company performance through creating successful Quality Management Systems, with expertise in ISO:9001; ISO:13485 ; AS9100 rev C and ISO/TS:16949 ; ISO 14001 manufacturing standards that meet company objectives. I am strong leader, focused on improvement and growth. Skilled at analyzing business needs, managing quality programs, and implementing systems to optimize and lead people; improve processes and quality. Passionate about building a company-wide innovation DNA and supporting the organization across the business value chain to imagine, develop, and accelerate the implementation of ideas that enhance your company and grow the bottom line.

Things I've Done.

- Directing / Implementing /Creating a strategy for QMS / Provided leadership to ensure product quality and quality system compliance with focus on AS9100 , ISO:13485 and ISO/TS 16949 initiatives. Over 10 years in QA/RA and QMS field for various industries.
- Creating strong improvement focused teams with cross training.
- Directing internal auditing programs.
- Significantly improving average production performance through implementing Lean Principles, 5S, Six Sigma and Kaizen methods.
- Successfully promoting Continuous Improvement to employees leading to further gains in productivity and quality.
- Adept at simplifying complex concepts, optimizing the project lifecycle, and managing diverse projects.
- Provided leadership to the quality & regulatory organization, ensuring clear and aligned objectives, support employee development with feedback and coaching, drive employee engagement, and encourage collaboration with all stakeholders.
- Provided regulatory expertise and guidance, including expert interpretation and insight to all business functions ensuring regulatory strategy supports product development goals and release schedules.

Thank you very much for your time. I look forward to speaking with you.

Anna (Ania) Szulc

PROFESSIONAL EXPERIENCE

Cabot Corporation, Billerica, MA: 2012 (Current)

Capital Projects Quality Manager: The Company's major products are carbon black, fumed silica, inkjet colorants, capacitor materials, and cesium formate drilling fluids. Cabot operates 39 manufacturing facilities in 21 countries worldwide (FY11 Revenue: $3.10B Employees: 4,100). I am directing all Quality initiatives for Global Engineering group for Cabot Corporation. Responsible for creating and directing mission and vision and designing **Quality Management System** QMS for Global Engineering and all Capital Projects ($5 million- $100 million projects). Developed a strategy and working relationship with purchasing and finance in order to support improvement and close process gaps within all Capitals Projects for Cabot Corporation.
Managed group up to 44 associates including: AP, NA, EMEA and US.

- Completed multiple international projects that included Quality execution changes that affected over 300 people and the new process were translated to 4 languages.

Lead Auditor Training for ISO:13485 at Oriel STAT A MATRIX : November 2011

- Completed Certified Lead Auditor Training for ISO:13485. Specialized in designing **Quality Management Systems** QMS for medical industry.

University of Technology, Wroclaw, Poland ("PWR") : 2010- July 2011

- Graduated with Master's Degree in Engineering with Specialization in **Quality Management**.
  Expertise: ISO 9001, AS9100, ISO: 13485, ISO/TS: 16949, ERP systems, risk management, internal and external auditing programs, successful **Quality Management Systems** QMS.

Phoenix Logistics, Tempe, AZ: 2008-2010

Quality Manager: Personally responsible for directing all **Quality Management Systems** QMS for entire corporation. Ensuring the vision of Quality for the company is consistent with the company vision. Leading and directing all Quality activities related to processes, procedures and policies; responsible for compliance with all applicable regulatory agencies. I was in charge of managing total quality programs, policies, implementation of ERP and all engineering /production improvements. Responsible for identifying, analyzing and developing improvements in throughput, productivity, quality, client relationships, and customer service.

Client list included: Lockheed Martin · Boeing · Northrop Grumman · Honeywell · NASA · Bell Helicopter · Raytheon · Sikorsky Aircraft · U.S. Department of Defense · Fermi Laboratories · L3 Communications.
Managed group of 20 associates indirectly and 6 directly.

- Directed AS9100 recertification and assessment audits.
- Improved Company's metrics: Reduced RMA's per month from 10 to 4.
- Improved metric of Scrap Percentage of Material Cost from 4.50% to 0.90% - which improved Gross Margin and Cash Flow.
- Improved efficiency and effectiveness of receiving documentation and procedures, which also included vendor documentation improvements.
- Hired and trained a world level Quality Team that is focused on enhancing success of customers, suppliers and associates.
- Managed successful development of an ERP/MRP system, including creation of Document Control, a Supplier Module, a Compliance Module, a FAI module, and a Control Plans Module.
- Established a process for effective Root Cause and Corrective Action analysis which included cross departmental participation.
- Participated and coordinated with the IPT Team - Integrated Program Team - with focus on customer service.
- Continuously developed a Quality Focused Culture with Production and Engineering Management.
- Organized training for Lean Manufacturing, 5 S, and RCCA – promoting a problem solving culture.
- Updated Quality Manual and Corporate Procedures and Policies to meet AS9100 requirements and simplify documentation processes.

- Managed on-site and off-site audits and quality surveys to assess compliance with AS9100 requirements.
- Project Manager for recovery Prefer Vendor Status for prime aerospace and defense customer.

CS Innovations, Scottsdale, AZ : 2008 (6 months)

Project Manager: Responsible for managing projects for a nuclear power control system project for CS Innovations, which is a electronic control systems engineering and design company, including hardware and system development with expert designers in embedded system architecture, integrated circuits, analog systems, digital systems, wireless systems and specialized operating software.
Client list included: Westinghouse
Managed group of 6 associates directly.

APSM Systems, Phoenix, AZ: 2006 - 2008

QA/QC Systems Analyst: Personally responsible for all **Quality Management Systems** QMS and ISO compliance for 3 facilities: Phoenix, Mexico and Las Vegas. APSM Systems is a large multi-facility contract manufacturing company, specializing in engineering sheet metal with wet and dry paint applications; PCB assembly (electronics), cable assembly, and box build logistics. I took over all Quality Management responsibilities starting in 2007 under the same position.
Client list included: Taser, Atronics , Ventana Medical , 3M , Arrow etc.
Managed group of 32 associates indirectly and 1 directly.

Quality Management responsibilities included:

- Strategic Quality Planning included preparing and executing business plans to improve the efficiency and effectiveness of Quality Management Systems.
- Implemented or eliminated unnecessary Procedure / Work Instructions for manufacturing processes and simplified documentation rules.
- Trained employees in Root Cause Analysis, ISO awareness, and on the importance of accurate and complete Work Instructions and Flow Charting with considerable employee "buy-in" and participation.
- Leader / Manager/Team Player for the implementation of Document Control Software, ERP Quality Module, Lean Manufacturing principles, 5S and SPC.
- Responsible for Customer and Vendor Surveys
- Created a CAPA (Corrective Action/Preventive Action) program to support continuous improvement initiatives.
- Effectively communicated changes and initiatives to the Quality Team and to Manufacturing Teams.
- Fostered an environment of open communication and honesty.
- Created strategy for compliance with ISO 13485 clients (FDA Quality System Regulation, 21 CFR Part 11) and ANSI/ESD.

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TECHNICAL SKILLS

- CAD-CAM, including IDEAS and Pro Engineer
- ERP/MRP systems : Plex, Global Shop
- Microsoft Word, Excel, Power Point, and Project
- IPC-610
- Lean Manufacturing
- Statistical Process Control
- ISO9001: 2000; ISO 9000: EN46000, ISO13485, ISO 14001,AS9100, ISO/TS 16949, NQA-1
- FMEA, PPAP
- Six Sigma
- 5S
- ANSI/ESD
- GMP/Quality System Regulations

- Emotional Intelligence Training ; PMP training
- Share Point 2010

EDUCATION

- **Master Degree** in Mechanical Engineering with specialization in Quality Management at Wroclaw University of Technology, a leading European engineering university located in Poland
- Passed **TOEFL** exam at fluency level, proficient in both spoken and written English

CERTIFICATES

- Mesa Community College: **Lean Manufacturing** (MET131)
- Mesa Community College: **Statistical Process Control SPC** (GTC208)
- APSM Systems: **IPC**-A 610D
- MEP- **Lean Manufacturing** Workshop
- Completed Certified **Lead Auditor** Training for ISO:13485
- **PMP** certification

LEGALLY AUTHORIZED TO WORK IN THE UNITED STATES
REFERENCES AVAILABLE UPON REQUEST

I am skilled in the definition, implementation, and evolution of teams, products, business processes, and department/organizations. I am critical thinker skilled in interpreting strategic goals into operational tasks, analyzing and evaluating complex business, system and process opportunities. I have experience with applying federal and international standards in highly regulated environments including reporting to regulators.