



**Stephen Mundwiller, CMQ/OE, CQA, CQPA, CSSGB, and RAB
Principal Auditor**

**Director of Quality Assurance & Regulatory Affairs - Allied
Healthcare Products**

Past Chair - St. Louis ASQ Section 1304

Steve Mundwiller is currently a Director for Allied Healthcare Products in St. Louis, Missouri. In this capacity Steve oversees a staff of 13, including both union and non-union individuals. Steve has the responsibility to; oversee and maintain the ISO 9001 general quality and the ISO 13485 medical device Quality Management Systems, ensure the timely submission of all domestic and international regulatory materials, manage the investigation of customer complaints, manage quality improvement activities, and manage the \$1M+ budget. Previously, Steve has provided comprehensive consulting services, training and mentoring services, and systems development to manufacturing and service sectors, both public and private. All of Steve's activities have a focus on business improvement that is aligned with the organization's strategic goals. Key activities include:

- ISO 9001 (General Quality Management Systems) and ISO 13485 (QMS for Medical Device Manufacture); related systems development, transition and audit preparation,
- Compliance to the European Union's Medical Device Directive,
- Lean Manufacturing,
- Six Sigma Activity,
- Supply Chain Management & Improvement,
- Good Manufacturing Practices (GMP's) systems development & improvement meeting the requirements of the U.S. Food and Drug Administration (FDA), leadership coaching & development, team development, mentoring & improvement,
- Pragmatic cost-savings initiatives,
- Statistical Process Control (SPC) training and implementation,
- Continuous Improvement; Kaizen, Benchmarking and general problem resolution, and
- Project Management; training, organization and implementation

Steve has served many organizations through implementing Quality Systems, mentoring & providing instruction to thousands of individuals on both the hourly and professional levels, and by performing Quality System Audits, including; American Home Products, Sherwood Medical, Georgia-Pacific, Northrop-Grumman Ship Systems, Boeing, Willamette Industries, Woodward Governor, General Electric Jet Engine Systems, Tyco, Alcoa, Weyerhaeuser, Intercon Chemical, SAIC, Howmet Castings, and Edward Jones.

In addition, Steve has been an instructor for St. Louis Community College, teaching classes in ISO 9000 and Quality Tools. Steve has also served the St. Louis ASQ section as an instructor for the Certified Quality Auditor and the Certified Manager of Quality/Organizational Excellence Refresher Classes.

Steve is a board member of the St. Louis Section of the American Society for Quality (ASQ) and is the current Immediate Past Chair. He holds ASQ certifications as a Quality Systems Manager (CQMgr.), Quality Systems Auditor (CQA), Quality Process Analyst (CQPA), and Six Sigma Green Belt (CSSGB). In addition, Steve is an RAB/QSA certified Principal Auditor. Steve is a former Missouri Quality Award Examiner.