



Diane Kulisek, Founder, President, QA Coach

- **QA Superpowers: Quality Assurance Leadership, Quality Management Systems (QMS), Metrics, Cost of Quality (UnQuality), Corrective and Preventive Action (CAPA)**
- Medical Devices, Aerospace, Consumer Products, Filtration, Plastics, Metal Fabrication, Electronics, Assembly, Packaging.
- MS Engineering, BA Biology, Grad. Cert. Program Management, American Society for Quality Certified Manager of Quality/Organizational Excellence, Quality Engineer (ASQ CMQ/OE, ASQ QE), Lean Six Sigma Green Belt (LSSGB) Institute of Certified Professional Managers Certified Manager (ICPM CM).



A video introduction from Diane: [CLICK HERE TO VIEW.](#)



To View or Print Diane's Complete Resume, [CLICK HERE.](#)

Some 'get acquainted' resources for you from Diane (Free Downloads):

Type of Item	Title / Description
Adobe PDF	Quality Performance Metrics Presentation
Excel Template	Simple Dashboard
Excel Template	Balanced Scorecard Template
Word Template	Standard Operating Procedure for Quality Planning
Adobe PDF	Quality Plan Example
Word Template	Quality Plan
Adobe PDF	Corrective and Preventive Action (CAPA) Presentation
Adobe PDF	CAPA Request
Adobe PDF	CAPA Response (Short Version)
Adobe PDF	CAPA Response (Long Version)
Word Template	Improvement Workbook ("Luck Journal" --- Great for CAPA Root Cause Analysis!)
Excel Template	Simple CAPA Status by Manager

Organizations Diane has worked with:





Some of Diane's Endorsements:

"...during our most challenging project, bringing Regulatory Affairs into compliance for the start-up operation. ... Diane coached the management team in creating the documents for their area. Diane was instrumental in establishing a good working relationship with the FDA. I highly recommend Diane Kulisek to any company seeking outstanding quality engineering or regulatory compliance expertise." – **Patricia M.**

"Diane is a very responsive person with outstanding communication and leadership skills. Combined with unusually broad knowledge in different fields, makes Diane a great value in professional and social relationships. I ...would strongly recommend her to any organization looking for quality and an extraordinary leader." – **Alex Z.**

"The expert advice and documentation provided by [Diane], to support key validations, was critical to ensure program success. [She] worked to create constant communication and proved that no detail was too small. I would not hesitate to recommend [her] services." – **Shawn C.**

"We relied upon... Diane Kulisek to help us address several highly technical regulatory compliance concerns. Her work was thorough and was completed exactly as promised. I would recommend her services to any company wanting to be confident that all of the necessary actions have been taken to satisfy customer quality or regulatory requirements." – **Anthony M.**

"Diane is a pleasure to work with. She is extremely knowledgeable in the areas of quality manufacturing and engineering. She has an amazing ability to articulate solutions to complex business problems. I highly recommend her to anyone seeking improvement to their quality systems." – **Greg B.**

"I would absolutely recommend Diane, not only on her knowledge of ISO and FDA qualifiers, but also... on her ability to take the complex and break it down to understandable portions. She is very professional, as well as easy to get along with." – **Becky M.**

"I worked with Diane on Customer Feedback/Product Complaints forms. Our customers use this form to submit their complaints and suggestion. This form is one of the critical forms that were required by FDA and ISO standards. I was able to finish this web form successfully by Diane's help." – **Fawad R.**

"Diane led our efforts to implement a ISO quality system. Starting with a very rudimentary quality system and limited Quality Assurance resources. Her effective management of the 3rd party auditors was also instrumental in achieving our goal. One of the greatest favorable operating impacts came from implementation of Quality metrics to track company performance. Using these data, we identified several product and process improvement programs that yielded increased profitability. She was our Quality System visionary, our Quality Program guide and our Continual Improvement tutor. I recommend Diane to any company which has these needs." – **Jim B.**

"[Diane] demonstrated excellent leadership and communication skills, well versed in quality system and improvement tools in CAPA, SPC, AS9100, Lean, 5S, Kanban, and Six-Sigma. She is reliable, energetic, and makes good decision. Knows MRP, understands manufacturing processes, and earned respect from colleagues for quality work and professionalism. I highly recommend Diane K. in the quality field." – **Peter W.**

"It was very rewarding for me to work with Diane, as Diane served as a mentor to many of us. Diane has an exceptional amount of experience in the quality assurance field - not only technical knowledge of quality assurance principles, practices, and systems --- but in their application and use in the real world. Diane has breadth of work experience. I found Diane to have a great deal of integrity. She was a problem solver. Diane is results oriented." – **Diane M.**

"Diane was an enthusiastic... mastermind of many of the various interaction techniques employed to break down... pre-existing barriers between disciplines. Diane was instrumental in creating a cohesive team that worked in concert to create CPI-TQM (Continuous Process Improvement - Total Quality Management). Through a combination of her introduction of these techniques and her effervescent personality, Diane created an environment that was both conducive to innovation and comraderie in the team and one that reduced the stress of everyday work - work that literally had people's lives (astronauts) hanging in the balance. Disciplines whose stances on certain issue were formerly diametrical, had those stances softened under her nurturing and welcoming of open discussion. Diane... created such a cohesive group... the process had worked and a significant amount of money was saved. Diane is passionate about her work and I would recommend her to any organization." – **Larry D.**