

11003 Old Forge Road, Waynesboro, PA 17268
Office: (717)-387-5553

Cell phone: (717) 339-8365

Website: www.isoadvantages.com
email: isoadvantage@comcast.net

Judith A. Markel

Mission Statement

To make a significant positive impact each day

Experience:

Owner / Consultant at ISO Advantage LLC

- Quality Management System Consulting and New System Implementation and Training ISO 9001:2015; ISO 13485:2016; ISO 14001:2015 Standards for Manufacturing and Service Companies
- Internal Audits and Internal Auditor On-Site or Virtual Training QMS Documentation Development and Updates
- Perform ISO 9001:2015 3rd party Audits for ANAB Accredited Certification Bodies over 1500 days onsite
- QMS Documentation Development and Updates
- APQP- Advanced Product Quality Planning and other Core Tools
- Process Control Plan Development
- Supplier Management / Supplier Audits
- Advanced Corrective/Preventive Action and Problem Solving

Quality Management System Lead Auditor

- Prepare for and conduct third-party audits as lead or solo auditor
- Pre-audit planning, client communications pertaining to site and audit
- Pre-prepare audit reports, review/close out of corrective actions from clients resulting from audits
- Have conducted over 1500 audit days as 3rd party auditor - Lead or solo activities
- Over 50 3rd party audit days in companies in the service sectors vs. manufacturing
- Qualified to conduct audits in multiple industry codes

Quality Manager

- Established goals for all Chambersburg quality improvement activities
- Managed Quality Department & all aspects of the quality management system
- Visited key customers to develop continuous improvement plans
- Performed internal audits, trained internal auditors
- Monitored/analyzed external and internal PPM and tracked progress on countermeasures
- Utilized Microsoft Access database to analyze trends on customer and internal complaints
- Performed supplier audits for new and existing suppliers

R & D - Product Development Manager

- Managed Product Development Group of (8): 5 Engineers/Engineer assistants, 3 technicians
- Was responsible for project management for over 150 new products across all market segments
- Responsible for Design & Development ISO 9001:2000 requirement on new products/applications
- TS:16949, ISO 14001 and ISO 13485 Internal Auditor
- Developed new product applications utilizing criteria on cost targets and margins
- Lead Design reviews for new products, Advanced Product Quality Planning, FDA reviews
- Lead customer teleconferences on new applications and/or product performance analysis
- Solved technical issues for processes relating to new products/ business opportunities

Quality Engineer

- Utilization of Core Tools Control Plans, Flow Charts, DFMEA, PFMEA
- Interfaced with customers and responded to product quality issues
- Reviewed engineering prints for conformance to customer requirements
- Developed raw material specifications and test plans with customers & suppliers
- Prepared PPAP submissions and all related documentation for part submission warrants
- Reduced in-house and supplier scrap rates utilizing Kaizen approach, 8D problem solving methods

Process Engineer

- Performed Design of Experiments (DOE) to optimize processes/product characteristics
- Managed projects related to material substitutions for release liners & analyzed test data
- Visited customers to troubleshoot application issues or on technical projects
- Developed SOP's, process control plans, FMEA's and flow charts, plant layouts and time studies
- Qualification of new release liners and adhesives for significant cost savings

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Training/ Certifications & Professional Affiliations	<p>EXEMPLAR GLOBAL Certified: <i>ISO 9001:2015 QMS LEAD AUDITOR</i> <i>Certificate# 110043 Since 2008</i> Qualified to audit over (17) EAC Codes in multiple industry sectors:</p> <p>AMERICAN SOCIETY FOR QUALITY: Certified Quality Engineer (CQE) <i>Certificate# 34309 Since 1995</i></p> <p><u>TRAINING:</u></p> <p>2021: ISO 13485:2016 Lead Auditor TPECS</p> <p>2021: IATF 16949:2016/ISO 9001:2015 AIAG Internal Auditor Training Sponsored by Plexus International</p> <p>2020: ISO 27001:2013 Lead Auditor TPECS 2014: ISO 14001:2015 Lead Auditor TPECS</p>	<p>TRAINING/AFFILIATIONS: 2008: ISO 9001:2018 RABQSA Certified Lead Auditor Course TPECS</p> <p>2008-present: Training Sponsored by Registrars 50 hours per year minimum total</p> <p>2008 – Lean Mfg. Training - TB Woods, Inc.</p> <p>2007 – Advanced Problem Solving – Lean Manufacturing Training TB Woods, Inc.</p> <p>2001 - Speaker at ASQ-Granite State 5th Annual Conference-Process Capability</p> <p>Member of ASQ American Society for Quality (since 1988) Current member of ASQ Harrisburg, PA section Member of ASQ Quality Management Division (since 2002) Member of Cumberland Valley Business Alliance Member of Waynesboro, PA Chamber of Commerce</p>	
Education	<p>1993 - Bachelor of Science Mechanical Engineering Northeastern University Boston, MA</p>	<p>1990 – Associate’s Degree Mechanical Engineering Northeastern University Boston, MA</p>	
Other	<p>Experience with Oracle, various statistical and gage tracking databases Experience leading teleconferences utilizing web conferencing tools, projectors, cameras Proficient in Microsoft Office Suite</p>		
Employment History/Industry Sectors	<p>Owner/Consultant/Auditor</p> <p>Quality Engineer</p> <p>Full-Time Regional 3rd Party Lead QMS Auditor-New England Area</p> <p>Contract Quality Engineer</p> <p>Quality Manager/Engineer</p> <p>Quality Engineer</p> <p>R & D / Product Development Manager</p> <p>Quality Engineer</p> <p>Quality Engineer II</p> <p>Quality Engineer, Process Engineer</p> <p>Quality Engineer, Industrial Engineer, Production Control/Scheduling, Customer Service and Shipping Supervisor</p> <p>Engineering Aide</p>	<p>ISO Advantage LLC, Waynesboro, PA Quality Management System Consulting Contract 3rd Party Auditing with ANAB accredited Registrar(s)</p> <p>Manitowoc Cranes, Shady Grove, PA Mobile hydraulic, lattice-boom crawler, truck-mounted & tower cranes</p> <p>NQA-USA, Acton, MA ANAB Accredited Certification Body</p> <p>NEI Inc., Brentwood, NH Roofing Substrates</p> <p>TB Wood’s Inc., Chambersburg, PA Mechanical Drives, Machine Shop, Foundry</p> <p>Teleflex Marine, Hagerstown, MD Mechanical Steering/ Controls, Electronic Controls, High-performance cables</p> <p>Velcro Group Corp. Manchester, NH Textiles, Plastics, Adhesives, Medical 1st Tier Automotive Supplier: Ford Chrysler Class I & Class II Medical Devices</p> <p>Park Nameplate, Dover, NH Metal Stampings/Printing- Tier II Automotive Industry Supplier</p> <p>Thermo Electron/Thermo-Fisher Scientific Newington, NH Temperature Apparatus, Electrical/Semi-conductor Industry</p> <p>Velcro USA, Inc. Manchester, NH (See above for business description)</p> <p>McCord Winn Textron Automotive Division Armatures/Fuel Pumps- 1st Tier Automotive Supplier to GM Plastic Injection and Insert Molding</p> <p>Textron Defense (AVCO Systems Div.)</p>	<p>June 2011 to present</p> <p>2011</p> <p>2009-2010</p> <p>2008</p> <p>2006 to 2008</p> <p>2006</p> <p>2003 to 2006 (12 years total)</p> <p>2001 to 2003</p> <p>2000 to 2001</p> <p>1991 to 2000 (12 years total)</p> <p>1984 to 1991</p> <p>1983 to 1984</p>