Presentations and Speakers

"Holistic Coaching: Integrating Deming with the 3 Parts of the Mind"
John H. Barr, MS, President: Transformation Through Leadership

"What we need is cooperation and transformation to a new style of management. The route to transformation is what I call Profound Knowledge." - W. Edwards Deming

Abstract: Much of what we do at the ASQ is about process and measurement and the foundation of W. Edward Deming has been somewhat lost. For most of the 20th century Dr. W. Edwards Deming continuously studied and learned as he developed his general theories, the 14 points and 7 deadly diseases. outlined in Out of Crisis published in 1982. He continued to develop his theories and presented the key to transformation in The New Economics for Industry, Government, Education published in (1993) where he introduced Profound Knowledge.

Deming defined Profound Knowledge as: appreciation for a system, knowledge about variation, theory of knowledge, psychology. Deming (1983, p 96).

Kathy Kolbe's work over the last 40 years defined the 3 parts of the mind as: cognitive, conative, and affective. Cognitive is IQ, education, knowledge and experiences. Conative is the innate methods people use when they are striving to succeed. It is our natural way of solving problems and measured by the Kolbe A™ index. Affective is our preferences, as measured by instruments like the MBTI.

Bio: For the past 30 years I have been coaching executives in areas of leadership, strategy and transformation. I will present an integrated model based on Deming and Kolbe and some background into how our brains enable us to accept or reject coaching.

Keynote Presentation

"Leadership & Management of Quality in Different Industries, Is It All the Same?"
Ron Shah, Global Quality Manager, Ocean Optics

Bio: Ron Shah has used his key skills of: Focus (80/20), Clarity of mind, Sense of Urgency, No Complacency in parallel with his core values of: Honesty, Attitude, Respect, Trust & Passion to successfully complete a broad range of accomplishments. Ron has led and managed a Global Quality Team to continually improve KPI goals and initiatives. He has improved Customer satisfaction of Fortune 500 Customers for multiple Business Units - Aerospace, Micro Electronics, Energy and Machinery & Equipment, and created a Quality Culture through continual Communication, Awareness and Training of employees.

Quality 201
Track 1 - Session 1

"How to Protect Yourself from the Computer Industry"
Marc-Anthony Arena, President: Teknosophy, LLC

Abstract: I'm a huge proponent of industry standards of all types, seeing as companies in my industry has a tendency to stray from them in favor of their own proprietary hare-brained protocols!

We'll discuss a few examples of how tech companies create proprietary schemes, in an attempt to create a monopoly. Most fail spectacularly, and the ones that succeed end up creating misery, confusion, and helplessness for all.

We'll discuss:

- The current problems of today's computer industry and the rampant misconceptions that cause them, based on my book "How to Protect Yourself from Your Computer"
- Proprietary uniqueness vs. monopolistic ambitions
- Defining a proprietary scheme vs. an industry standard
- Examples of standards-based success (USB, Bluetooth, QR codes, NTSC) vs. spectacular failure (Akimbo, Brother PowerNote, Sony Betamax and LocationFree, Smart TVs)
- Ultracentralized software activation/DRM and keyless entry
- "Keep Out": Baked-in control vs. open source
- The upcoming Internet of Headaches

Bio: Marc-Anthony Arena is President of Teknosophy, LLC was born in the 80s, back when technology was hopeful. He has studied Business Management with concentrations in Entrepreneurship, Spanish, and Russian. Marc has worked in the IT industry since 2000, and is currently President and Founder of both Teknosophy, LLC, and Streamplicity. He is the author of "How to Protect Yourself from Your Computer", a Plain English guide to the concepts, scams, and scandals of the computer industry that aims to debunk the myths and stop the fear. He is also the host of "The Computer Exorcist Show" on WYSL Radio, available on AM, FM, and online. In his free time, he enjoys funny Internet videos, road trips down the Eastern Seaboard, cigars, Tai Chi, foreign languages, buying old convertibles, and paying dearly for their repairs.

Track 1 - Session 2

"Example of Pre-Emptive Six Sigma © and Risk Management Tools via a Health Sector Case Study"

Thomas (Thom) Serafine, Principal, Pearson Briar LLC, in partner w/ J Nelson Enterprise LLC/OQL Solutions

Abstract: When making critical business decisions, most organizations consider both the benefits and risks associated with various options. However, few if any bring a systematic approach to conducting such an analysis. *Pre-Emptive Six Sigma©* is a methodology that uses new and 'reconstituted' Six Sigma tools to more formally assess organizational tolerance for risk, identify unintended consequences and evaluate pending decisions, strategies and offerings against these factors.

The new ISO 2015 standards have raised the bar on using risk management concepts in traditional manufacturing environments. Many other industries, such as healthcare, have always had a heightened awareness of the need to manage risk. Yet few companies from any industry sector use a formal approach that proactively incorporates assessing and managing risk into the decision-making process.

This presentation shares a summary overview of *Pre-Emptive Six Sigma ©* and demonstrates the integrated use of several of these tools as applied to a health sector case study. Participants will examine key aspects of today's healthcare environment, the types of business decisions that routinely challenge healthcare leaders and how the use of *Pre-Emptive Six Sigma©* tools can bring a structured approach to evaluating options and make effective decisions.

Bio: Thom Serafine specializes in developing growth strategies for healthcare providers. His firm delivers objective, results-oriented assistance to health systems, community hospitals and physician groups in the areas of strategic planning, physician and community partnerships, as well as executive search and talent development.

An accomplished relationship manager, Thom works with executive teams and boards leading strategic planning initiatives, ambulatory growth strategies and advising on partnership opportunities. He is also recognized as a trusted advisor for recruiting and developing executive talent in the healthcare industry.

Thom brings to his practice 15 years of experience working at Advocate Health Care and Humana. While at Advocate, he provided internal consulting services including strategic planning and competitive assessments, led system growth initiatives and directed the market intelligence team responsible for decision support for hospital and physician acquisitions.

Thom has a MBA in Health Industry Management and Strategy from Northwestern University's Kellogg School of Management and a Project Management in Health Care Certificate from the Harvard School of

Public Health. He currently serves as Vice-Chair of the Board of Directors for Heartland Health Centers, a Federally Qualified Health Center in Chicago. In partnership with J Nelson Enterprise LLC, Thom is engaged in the use and deployment of Pre-Emptive Six Sigma© in healthcare.

Track 1 - Session 3

"The Challenges of Meeting Rapidly Changing Regulatory Expectations in the Consumer Finance Accounts Receivables Industry"
Susan Norton, Director of Compliance, ConServe

Abstract: As with other regulated industries, the accounts receivables management industry is challenged with effectively integrating industry standards into operational systems to stay aligned with a rapidly changing regulatory and legal landscape. The importance of a robust and adaptable auditing program to demonstrate operational compliance to shifting regulatory expectations will be discussed

Bio: Sue Norton is currently Director of Compliance at ConServe. Prior to her transition to the consumer finance industry, Sue spent more than 20 years in the medical device and pharmaceutical industries, working in Quality and R&D. During this time, Sue was active in ISO standards development for medical device testing.

Track 1 - Session 4

"Positive Impacts of Integrating Quality Tools with Situational Leadership"
Lon Smith, Quality Assurance Manager, FluxData, Inc.

Abstract: As Quality Managers, we are called to draw upon many skillsets to achieve the best outcomes for the organizations we serve. There are times when directing a quality improvement is urgent and requires immediate results to prevent product defects making it out the door or having a negative impact to the bottom line of a company.

However, more oftentimes, there are opportunities and great long term returns on investment when we take the time to develop the knowledge and effectiveness of the organizational team. As leaders, we can make a significant impact when we teach basic quality tools and use "Situational Leadership" while adjusting leadership style to fit the development level of the followers we are trying to influence.

Teaching cross functional teams quality tools such as: developing flowcharts, documentation, evaluation of Pareto diagrams, brainstorming, creating Cause and Effect Diagrams, Tally Sheets and SPC charts can be very straight forward. Integrating quality tools with "Situational Leadership" can lead to benefits beyond your wildest dreams. Some of the benefits we have seen are: significant increase in first pass yield which positively impacts corporate profits, improved supplier relationships that led to collaboration to significantly reduce RMAs, and perhaps most importantly, the development of the individual contributions and the building of the team environment.

Teaching and implementing simple Continuous Process Improvements while using "Situational Leadership" has had broad and far reaching positive effects for product quality and the shaping of our corporate culture.

Bio: Lon Smith is currently the Quality Assurance Manager at FluxData, Inc. He has leveraged his BSEE and MS in Computer Integrated Manufacturing degrees from RIT to develop products and processes in a broad range of technologies from color and imaging science, fiber optics, bio-medical applications, military applications and manufacturing processes.

Lon has developed quality management systems, developed training programs, secured bio-medical patents, designed and fabricated test equipment, and enjoys leveraging continuous process improvements to save millions of dollars for corporations.

Track 1 - Session 5

"Root Cause Investigation through Design of Experiments"
Eric Alden, Production Systems Reliability Engineering Manager, Xerox Corporation,
LSS MBB, CQE, CRE, ASQ Fellow

Abstract: Review the root cause Investigation process through Design of Experiments (DOE):

- Early high rate of returns of new "scratch proof" anti-reflective optical coatings.

- Dead on arrival inkjet print heads that were 100% inspected

- Brand New Ink Tanks that look great but don't dispense

These and other experiences had significant impacts to the business and perplexed the process experts.

Each of these problems were resolved through root cause determination through the use of Designed Experiments.

The first and most difficult challenge was to determine a Response Variable.

The next challenge is to determine the factors and levels to investigate. These were determined through teamwork involving subject matter experts and their respective strong opinions.

Finally, a series of Resolution IV, Split Plot experiments were carried out and analyzed to reveal the interactive root causals so that fixes could be effectively implemented.

This discussion will introduce and explore many of the techniques that enable experimental designs to be effective at determining root causals of highly complex processes.

This talk will be entertaining and intended for all levels.

Bio: Eric Alden, Production Systems Reliability Engineering Manager, Xerox Corporation, LSS MBB, CQE, CRE, & ASQ Fellow, has been practicing quality and reliability engineering in the Rochester Area for over 20 years. Eric is a Xerox Certified Lean Six Sigma Master Black Belt, and is currently working for Xerox in production products reliability. He holds a Master's degree from RIT in Quality and Applied Statistics, and an undergraduate degree from RIT in Mechanical Engineering. Eric served as the 2003 – 2005 Chair of the Rochester ASQ section, and holds CRE, CQE, CQM and CSSBB certifications.

Eric has presented at numerous local ASQ dinner meetings and conferences, and also at the 2014 ASQ World Conference. He tackles his subjects with passion and exuberance in an entertaining style.

Quality 101 Continued…..
Track 2 - Session 1

"Staying Current with Standards Is Key to Business Excellence"
Lori Cohen, Compass Quality Solutions

Abstract: Standards are essential in operating a business and staying current with standards is important for sustained success. But how does an organization adapt as standards change? This presentation will explore the business value of standards and provide guidance on how to stay current when standards are revised. The talk will focus on ISO management system standards, including an overview of the changes and new requirements in ISO 9001.

Bio: Lori Cohen is a Quality Management Consultant specializing in ISO-based Quality Management System implementation and improvement. Her extensive knowledge in this area and project management expertise helps organizations achieve and maintain ISO 9001 certification, resulting in improved business performance through increased sales opportunities and measurable savings from process improvements.

Lori is a certified ASQ Quality Engineer and corporate-trained certified Six Sigma Black Belt. She holds a BS degree in Mechanical Engineering from Rochester Institute of Technology and an AAS in Optical Technology from Monroe Community College.

Track 2 - Session 2

"The Ostrich Paradox"
John Predmore, Process Engineer - Equipment Manufacturing, Ortho Clinical Diagnostics

Abstract: In the newly published book, The Ostrich Paradox (Wharton Digital Press, Feb 2017), authors Kunreuther and Meyer identify six biases why decision-makers discount or fail to fully comprehend historical or foreseeable risk situations. The six Biases are

- Myopia – Fail to foresee potential consequences

- Amnesia – Forget/Ignore severity from past incidents

- Optimism – Belief that losses happen to others, not me

- Inertia – Preference for inaction and the status quo

- Simplification – Fail to base decision on full information

- Herding – Imitation of the behavior of others

The examples in the book deal with natural disasters, why homeowners rebuild in flood plains, for example. The authors offer one tool, the Behavioral Audit, to help uncover and mitigate the impact of these biases (or blindnesses) as they occur in a planning or decision-making context. There are obvious and profound extensions to the Quality field. This innovative work advances the state-of-the-art in Risk Management, helping practitioners address why smart people sometimes make dumb decisions.

The presenter has experimented with applying the Behavioral Audit to other risk scenarios: non-conforming supplier parts in a manufacturing enterprise, inadequate infection control in a health care setting, and liability from serving alcohol at an open party. In this presentation, the six biases are explained and Behavioral Audit examples are illustrated, leading to group discussion on how the Ostrich Paradox empowers Quality professionals to better predict and proactively address how people react to risk hazards in a variety of settings.

Bio: John Predmore worked for 30-plus years as a manufacturing quality engineer, primarily in the automotive industry. Since 2008, John has worked for various companies in different regulated industries, allowing comparison of best practices in problem-solving and in risk reduction approaches. John is a Mechanical Engineer with a Management MBA degree from Wharton and a Masters degree in Engineering Management and statistics from University of Dayton. John's professional interest in the prevention of human error, led to his interest in the psychology of well-meaning people who make mistakes or poor decisions. In his spare time, John has been involved in many volunteer organizations, was trained as an EMS incident commander, has taught Health and Safety classes for the American Red Cross, and is an alumni officer for a national Greek letter fraternity.

Track 2 - Session 3

"Considerations in the Development
of Color Measurement Traceability and Uncertainty"
Lon Smith, Quality Assurance Manager, FluxData, Inc.

Abstract: Color is a matter of perception and subjective interpretation. Human beings draw upon different references and personal experiences when they try to express color in words. Color maybe described as "olive-green", "ocean-blue" or "white as snow". Differences in hue, lightness and saturation require more objective descriptions.

Precise color measurement and the communication of color measurements have led to a dedicated science and development of color measurement standards and their associated measurement uncertainties. Color science requires one to use measurement protocols to document the what, when, where, why, how and how often a measurement should be made as well as the storage and planned analysis of the measurement data collected.

Relative data has value, but there is much greater confidence in manufacturing when measurements are tied to a defined and agreed upon standard. Traceability to intrinsic standards and artifacts that are defined by National Standards Laboratories is required and is a costly venture, but necessary. One needs to carefully consider several factors before deciding how to best develop and support internal reference. What measurement equipment should you use? How do you compare equipment capabilities, what needs to be developed in your protocol? These are some of the questions one must ask when developing internal standards.

Ultimately, the development of traceable color measurement standards and the associated measurement protocols leads to product improvements, more reproducible manufactured goods and increased customer confidence.

Bio: Lon Smith is currently the Quality Assurance Manager at FluxData, Inc. He has leveraged his BSEE and MS in Computer Integrated Manufacturing degrees from RIT to develop products and processes in a broad range of technologies from color and imaging science, fiber optics, bio-medical applications, military applications and manufacturing processes.

Lon has developed quality management systems, developed training programs, secured bio-medical patents, designed and fabricated test equipment, and enjoys leveraging continuous process improvements to save millions of dollars for corporations.

Track 2 - Session 4

"Validation: What's In It for Me?"
Kathy Bannon, Ortho Care Global Quality Manager, Ortho Clinical Diagnostic

Abstract: Whether or not your business quality system is set up against an ISO standard or any regulation, validation is a smart business practice that supports the consistent delivery of quality products, impacting customer satisfaction and the bottom line.

The validation process is made up of various qualifications, from the process design stage through commercial production. Are you starting a new production line or introducing a new product onto an existing line? Are you changing out a part in your manufacturing equipment or changing a raw material source? Each scenario requires a custom validation plan to fit its circumstances and meet the desired outcome.

This interactive presentation will review benefits of validation, the Qualifications ("IQOQPQ"), and considerations for building a robust validation plan. We will use relatable examples to demonstrate a variety of validation concepts.

Bio: Kathy Bannon has over 30 years of Quality Management System experience, leading teams supporting change control, validation, corrective and preventive actions, training, and project management. She is a Johnson & Johnson Certified Process Excellence Black Belt and an AdPro Certified Change Management Professional. She currently serves as ASQ Rochester Section Vice-Chair and co-chair of the Women's Leadership Initiative at her company.

Track 2 Session 5

"Is it a Quality Problem or a Decision-Making Problem?
Assessing/Ensuring Your Product's Conceptual Integrity"
Greg Keyes, Principal at Conceptual Integrity Consulting

Abstract: Do your products suffer from hardware/software defects, even after "complete verification testing"? Do you deliver features "according to requirements", but still miss the mark of expected user-

experience outcomes? Does your organization ever fail to make the "right decision" with respect to feature addition or defect-fix prioritization? Do you want to help your organization get it right the first time?

If you've answered yes to any of these questions, it's time to assess your product's conceptual integrity and how it can be used to improve decision-making, planning, and quality of your products.

This talk is inspired by Fred Brooks' The Mythical Man-Month, which introduced the term conceptual integrity, and AAMI/ANSI/IEC62304 Medical Devices – Software Lifecycle Processes, which emphasizes an analytical risk-based process. A framework will be presented that enables transparent cross-functional decision making to be applied to feature assessment, defect assessment, and prospective solution designs.

It is a qualitative and analytical method, which, when applied appropriately, prior to development and testing, yields products of higher reliability and higher customer acceptance than traditional product development and testing-centric quality methods. While compatible with software life-cycle-processes (e.g., agile, waterfall), it is also applicable to hardware products.

Attendees will learn to recognize key factors enabling consistent product features and quality, i.e., conceptual integrity, and how to apply those factors against the products, features, and known defects planning and implementation schedules. Further, they will learn how to engage the appropriate stakeholders in the decision-making and prioritization process such that there is organizational transparency and alignment. Detailed examples will be given.

Bio: Greg Keyes has over 30 years of experience in software and medical devices development. He has held roles in software engineering, software simulation, software architecture, systems engineering, and software engineering management. As a former employee of Johnson & Johnson's Medical Devices and Diagnostics Group, he was a recognized software engineering and software quality process expert, helping to establish processes and best practices for software quality and software vendor engagement. As Manager of Software Engineering, at J&J's former Ortho Clinical Diagnostics business in Rochester, as he simultaneously oversaw the software releases of several different medical devices and managed the people who developed the software for those products. He revamped Ortho's software development process to be compliant with IEC62304, an FDA-recognized consensus standard, and he developed best practices that further increased the quality of Ortho's products.

Greg has an M.S. in Software Development and Management (now Software Engineering) from R.I.T. and a B.A. in Computer Science and Mathematics from S.U.N.Y. Potsdam. He received the Johnson & Johnson Global Leadership award for contributions to the successful development and commercialization of the VITROS 5600 blood analyzer. He holds a patent, "Liquid level detection using container bottom sensing", which provides a software-based risk mitigation to the automated sample dilution process on the VITROS 250/350 clinical chemistry blood analyzer. He is Principal at Conceptual Integrity Consulting, a software process compliance and software innovation business, where he shares his experience and knowledge in a way that continues to positively impact patients and healthcare professionals as well as overall healthcare.