Philadelphia Section
ASQ The Global Voice of Quality™

Special Thanks to Minitab for Sponsoring this event!

ASQ Region 5 Quality Conference

7:30 - 8:30	Registration, Breakfast and Announcements			
8:30 - 9:20	Keynote: Bill Troy, CEO American Society for Quality, Ball Room			
AM Sessions	Track A	Track B	Track C	Track D
	Lean 6 Sigma	Device/Drug	Audit/ISO	Healthcare
				
Session 1 9:30 - 10:30	Statistical Engineering - QBD Ron Snee	Sterilization Clark Houghtling	ISO 9001-2015 Charles Cianfrani	The Joint Commission HRO (Part 1) Coleen Smith
10:30 - 11:00	Break, Networking and Exhibitors			
Session 2 11:00 - 12:00	The Vanguard Group Case Study Nina Lotfi	PMA/510K Submission Robin Fatsinger	Your Auditor Never Told You! Mike Paquin	The Joint Commission HRO (Part 2) Coleen Smith
12:00 - 1:45	Lunch, Networking and Exhibitors			
PM Sessions	Track A	Track B	Track C	Track D
Session 3 1:45 - 2:45	Enterprise Value Stream Mapping JR Magee	FDA-Device Foreign/Domestic Inspections, "Is there a Difference?" Dennis Hock	ISO 19011 Auditing Management Systems Richard Litts	Penn Medicine Strategic Approach To Improvement M. Posencheg, MD P. Sullivan, PhD
2:45 - 3:00	Break, Networking and Exhibitors			
Session 4 3:00 - 4:00	Non-parametric data analysis using Minitab Meredith Griffith	FDA-Drug Darning: the Quality Safety Net Gayle Lawson	ISO 13485 Bill McLain	Baldrige Journey Maureen Frye

Keynote Presentation: "The Future of Quality", presented by Bill Troy

Several questions will be addressed:

- What is the future of quality professionals, especially ASQ members?
- What is the strategic plan to retain and recruit ASQ members, especially at the Section level?
- What are some of the national and global issues that ASQ is working on?
- What new certifications are being considered and what certifications just aren't being pursued and could possibly be eliminated?
- What is ASQ's marketing plan on the Regional and Section level to publicize the value of ASQ?

Bill Troy is the current ASQ CEO. He is a retired three-star general who has expertise in running a non-profit and the topic of change management. He is a distinguished, results-driven CEO with an impressive portfolio of accomplishments and transferable skills including a Senior Fellowship at Harvard University's Weatherhead Center for International Affairs, article publication in the Washington Post, budget management of up to $5 billion and staff leadership of up to 12,000 soldiers. For more information please go to: http://asq.org/blog/2014/06/02/meet-new-asq-ceo-bill-troy/. Bill is actively engaged in developing the next generation of quality professionals through STEM educational efforts at all levels.

Session A1: Statistical Thinking: Increasing the Impact of Quality by Design (QbD) and Other Analytical Approaches, presented by Ron Snee

It is broadly recognized that statistical methods are very useful in the design, control and improvement of businesses and organization of all types. Statistical methods are used today in industries and functions varying from pharmaceuticals and biotech to electronics, Google searches and business analytics. Attention is brought to the central importance of the "process" that provides the context for the work. Examples are used to show how Statistical Thinking can increase the impact of Quality by Design, speed up the process of experimentation and enhance the effectiveness of how problems are solved and how processes are controlled and improved.

Ron Snee is the Founder and President of Snee Associates, LLC, a firm dedicated to the successful implementation of process and organizational improvement initiatives. He provides guidance to senior executives in their pursuit of improved business performance using Quality by Design (QbD), Lean Six Sigma and other data-based improvement approaches that produce bottom line results. He has played a leadership role in 32 major improvement initiatives for firms such as Merck, Novartis, Schering Plough, Human Genome Sciences, Celgene, Boehringer-Ingelheim and Kraft Foods. Ron recently authored three books on QbD topics including his latest book "Strategies for Formulations Development", with Roger W. Hoerl of Union College (GE retired). He received his BA from Washington and Jefferson College and MS and PhD degrees from Rutgers University. He is an academician in the International Academy for Quality and Fellow of the American Society of Quality, American Statistical Association, and American Association for the Advancement of Science. Ron is an Honorary Member of ASQ has been awarded ASQ's Shewhart, Grant and Distinguished Service Medals, and ASA's Deming Lecture, Dixon Statistical Consulting Excellence and Gerry Hahn Quality and Productivity Achievement Awards as well as numerous awards and honors. He is a frequent speaker and has published six books and more than 300 papers in the fields of performance improvement, quality, management, and statistics.

Session A2: The Vanguard Group: LSS Case Study, presented by Nina Garrow Lotfi

Nina along with two of her Vanguard associates will present a case study for quality in financial environments including samples with some reservations of client confidentially.

Nina is the head of Vanguard Implementation Services, which is responsible for defined contribution plan conversion, setup, data management, service enhancement, and money movement. Her group serves some of the world's largest organizations in the administration of their company retirement benefits. Ms. Lotfi is responsible for overall leadership of the department and also is a member of the Recordkeeping Services senior leadership team.
Since joining Vanguard in 2004, Ms. Lotfi has held numerous leadership and individual contributor roles in Operations and Shared Services groups, she has also served as the chief of staff to the general counsel and managing director, and a VUE Expert in the Center for Excellence.She is an active leader in Vanguard's diversity and inclusive efforts and has served as divisional chair of Vanguard's diversity advancement committee and is currently co-leading the Vanguard Black Professional Network Attraction and Onboarding Sub-team.

Ms. Lotfi earned a B.S. in business administration with a focus in Economics, Marketing, and International Business from Saint Louis University and an M.S. in Finance from Temple University.

Session A3: Enterprise Value Stream Mapping, presented by J.R. McGee

During this presentation you will learn how to use enterprise Value Stream Mapping (e-VSM) as a powerful tool. J.R. will show you how e-VSMs are different than a regular value stream mapping – typically just mapping one process from end to end. Two dramatic case studies are presented. The first is in a hospital setting and the second is in a textile manufacturer in the Midwest that was able to bring back jobs from China.

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JR is a Certified Lean Six Sigma Master Black Belt Sensei. He designed and implemented the MBB program at Lockheed Martin and has trained more than 30,000 Green Belts, 10,000 Black Belts, and certified 73 Master Black Belts. He is also the current Chairman for Professional Development for the LEAN Enterprise Division of the American Society for Quality. He is responsible for LEAN Content, Certification, Web Training, and Awards and Recognition world-wide. He has facilitated and coached more than 700 Lean Six Sigma projects worldwide. As Program Manager at "Top Gun" ranges world-wide. J.R. specialized in operations, training, and development of Fighter Pilots, Special Forces, Combat Field Engineering, and providing operational support to Intelligence and Counter-Terrorism operations around the world. He authors an Executive Coaching column for ASQ's Quality Forum Magazine. He was awarded the ASQ Roger Berger Award for outstanding leadership support for Quality Knowledge and Operational Excellence to the Global Quality Community. He is the 2017 Chairman for Professional Development for the ASQ Lean Enterprise Division and a Voting Member of the Board of Directors. He sits on the Board of Directors for the ASQ NextGen Program for Future Leadership Development for Quality Management. He holds a Degree in Electronic Technology from Troy State University (European Division); a Degree in Business Management from the University of Maryland; He completed the Strategic Studies Program at the Tepper Carnegie Mellon Business Institute; and the Strategic Leadership Program at the Goizueta Business School, Emory University. He is currently the CEO of X-Stream Leadership Group.

Session A4: Non-parametric Data Analysis using Minitab, presented by Meredith Griffith

Nonparametric analysis is an underserved area of training or even familiarity. Especially when cycle time is a common metric where the data is not normal and transformation can send people in to a math coma.

Meredith is currently a Senior Technical Project Manager coordinating the design, development, and delivery of Minitab's e-learning course. She is also a Quality Trainer. She earned a M.S. Industrial Engineering with a focus on Quality Engineering from the Pennsylvania State University. She Graduated from Virginia Polytechnic Institute and State University with a B.S. in Statistics and minors in Mathematics and Actuarial Science. She has strong analytical and technical skills with a background in statistics. Her expertise is exhibited in a variety of business applications, ranging from product development and technical project management, to customer-facing and product marketing experience. Her technical and statistical expertise, paired with Minitab product expertise, offer a unique perspective in orchestrating the development of new Minitab products from proposal through delivery. Passionate about using data to drive business decisions, identifying opportunities for process improvement, and delivering high-quality products.

Session B1: Sterilization for Device/Drug, presented by Clark Houghtling

Covering sterilization procedures/process for all applications and benefits. Sterilization technologies, used in medical device manufacturing, finished goods testing, business development, plant and quality management, sales, marketing, and regulatory affairs.

Clark Houghtling isthe Vice President of Business Development and Technical Affairs for Cosmed Group, Inc. Cosmed was founded in 1981 to sterilize medical devices and pasteurize agricultural commodities. The company grew to be among the largest contract sterilization companies in the United States until it divested its five medical device sterilization facilities in 2005 to focus on food safety. Cosmed reentered the medical device sterilization market in 2012 to offer a complete line of world-class sterilization and ancillary equipment, as well as other sterilization related services. Cosmed has designed and built many complete sterilization facilities, and built well over 100 sterilizers. In 2016 the company returned to the medical device contract sterilization business with the acquisition of an ethylene oxide (EO) contract sterilization facility in Erie, PA

Clark's varied background includes extensive knowledge in sterilization technologies, medical device manufacturing, finished goods testing, business development, plant and quality management, sales, marketing, and regulatory affairs. Prior to this position, Clark worked in various upper management positions for companies including Comet ebeam Technologies, Synergy Health, Stryker Orthopaedics, Microtest Laboratories, Steris, Mallinckrodt, and Ethox. He holds a Bachelor of Science degree in Biology from the State University of New York at Geneseo, and attended graduate school in Biology at Niagara University.

Session B2: PMA/510K: Issues related to PMA/510K Submissions and New Requirements, presented by Robin Fatsinger

Robin has extensive U.S. and foreign Regulatory Affairs experience with class I, II, and III medical products including implants, single use, reusable devices and combination products. Robin is currently Vice President of Regulatory Affairs and Quality Assurance for Aesculap, a division of BBraun.

Session B3: Foreign Domestic Inspections, Is there a Difference, presented by Dennis Hock

Presentation related to inspections of medical devices to meet the US regulatory requirements and evaluation of inspection in the US against foreign. Are there any differences?

Dennis Hock has worked for the Food and Drug Agency for over six years and is knowledgeable in evidence development, manufacturing GMPs and, domestic and foreign inspections. He has developed inspections resulting in numerous regulatory actions, including: Injunctions, Seizures, Warning Letters, Regulatory Meetings, Detention Orders and Temporary Restraining Orders. He has also conducted inspections that resulted in criminal cases, including participating in the search warrants. Prior to the FDA, he worked for a company as a research liaison to Principal Investigators, Government and private research organizations, both foreign and domestic, utilizing telemetry and pulse oximetry technology.

He graduated Magna Cum Laude from Indiana University of Pennsylvania receiving a BS from the College of Natural Science and Mathematics. Dennis completed multiple military deployments as a combat veteran and was a part of the Northern invasion of Iraq in 2003.

Session B4: FDA Drug - Darning the Quality Safety Net, presented by Gayle Lawson

The presentation will examine the problem management system to inspire attendees to identify gaps and strengthen quality activities. The presentation will also offer a workshop section so that participants can ask/discuss issues, concerns, and successes in quality systems and problem management.

Gayle Lawson is an officer with the US Public Health Service in the Pharmacy Category. At her assigned duty station with the FDA Philadelphia District, Gayle is a Drug Specialist and serves as the Pre-Approval Manager and primary Field Alert Report Monitor. She has been an Investigator with the Philadelphia District for 15 years and has conducted domestic and foreign inspections across several commodity areas with a focus on drugs and biologics. Her duties as an active duty US Public Health Service Officer also include serving as a member of an emergency response team to shelter persons with medical needs who are displaced or evacuated during emergencies.

In her first commissioned assignment, she served as the Chief Pharmacist at FCI Fort Dix with the Federal Bureau of Prisons. Prior to her federal service, she graduated from Rutgers University College of Pharmacy and practiced community pharmacy for 17 years.

Session C1: ISO 9001-2015 presented by Charlie Cianfrani

Quality Management Systems, the world's leading quality management standard, has been revised.

Why was ISO 9001 revised?

All ISO standards are reviewed every five years to establish if a revision is required to keep it current and relevant for the marketplace. ISO 9001:2015 is designed to respond to the latest trends and be compatible with other management systems such as ISO 14001. Learn more about the process of standard development.

What are the main changes to the standard?

The new version follows a new, higher level structure [PDF] to make it easier to use in conjunction with other management system standards, with increased importance given to risk.

Charlie Cianfrani is an internationally recognized authority on all elements of process control and quality management. He has held a variety of executive positions (Vice President-Operations, General Manager, Managing Director, Chief Quality Officer, Vice President-Quality) in general management, quality, manufacturing and service delivery. His principal areas of focus over the past ten years have been:

- implementing projects to measure and improve process effectiveness
- developing and deploying processes to continually improve the effectiveness of operations
- creating and implementing world-class quality management systems
- leading projects to achieve ISO 9001 compliance
- structuring and implementing self-assessment and internal audit systems including training of internal auditors and assessors
- driving corrective actions and preventive actions. He has had direct responsibility and accountability for numerous projects that achieved ISO 9001 compliance on six continents

Charlie attended Drexel University and Villanova University, receiving BS (physics and EE concentration), MS (applied statistics) and MBA degrees. He is an ASQ Certified Quality Engineer (CQE), Certified Reliability Engineer (CRE) and Certified Quality Auditor (CQA), and has been a NAWDP Certified Workforce Development Professional as well as being an Exemplar Global-certified Quality Management Systems Auditor. He is a Fellow of the American Society for Quality.

Session C2: Your Auditor Never Told You presented by Michael Paquin

This session could/should appeal to both sides of the audit table. As an auditee there are things you should probably know that your auditor won't or cannot tell you. As an auditor there are some things you wish you could tell your auditee but are not allowed to or, should not tell them during an audit.

This presentation is a compendium of things that have happened during audits over the last 18 years and how they have guided one auditor's style of auditing. Some of these things are what you should know to make audit a more effective tool for continual improvement.

Michael Paquin has been in the customer service business for 55 years. He has worked for the man, been the man and now audits the man. Bitten by the Baldrige bug he became a corporate examiner, a New Jersey state examiner. He then moved on to being an ISO 9000 lead auditor for 10 years in two different IBM groups. Michael then realized people are what fuel continuous improvement (i.e., creativity). Michael became an ASQ International Team Excellence Award (ITEA) judge and instructor until ASQ named him a master judge.

For the past seven years Michael has worked as a 3rd party auditor for the American Institute of Steel Construction (AISC) where he has performed over 750 audits of steel fabricators.

Session C3: ISO 19011, Auditing Management System presented by Richard A. Litts

ISO 19011 is the standard that sets forth guidelines for auditing management systems. The standard contains guidance on managing an audit program, the principles of auditing, and the evaluation of individuals responsible for managing the audit programs. An audit program consists of the arrangements made to complete all of the individual audits needed to achieve a specific purpose.

ISO 19011:2011 provides valuable information on how to improve an audit program systematically, just as other departments in an organization are expected to improve. One aspect of such improvement is continuously ensuring the audit program objectives are in line with the management system policies and objectives. Organizations, in pushing for auditing improvements, should consider the needs of customers and other interested parties.

An area of increasing importance in auditing management systems and business in general is the concept of risk. As of the 2011 edition, risk has been integrated throughout the audit program management section of the ISO 19011:2011 standard.

Richard A. Litts is the founder and president of Litts Quality Technologies, Inc.
Rick has many years of corporate, manufacturing and consulting experience. He is an Exemplar Global Quality Management Systems Registered Lead Auditor a PROBITAS Authentication AS9100 Aerospace Experienced Auditor AEA) and an IAQG Qualified AS9100 Aviation, Space and Defense auditor. In addition, he is an ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories Lead Assessor. He has been a member of and the AS9100 Subject Matter Expert (SME) on a Committee to Protect Impartiality for an international QMS registrar.

He is an U.S. Expert Representative for the U.S. Technical Advisory Group (TAG) to the International Organization for Standardization (ISO) ISO/PC 302 and member of the ASC Z1 Committee. This TAG is in the process of revising the ISO 19011 Guidelines for Auditing Management Systems Standard. The ASC Z1A Committee can approve ISO standards as American National Standards (ANS).

Rick has a BSME from Lehigh University and an A.A.S. in Aircraft Design Technology from the Academy of Aeronautics.

He is a senior member of ASQ, a Certified Quality Engineer and a Certified Quality Auditor. He was the Chairman of the Philadelphia Section of ASQ (2001-2002) and the Region 5 Deputy Regional Director (2002-2005, 2010-2011). Rick served as the ASQ Region 5 Regional Director (2005-2009) and was a member of the ASQ Board of Directors (2005-2009).

Session C4: ISO 13485 Firms, a Multitude of Expectations presented by William McLain

Medical device firms or component manufacturers face a multitude of expectations. From the FDA, to Notified Bodies, to registrars, to customers, everyone has their perspectives, styles, and expectations. This presentation will summarize those expectations and help you prepare for audits within the culture of the medical device industry. During this presentation we will also review the most significant changes in the ISO 13485:2016 standard so you can prepare your organization for successful transition.

William is the President and Principal Consultant for Keystone Regulatory Services, LLC. He has over 25 years' experience in product development, domestic and international regulatory affairs, risk management, and quality management system design in the medical device industry. He has contributed to the timely development and market introduction of cardiovascular, anesthesiology, gastro enteral, diagnostic, orthopedic, and general surgical devices by providing regulatory, quality system and risk management strategy, oversight, and support. Mr. McLain also serves as an auditor for the notified body, DEKRA. An active member of RAPS and ASQ Biomedical Division, Mr. McLain is a RABQSA Exemplar Global) Certified Principal Auditor.

Sessions D1 and D2: Joint Commission - High Reliability Organization presented by Coleen Smith

For more than 60 years, The Joint Commission has inspired hospitals and health care organizations to excel in providing safe and effective care of the highest quality by earning and maintaining The Joint Commission's Gold Seal of Approval™, a symbol of quality that is recognized nationwide and reflects an organization's commitment to meeting demanding performance standards.

At the Joint Commission Center for Transforming Healthcare, our mission to transform health care into a high reliability industry by developing effective solutions to health care's most critical safety and quality problems continues the quest for achieving the gold standard in health care. Why? Because, along with our participating hospitals and organizations, we believe high reliability in health care means consistent excellence in quality and safety for every patient, every time.

High reliability in health care improves:

- organizational effectiveness
- organizational efficiency
- customer satisfaction
- compliance
- organizational culture
- documentation

The road to high reliability is an ongoing journey. It's a commitment to patient safety and the way we deliver quality health care. So join the journey and let the Joint Commission Center for Transforming Healthcare guide you every step of the way.

Coleen McKenna Smith is a nurse leader currently serving as the Director, High Reliability Initiatives for the Joint Commission Center for Transforming Healthcare, a separate 501(c) 3 division of The Joint Commission. She is responsible for developing and supporting activities that lead to the adoption of high reliability practices in health care. She also leads work on Preventing Avoidable Heart Failure Hospitalizations and Safety Culture, two of the active projects within the Center, and supports pilot work on Reducing Colorectal Surgical Site Infections. Prior to this Coleen acted as Robust Process Improvement Black Belt and Center Project Lead within the Joint Commission Center for Transforming Healthcare. Previously, Coleen was a Patient Safety Specialist in The Joint Commission where she was responsible for evaluation of Root Cause Analysis findings and action plan development for accredited organizations that had experienced a sentinel event. She served as a certified Joint Commission accreditation surveyor in the Hospital program. Coleen also participates in the review of publications related to patient safety and sentinel events.

Her extensive clinical and leadership expertise is in the areas of pediatric acute and ambulatory care with a focus in pediatric rheumatology and neurology. Coleen led a multitude of successful performance improvement projects that resulted in improved patient satisfaction, operational efficiency and patient safety.

She is a Certified Professional in Healthcare Quality and holds an MBA in Health Care Administration as well as a Bachelor of Science in Nursing. She speaks nationally on topics related to High Reliability, Patient Safety and Culture of Safety in Health Care.

Session D3: Penn Medicine - A Strategic Approach to Improvement presented by Michael A. Posencheg and Patricia G. Sullivan

Many health systems have success piloting improvement initiatives in specific local areas with good results. However, many of these local improvements are either not sustained or ineffectively spread to other areas of the health system where other patient populations could benefit from the initiatives. Penn Medicine has organized a team of clinical, quality, data science, human factors, and finance representatives to build a model to orchestrate system level change for these types of quality value initiatives. Adopted from the Breakthrough Series (BTS) Model designed by the Institute for Healthcare Improvement (IHI), our model utilizes problem investigation and design of evidence-based interventions by an expert panel, followed by recruitment of local teams throughout the health system who come together both in-person and virtually over 9-12 months to facilitate cross system change. Each collaborative effort is complimented by a dashboard created with appropriate outcome, process, and financial measures that are followed over time to understand the impact of our efforts. In this session, we will describe this model in further detail as well as share some of our success and obstacles to date.

Michael A. Posencheg, MD, is an attending neonatologist at the Children's Hospital of Philadelphia and the Hospital of the University of Pennsylvania (HUP) where he is the Medical Director of the Intensive Care Nursery. Michael is also the Associate Chief Medical Officer for Value Improvement for Penn Medicine, driving spread initiatives across the health system. Regarding his quality improvement background, he has completed the Improvement Advisor (IA) and Graduate IA program at the Institute for Healthcare Improvement. He led multiple improvement projects over the past 7 years resulting in publication and health system awards. He has also served as a Patient Safety Officer at HUP and was involved in the redesign of the Root Cause Analysis process across the health system.

Patricia G. Sullivan, PhD, is the Chief Quality Officer for the University of Pennsylvania Health System where she is responsible for Clinical Effectiveness and Quality Improvement across Penn Medicine. In her role she partners with the Chief Medical Officer and other senior leaders across the health system to design and implement organizational strategies that actualize the Penn Blueprint for Quality. Pat works closely with quality leaders and front line Unit Based Clinical Leadership teams to deploy effective quality improvement tools that have reduced preventable deaths and readmissions, decreased patient harm and improved the patient experience.

Session D4: A Baldrige Journey – Why aren't we THERE yet? presented by Maureen Ann Frye

All organizations want to move from Good to Great. They need to in today's environment. While there are many approaches and tools to assist in that journey, the Baldrige Excellence Framework offers a systems-approach or 'blueprint' to help an organization focus, align, improve and achieve sustainable results. As a Senior Examiner for the National program and with experience applying the framework to her own organization, Maureen will lead participants into the criteria, why it works, and how to apply some fundamental Baldrige questions to their own organization – all while developing transferrable skills in the workshop! Through fun and interactive scenarios and examples, participants will discover how the use of the Baldrige Framework will enable their organizations to achieve breakthrough results.

Maureen Ann Frye, MSN, BC, CRNP, CPPS, CPHQ, is the Director of the Center for Patient Safety and Healthcare Quality at Abington Jefferson Health. With over 25 years of direct patient care experience as an Emergency/Primary Care Nurse Practitioner in Abington's Emergency Trauma Center, Maureen was named the inaugural Director in 2005, leading the organizations journey to high reliability and zero harm. During her tenure, the organization began its Baldrige Journey and earned the Keystone Alliance for Performance Excellence Award in 2010. Over the last 8 years, Maureen has served as an examiner for the National Baldrige Program, currently as a Senior Examiner and has recently completed the Baldrige Executive Fellowship in April 2017. She holds a Bachelor of Science in Nursing from the University of the State of New York and a Master of Science in Nursing from the University of Alabama. After 27 years providing direct care as a certified registered nurse practitioner in Emergency Trauma Center at Abington Hospital, she now focuses on organizational improvement from the systems perspective. She is a Certified Professional in Patient Safety from the NPSF and a Certified Professional in Healthcare Quality from NAHQ.