North Jersey Section
The Global Voice of Quality™

ASQ NORTH JERSEY SECTION 304
SPRING QUALITY CONFERENCE

2018

CELEBRATING XL OF QUALITY EXCELLENCE

Thursday, March 29, 2018

Hanover Marriott
Whippany, NJ
Route 10 East
Near I-287

Four Concurrent Tracks with Sixteen Presentations

Visit our website at
www.springqualityconf.org
to initiate registration

The North Jersey Section 0304
of the American Society for Quality (ASQ)
Presents

"CELEBRATING XL OF QUALITY EXCELLENCE"

You are invited to attend the ASQ Spring Quality Conference

Featured topics in four concurrent tracks are: Best Practice, Leadership, FDA/EU Regulated, and Quality Approaches.

There are sixteen different presentations: Dangerous Documents: Avoiding Landmines in Your Records and Emails, " Quantifying the Payoff for Enhanced Customer Experience 3.0, Making Your Company Proactive, Preventive & Engaging, Culture: A Decisive, and Almost Free, Competitive Advantage. Changes Affecting Medical Device Manufacturers - Going from Directive to Regulation in Europe Why Do Continuous Improvement Environments Repeat History & How Can Project Management Help, Talking to Decision Makers :"What to Say and How to Say it", ISO 14971 Update for FDA Regulated Industries, 9 Steps to Designing Flow in Manufacturing Offices, Business Quality Management System: progress in lean/Quality, Understanding and Overcoming Procrastination: Communication and Quality, The Crucial Role Communication Skills Play in Quality Management, An Expert Panel Discusses FDA Inspections: Handling Stressful Situations During an FDA Inspection, Global Leadership for New Economy

Note: **"Business Casual"** dress code is encouraged! (Bring your business cards.)

Date: **Thursday, March 29, 2018**

Time:

7:20 am - 8:20 am	Registration and Continental Breakfast
8:20 am - 4:00 pm	Presentations
7:30 am - 3:00 pm	Exhibits

Location: Hanover Marriott, 1401 Route 10 East, Whippany, New Jersey

- The hotel is off the EAST bound lanes on Route 10, 1/2 mile west of the I-287 – Rte. 10 intersection
- If coming from I-287, take the Route 10 west exit. After driving 1/2 of a mile west, take Ridgedale/Cedar Knolls exit and U-turn to Route 10 East. The first driveway is the Marriott.

Cost: $350 until January 31, 2017, Regular fee $375 until Feb 28, 2018, $400 after Feb 28, 2018.

Cancellations and no-shows will be billed.

If the registrant is unable to attend, you can:

- Send a substitute at any time, even at onsite registration
- Received a full refund, less $50.00 processing fee by **Feb 28, 2018**
- No refunds after **March 10, 2018**

Registration information: Visit our Website at www.springqualityconf.org.

Conference Chair: Lucy Kahn, lkahn3@verizon.net
Program Chair: Mike Parrillo, parrillosr@aol.com
Exhibit Chair: Carl Perini, cperini@njit.edu
Registration Chair and Co-Chair: Stephen W. Becker, swbecker3@comcast.net, 908-966-6744 cell, 908-931-0247 home

0.8 RUs WIL BE EARNED BY ATTENDEES

"Special prizes will be raffled at the end of the last session for free four (4) ASQ Certification Courses worth $690.00 each."

Management reserves the right to make cancellations and changes without notice.

Keynote Speaker

Nancy Singer, JD, LLM, RAC, FRAP

Assistant Professor at George Washington University School of Medicine and Health Sciences

Nancy Singer JD, LLM, RAC

Abstract - In this hands-on session, attendees will see how sarcastic emails, cryptic Post-It notes, and hastily written documents can have dire consequences for the employee and the organization. The attendees will be given the tools to create a program to educate their colleagues on how to write documents that just state the facts, issues, and actions.

About the speaker –

Nancy Singer, JD, LLM, RAC, Assistant Professor George Washington University's School of Medicine and Health Sciences

Nancy Singer specializes in the professional development for government and industry professionals.

She presently teaches good documentation practices to the investigators and compliance officers in FDA District Offices, and the reviewers in FDA Staff Colleges. Previously she served as Special Counsel for the Advanced Medical

Technology Association. For her efforts to improve communication between the government and the regulated industry, Nancy received Vice President Gore's Reinventing Government Hammer Award and the FDA Commissioner's Special Citation.

She began her career as an attorney with the United States Department of Justice doing litigation for FDA enforcement cases. Subsequently, she was a partner at the law firm of Kleinfeld, Kaplan, and Becker. Nancy is a retired commander in the Naval Reserve.

Track 1 -

Moderator: Jennifer Page

Quantifying the Payoff for Enhanced Customer Experience 3.0, Making your Company Proactive, Preventive & Engaging

John Goodman, Vice Chairman of Customer Care Measurement and Consulting

Abstract-

Objectives:

- Understand both consumer and B2B customer behaviors that lead to preventable problems, dissatisfaction and increased service costs
- Create a Business Case the CFO and CMO will accept for investment in Quality
- The difference between tactical quality and strategic customer experience
- Non-traditional approaches to measuring client satisfaction
- How to evaluate and enhance your VOC process to double its impact

You will learn

- Why your best customers, especially in B2B, often do not complain when they are unhappy
- How to quantify the revenue payoff of better quality to the CFO in a manner they will accept
- How Voice of the Customer is critical to selecting the right Quality/LSS projects
- How to migrate LSS projects to marketing and sales
- How to use an enhanced VOC to identify opportunities for anticipation and prevention
- Eight key factors for an effective, impactful Voice of the Customer process
- How to work with the CIO to produce data valuable to quality and use the CRM to anticipate and prevent service issues.
- Via a practical group exercise, identify candidates and evaluate and quantify each participant's company's three biggest short term opportunities

About the speaker(s)–

Mr. Goodman is Vice Chairman of Customer Care Measurement and Consulting (CCMC). He graduated from Carnegie Mellon University with a B.S. in chemical engineering. He received an M.B.A. from Harvard Graduate School of Business Administration in 1971. In 1972, Mr. Goodman became a co-founder of TARP where he led research on customer service and complaint handling. His team created CCMC in 2001.

The American Management Association published his book, *"Strategic Customer Service"*, in May, 2009. This book has been translated into four other languages and reach number 1 on Amazon.Japan.com business books. His new book, *"Customer Experience 3.0"*, was published in 2014 and is now also available in Chinese and Japanese. He has nine articles in Quality Progress, the latest on *"Applying LSS to Marketing and Sales,"* published in June 2017.

Over the past 40 years, Mr. Goodman has managed more than 1,000 separate customer service and experience studies for 45 of the Fortune 100 where a key focus was quantifying the payoff of enhanced quality and experience. His research fostered the conventional wisdom, "It costs five times as much to win a new customer as to keep one." and "Twice as many people hear about a bad experience as a good one."

He managed the White House sponsored evaluation of complaint handling practices in government and business; studies of word of mouth and the bottom-line impact of consumer education sponsored by Coca-Cola USA; and a dozen benchmarking studies of customer service, complaint handling, voice of the customer processes and the use of technology for service. He has taught service quality and service reengineering courses at Wharton Business School's executive education program as well as in Ohio State's MBA program. He has appeared on *"Good Morning America"*, National Public Radio, the Discovery Channel, the ABC Evening News, and as a panelist on the PBS show, *"The Editors."*

He personally visited and assessed the customer service/complaint handling systems of over 1200 corporations and government agencies. Some of his private clients have included American Express, Salesforce.com, Harley Davidson, USAA, Apple, SunTrust, CitiGroup, 3M, Xerox, FedEx, J&J, Allstate, Zurich Risk Management, American Agriculture Insurance, Chick-Fil-A, Toyota/Lexus, Hyundai, McDonnell Douglas, Milliken, Baxter Healthcare, Prudential, ServiceMaster, GE Capital, Sprint, Sears Home Improvements, IBM, Neiman Marcus, McDonald's, Pitney Bowes, Charles Schwab, British Airways, British Gas, Cathay Pacific Airways, Komatsu, John Deere, Amtrak, Kroger Co., Goodyear Tire & Rubber, Marriott, General Motors and Clorox.

Government clients have included the U.S. Department of Agriculture, the National Highway Traffic Safety Administration, the Federal Reserve Board of Governors, the Consumer Product Safety Commission, the Federal Aviation Administration, the Food and Drug Administration, key member agencies of The Intelligence Community and the US Postal Service.

Why do Continuous Improvement Environments Repeat History & How can Project Management Help?

Brian J. Galli, Ph.D.
Professor, School of Computer Science, Innovation, and Management Engineering

Abstract - There are countless examples where organizations deploy continuous improvement initiatives in order to improve their organizations; while the gains last for a time, more often than not, many organizations fail to sustain their continuous improvement initiatives and these programs either have to be redeployed or abandoned. Many chose to redeploy the continuous improvement initiative, but without changing their approach, so history tends to be repeated. Research shows there are several reasons why organizations fail to deploy and sustain continuous improvement initiatives. The purpose of this research is to discover and analyze the risks involved with deploying and sustaining Lean Six Sigma. These risks often lead to success or failure of Lean and Six Sigma deployment or sustainment. The risks identified fall into several major themes, including: process, organizational, cultural, technical, political, and operational. Many of these risks can be resolved by integrating tools and concepts from project management into continuous improvement. From here, a theoretical framework and roadmap was developed which overlaps and outlines how and where project management tools can be deployed in a continuous improvement approach (such as DMAIC) in order to increase the likelihood of a successful deployment and sustainability.

About the speaker(s)–
Dr. Brian J. Galli works as an Assistant Professor of Project Management and Management Engineering at Long Island University – Post. He holds a doctoral degree in Engineering Management from Old Dominion University, earned December 2013. He also holds a Bachelors of Science in Industrial Engineering, earned May 2007, from

Binghamton University (SUNY Binghamton), as well as Masters of Science in Engineering Management, earned July 2009, from Missouri University of Science & Technology. He is a licensed professional engineer in New York State and holds a certification as a Lean Bronze, Lean Six Sigma Blackbelt, Project Management Professional (PMP), Professional in Engineering Management (PEM), and an Improvement Advisor.

The author's major field of study is deployment and sustaining of continuous improvement and project management. His work has been published in a variety of different publications and has been presented at several venues and professional organizations including: Institute of Industrial & Systems Engineers (IISE), American Society for Quality (ASQ), American Quality Institute (AQI), Society for Health Systems (SHS), American Society for Engineering Management (ASEM), Project Management Institute (PMI)

He currently teaches undergraduate and graduate courses in areas of continuous improvement, management engineering, and project management in the College of Management at Long Island University – Post. He also owns Apex Strategies, Ltd, a company that that specializes in continuous improvement consulting and training initiatives. He has over 9 years of experience in applying industrial engineering and continuous improvement tools and concepts in a wide variety of arenas, including healthcare, manufacturing, transactional, and service environments. He has spent several years working for Northwell Health (formerly known as North Shore LIJ Health System) in New York and 1 year in the health plan business at the EmblemHealth Service Company.

Lean into ISO 9001

James August, ASQ CMQ/OE, CQA
CCL Label Co.

Abstract - Many of us are faced with simultaneously managing a traditional conflict: balancing innovation in operations against stiffening process controls driven by our customers. To accomplish this, our businesses may follow several regimes in the ISO family as well as some that are not: Lean/Six Sigma, FDA cGMP, BRC, and Baldrige framework, to name a few. And each of these contributes unique concepts as to how we might better manage our business.

CCL Label East Coast Operations is made up of three manufacturing entities that work synergistically to provide value to our employees, our customers and our stakeholders. We share the best of our methods to maximize our effectiveness without compromising the uniqueness of our individual offerings. As part of our lean philosophy, we seek ways to reduce overlap (waste) across our functions.

This presentation walks through the process that East Coast Operations has made in lean/Quality, from initial concept and lean training to integration with the business quality model. The authors present a structured Business Quality Management System (BQMS) that integrates a classical lean approach within a Plan-Do-Check-Act process for developing and executing its business plans.

About the speaker(s)–

James August is a quality professional with over thirty years' experience in commercial, industrial and military/aerospace manufacturing. Currently, Jim is Quality Assurance Manager for CCL Label (Robbinsville) where he is working on integrating ISO 9001, GMPs and Lean Manufacturing into a single business quality management system.

As a Senior member of ASQ, Jim belongs to the Princeton and South Jersey sections. He is an ASQ Certified Quality Auditor since 1993 and a CMQ/OE since 2008. Jim was

active in Quality New Jersey between 1991 and 2007 where he served as a state Baldrige examiner and the Administrator for their Performance Excellence Network.

Always interested in Quality education, Mr August has taught quality management courses at Rutgers, Raritan Valley Community College and Middlesex County College. Jim is a workshop leader and trainer for ISO 9001 and ASQ CMQ/OE and CQE certification refresher courses. He has a wide range of professional interests and is often a guest lecturer at Rutgers in addition to being a regular presenter to ASQ local section and regional programs.

Global Leadership for New Economy

Jay P. Patel, President and CEO
Quality & productivity Solutions

Abstract - Effective leadership skills create and sustain organizational values, direction, customer focus, robust processes and promote performance excellence.

The presentation will cover:

- Acquiring the leadership skills necessary to champion global improvement
- Creating and promoting an environment of quality and productivity
- Deploying robust processes within an organization
- Communicating, empowering and motivating employees
- Focusing on organizational objectives and improving performance to realize the vision
- Fostering Management responsibility for Quality Management Systems

About the speaker(s)–

Jay Patel is CEO of Quality & Productivity Solutions, an international consulting and training firm specializing in Six Sigma, Quality Systems, Lean and Business Improvements. He has more than 25 years of experience in management and quality and has held wide-ranging positions including Plant Manager and Corporate Director of Quality, Program Manager besides a consulting assignments at many reputed companies. Jay has 10 ASQ certifications including Certified Six Sigma Black Belt. He has taught Black Belt, Master Black Belt, and Design for Six Sigma, Lean Certifications, ISO Auditor Certifications, He has Bachelor and Master Degrees in Engineering and an MBA. Jay is a RAB-Quality System Lead Assessor. Mr. Patel served at local and regional levels for the Project Management Institute, Institute of Industrial Engineers and American Society for Quality besides recipient of many awards. He is an ASQ fellow and has been ASQ Worcester Section Chair. Jay is Chairman of North East Quality Council (NEQC) and Conference \Chair besides NEQC's prestigious R. Shaw award recipient.

Track 2 -

Moderator: Bob Spinosa,

Culture: A Decisive, and Almost Free Competitive Advantage

William Levinson
Consultant

Abstract - The ISO 9004:2018 draft adds culture and values as "elements of organizational identity," and their importance cannot be overemphasized. Culture is defined in turn as • *"How do we live and how do we do things around here?"*1 • *"What people do when nobody is telling them what to do."*2

*"But in about 85% of companies, our research finds, employees' morale sharply declines after their first six months—and continues to deteriorate for years afterward."*3 If our company can be among the roughly 1 in 6 exceptions, we gain a decisive and quite probably overwhelming competitive advantage. The ideal organization will realize a condition in which *"The health of every organization depends on every member—whatever his place—feeling that everything that happens to come to his notice relating to the welfare of the business is his own job."*4 This is the ultimate deployment of culture as *"what people do when nobody is telling them what to do,"* and the Ford Motor Company's world-changing influence during the early 20th century delivered results in the language of money, along with unprecedented hourly wages, a 40 hour work week, and the true origin of what we now call the Toyota production system.

Ford himself stated very explicitly that most of the company's productivity improvements came from hourly workers rather than from engineers. The phrase *"It worried the men"* (the workforce was then primarily male, although Ford paid women equal wages) appears frequently in the context of any kind of waste. Metal turnings from machining operations, which are normally taken for granted as recyclable outputs from product transformation, attracted immediate attention from workers who recognized them as waste. Workers recommended ways to repurpose and sell slag from the blast furnaces (as cement), which would support ISO 14001 today.

Ford's production chief Charles Sorensen added of the culture among the leaders, *"With this group, work was play. If it had not been play, it would have killed them. They were as men possessed. They often forgot to eat. They drove themselves much harder than they drove anyone else."*5 We would now call this a condition of intrinsic motivation, in which the job is its own reward. Leaders must love their work if they are to get the workers to love theirs.

Ford was not however the first leader to create a culture of engaged, committed, and empowered front-line workers. The Russian commander Aleksandr V. Suvorov (1729-1800) converted conscripted serfs, whose desire to be anywhere but the Tsar's or Tsarina's Army was so intense that they sometimes knocked out their front teeth to render themselves incapable of biting open musket cartridges, into enthusiastic, committed, and engaged soldiers who were empowered to act on their own initiative. This was in an era in which no enlisted soldier in any other army would dare do anything without an order from a superior. Suvorov's enlisted soldiers, however, saved his army by improvising a bridge entirely on their own initiative to replace one that the enemy had destroyed during the campaign in the Alps.

This kind of employee engagement requires, however, leadership commitment. Lord Byron's Don Juan dismissed as a waste of time Suvorov's success secret:

It is an actual fact, that he, Commander in Chief, in proper person deigned to drill The awkward squad, and could afford to squander his time, a corporal's duty to fulfil.

The idea that any officer and gentleman of that era would handle a musket (an enlisted man's weapon), much less demonstrate its use, was as unthinkable as the idea that a member of the gentry would work at a trade. Suvorov's personal participation, however, made it unequivocally clear that (1) the musket was important, and the enlisted soldier who used it was therefore important and (2) training was the most important thing the Russian Army did. The result was that training was every officer's top priority, which created an organization of individually competent enlisted soldiers—and competence is a prerequisite for empowerment. Suvorov won 63 battles, including those against very capable opponents like Tadeusz Kościuszko and some of Napoleon's future Marshals, while losing none. It was believed that Suvorov would

have defeated Napoleon had they met on the battlefield, and Suvorov's protégé Kutuzov eventually did.6

Henry Ford similarly spent so much time on the shop floor (gemba) that unpaid bills and undeposited checks accumulated on his desk. He fortunately had a good accountant to take care of these matters while he interacted with and got ideas from his workforce, which conveyed the unequivocal message that the shop floor and not the corner office was where the company produced value.

A modern poll shows, however, that only about 1 in 3 people rate contemporary leadership support as Excellent or Very Good (34%) while the rest rate leadership support as Fair or even worse.7 This means there is an enormous opportunity for organizations that can build cultures comparable to those created by Ford and Suvorov, and enormous peril for those that cannot. The latter are exemplified by a CEO who invited W. Edwards Deming to teach his executives Total Quality Management. The CEO introduced Deming, and then walked out of the room. Even Deming could not hold the executives' attention afterward.8 The Ford Motor Company's infamous labor relations problems meanwhile developed in the late 1930s after Ford's successors went explicitly against his leadership principles, which included a no-layoff policy that banned the discharge of workers whom productivity gains made temporarily unnecessary.

Culture, unlike sophisticated manufacturing equipment with Six Sigma capability, requires no significant capital expenditures. To paraphrase Philip Crosby, culture is free—but only if leaders devote the necessary time and effort to create it.

About the speaker–

William A. Levinson, P.E., FASQ, CMQ/OE is the President of Levinson Productivity Systems PC, which specializes in quality management systems and statistical methods. He is the author of several books on quality and management, including statistical methods for non-normal systems. He has also published an expanded and annotated edition of *Henry Ford's My Life and Work*, which encompasses the world-class lean manufacturing systems and workplace relations system that gave us the middle class and the 40 hour work week.

Talking to Decision Makers: What to say and How to Say it

Daniela Drago, PhD, RAC
Assistant Professor at George Washington
University School of Medicine and Health Sciences

Abstract - Managers are busy. They have too many things to do, and not enough time to do them. When an employee has a request, the manager expects him/her to explain the issue succinctly. Employees who are able to describe an issue in 30 seconds or less are considered assets to an organization. During this interactive session, attendees will learn how to prepare and describe an issue concisely and how to respond to a manager's probing questions. After the formal presentation, attendees will have the opportunity to apply the concepts.

About the speaker–

Daniela Drago, PhD, RAC is an Assistant Professor and the Director of Regulatory Affairs Programs at George Washington University's School of Medicine and Health Sciences. She has extensive experience in global regulatory affairs encompassing the US, Europe, Asia Pacific, and Latin America. Prior to joining academia, she worked in the pharmaceutical and medical device industry for companies ranging in size from start-ups to Fortune 500. Her experience includes regulatory compliance, strategy, and writing. Daniela has written and reviewed more than 300

global regulatory submissions, participated in numerous meetings with regulatory agencies, and provided strategic regulatory advice. During her tenure in industry, Daniela trained regulatory, quality and sales personnel.

Understanding and Overcoming Procrastination: A Guide for Procrastinators and Managers

Dave Chapman
Well Said Dave, LLC

Abstract - Everyone knows that managers never procrastinate. But sometimes we all have to work with talented, well-educated people who have a hard time with effective time management, utilizing calm work habits, and meeting production goals or deadlines. Procrastination doesn't only affect the procrastinator, it affects everyone with whom the procrastinator works. In this program, Dave gives an understanding of the causes of chronic procrastination and the techniques that are available for all of us to manage our procrastination habits more effectively. He also gives very valuable pointers for managers on how to spot team members who have a problem with procrastination, the severity of their problem, and how to help them become more productive.

About the speaker(s)–

Dave Chapman is a John Maxwell Certified coach, speaker, and trainer. He studies, writes and speaks in the areas of human productivity, social psychology and the religions of the world. Dave's work encompasses these goals:

- Helping individuals improve their productivity by overcoming the impact of procrastination in their lives.
- Training individuals and organizations in the fundamentals of leadership and understandable, effective communication.
- Providing students in high school and college the tools and techniques to manage their study time and efforts to enhance their learning skills and experiences while developing a strong sense of self-worth.
- Helping the young employees of small business understand the challenges of developing and managing a small business through his "Small Business Legacy Program."
- Helping people understand the wisdom of religious faiths and cultures other than their own.
- Understanding the science of social psychology and what enables people in one social group to impose psychological or physical harm upon people in different social groups and what we, as individuals and members of our own social groups, can do about it.

Dave teaches three courses at the Rutgers University Osher Lifelong Learning Institute:

- "Why We Hate and Why There's Hope: An Introduction to the Science of Social Psychology."
- "An Introduction to the Great Faiths of the World"
- "My Time Has Come, Now What Do I Do with It?" a course is designed to help people who have retired or are planning to retire have a richer, more fulfilling time during their retirement years.

Dave has led more than one hundred worship services at twenty Unitarian Universalist congregations in New Jersey, New York, Connecticut, Pennsylvania, and Maryland.

He is a ten-year member of Toastmasters and will receive his Distinguished Toastmaster certification in December of this year.

Dave is also a member of the Board of Directors and Secretary of the International Association for Senior Debate.

Dave's favorite writers are Dorothy Leigh Sayers, the author of the Lord Peter Wimsey murder mystery series, and C. S. Forester, the author of the Horatio Hornblower saga that takes place in the British Navy during the era of the Napoleonic Wars.

Dave surfs in the Atlantic Ocean off of Long Beach Island and loves to fly fish. He and his wife, Janice Buffalow, a Senior Manager for Regulatory Operations at the pharmaceutical company Sanofi, Inc., live in Flemington, New Jersey. You can reach Dave at *davechapman@wellsaiddave.com*

Communication and Quality: The Crucial Role Communication Skills Play in Quality Management

Dave Chapman
Well Said Dave, LLC

Abstract - What are the key components of first-class communications skills? What impact can they have on success or failure of any quality-oriented program? In this program, Dave demonstrates specific, practical and immediately useful communication skills that any member of a quality team, staff or management, can use to ensure the success of their program. Dave will also discuss some of the easy-to-avoid mistakes in communication techniques that can weaken a team's commitment to a program's goals.

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"CELEBRATING XL OF QUALITY EXCELLENCE" *http://asqnorthjersey.org* March 29, 2018

Track Moderator Room	**Track 1 - Best Practices** **Moderator Jennifer Page** Chief, Weapons, FC and SW Quality, Reliability and Safety Engineering QE&SA Dir **Salon D**	**Track 2 - Leadership** **Moderator Bob Spinosa** QA Director, Multi Packaging Solutions **Gallery**	**Track 3 - FDA/ EU Regulated** **Moderator Carl Perini** NJIT Instructor **Hanover**	**Track 4 -Quality Approaches** **Moderator Long P. Nguyen** Competency Dean, Reliability Engineering Chief, Reliability Management Office Quality Engineering & System Assurance Directorate **Salon C**
7:20 - 8:20	**Registration - Continental - Breakfast - Networking**			
Keynote 8:20 - 9:20	**<u>Keynote Speaker:</u> Nancy Singer, JD, LLM, RAC, FRAP Assistant Professor at GWU School of Medicine and Health Sciences** **Dangerous Documents: Avoiding Landmines in Your Records and Emails**			
Session A 9:30 - 10:30	**John Goodman** Vice Chairman of Customer Care Measurement and Consulting **Quantifying the Payoff for Enhanced Customer Experience 3.0, Making Your Company Proactive, Preventive & Engaging**	**William Levinson** Consultant **Culture: A Decisive, and Almost Free, Competitive Advantage**	**Tamas Borsai** Division Manager, TUV **Changes Affecting Medical Device Manufacturers - Going from Directive to Regulation in Europe**	**JR McGee** Certified Lean Six Sigma Master Black Belt CEO - Xstream Leadership Group **Overcoming Adversity with Attitude!**
10:30 - 11:00				
Session B 11:00 - 12:00	**Brian J. Galli, PhD** Assistant Professor School of Computer Science, Innovation, and Management Engineering **Why Do Continuous Improvement Environments Repeat History & How Can Project Management Help**	**Daniela Drago, PhD, RAC** Assistant Professor GWU School of Medicine and Health Sciences **Talking to Decision Makers: What to Say and How to Say it**	**Edwin L. Bills** Principal Consultant Edwin Bills, Consultant **ISO 14971 Update for FDA Regulated Industries**	**Tim Healy** Institute for Operational Excellence Senior Faculty **9 Steps to Designing Flow in Manufacturing Offices**
12:00 - 1:45	**Lunch - Networking - Exhibitors**			
Session C 1:45 - 2:45	**James August/Jake Martin** CCL Label Co. **Management System: progress in lean/Quality**	**Dave Chapman** Well Said Dave, LLC **Understanding and Overcoming Procrastination: A Guide for Procrastinators and Managers**.	**An Expert Panel Discusses FDA Inspections: Handling Stressful Situations During an FDA Inspection Facilitated by Nancy Singer, JD, LLM, RAC, FRAP** Assistant Professor GWU School of Medicine and Health Sciences	**Paul Armstrong** Teambuilding, Ideation and Strategy Consultant eNthusaProve **Have you been put in charge of a process improvement team when you're not the boss?**
1:45 - 2:46	**Break - Networking - Exhibitors**			
Session D 3:00 - 4:00	**Dave Chapman** Well Said Dave, LLC **Communication and Quality: The Crucial Role Communication Skills Play in Quality Management.**	**Jay P. Patel** President & CEO Quality & Productivity Solutions, Inc. **Global Leadership for New Economy**	**An Expert Panel Discusses Getting Buy-in For Regulatory Compliance Facilitated by Daniela Drago, PhD, RAC** Assistant Professor at GWU School of Medicine and Health Sciences	**William Fletcher** Partner, Pharma Logic Solutions, LLC **Update on the European and US Drug Supply Chain Security Act (DSCSA) and the Drug Tracing Pilot Programs**
4:00 - 4:30				

Management reserves the right to make cancellations and changes without notice. Backup TBD

Committee Chair: Lucy Kahn
lkahn3@verizon.net

Registration
http://asqnorthjersey.org/

Website
http://www.springqualityconf.org/

Program Chair: Michael A. Parrillo
parrillosr@aol.com

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Track 3 -

Moderator: Carl Perini

The New European Medical Device Regulation: What to Expect

Tamas Borasi, division Manager, TUV

Abstract - The new European medical device regulations (MDR) and in vitro diagnostic regulations (IVDR) will come into force in May 2017.Full implementation deadlines are now set for May 2020 and May 2022, respectively. The MDR will replace the EU's current Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC). Learn about major changes in the regulatory framework and ways in which device manufacturers are developing plans to meet these changes and to determine the impact on their business.

About the speaker–

Tamas Borsai is a Division Manager of Non-Active Medical Devices at TUV SUD America Inc. Tamas has over 20 years of experience in auditing medical devices manufacturers in the US, Europe, and Asia. In the past he held positions as lead auditor, technical certifier, and country manager. Much of his technical expertise is focused on active medical devices as a graduated electric engineer and IT expert.

ISO 14971 Update for FDA Regulated Industries

Edwin L Bills
Consultant

Abstract - The medical device risk management standard, ISO 14971, is currently being updated and will likely appear in the 4th quarter of 2019. The update will include revision of the companion guidance document ISO TR 24971. The companion guidance will now include all informative guidance formerly contained in the ISO 14971 standard, with the exception of the Rationale in Appendix A. The informative annexes are being extensively revised based on comments received by ISO during the recent voting process.

The requirements in the base standard, ISO 14971 will be only revised slightly to improve the understanding for the reader. In this presentation, we will provide information on the expected revision of the standard and guidance based on our participation as a member of the ISO Technical Committee, ISO TC 210 JWG1 responsible for the revision.

About the speaker–

During his career in medical devices, **Mr. Bills** has held a number of quality and regulatory affairs positions including a recent period as Corporate Director of Risk

Management. He has over 30 years' experience in the field of quality and regulatory affairs. Currently he consults and provides training in the area of medical device quality, regulatory and risk management. He co-authored Lifecycle Risk Management for Healthcare Products: From Research Through Disposal published by PDA.

Mr. Bills was also a member of the adjunct faculty serving Virginia Tech's graduate online degree program in Health Products Risk Management. ASQ has awarded Mr. Bills with Fellow status as well as Certified Quality Engineer, Certified Quality Auditor, Certified Manager of Quality and Organizational Excellence, and he is a Regulatory Affairs Certified by the Regulatory Affairs Professionals Society.

Mr. Bills serves in international standards work, currently participating in the revision of ISO 14971 risk management standard as an international member of the technical committee. He also serves on the US national committee for the medical devices quality system standard, ISO 13485 and the technical committee developing a combination products risk management guidance.

An Expert Panel Discusses FDA Inspections: What to Do When

Facilitated by Nancy Singer, JD, LLM, RAC, FRAP Assistant Professor at George Washington University's School of Medicine and Health Sciences

Panelists

Rita McIntyre, VP of Compliance Strategy and Analytics at Johnson and Johnson

Sally Thorsen, Senior Director, Global QMS& Complaints at C. R. Bard, Inc.

Steven Niedelman, Former FDA Deputy Assistant Commissioner of Regulatory Affairs

Abstract - FDA inspections are stressful because negative consequences can result if the investigator finds deficiencies in that organization's quality system. During this session, the attendees will be divided into teams and asked to discuss how they would respond to challenging situations. Then an expert panel will comment on the attendees' solutions.

About the facilitator–

Nancy Singer, JD, LLM, RAC, FRAP is an Assistant Professor at George Washington University's School of Medicine and Health Sciences. She specializes in the professional development for government and industry professionals. She presently teaches good documentation practices to the investigators and compliance officers in FDA District Offices, and the reviewers in FDA Staff Colleges. Previously she served as Special Counsel for the Advanced Medical Technology Association. For her efforts to improve communication between the government and the regulated industry, Nancy received Vice President Gore's Reinventing Government Hammer Award and the FDA Commissioner's Special Citation. She began her career as an attorney with the United States Department of Justice doing litigation for FDA enforcement cases. Subsequently, she was a partner at the law firm of Kleinfeld Kaplan and Becker. Nancy is a retired commander in the Naval Reserve.

About the panelists-

Rita McIntyre is the Vice President for Compliance Strategy and Analytics in the Johnson and Johnson's Office of the Chief Medical Officer. She is currently responsible for oversight of medical safety compliance and inspection readiness across all Johnson & Johnson sectors, including compliance in quality systems that support pharmacovigilance. Her broad background includes CAPA, medical device risk management, quality systems and compliance, product complaint and MDR reporting. Rita has

spoken extensively on subjects including risk management, CAPA, and MDR's. She holds a BS in Nursing from The University of St. Joseph; is a graduate of Johnson & Johnson Executive Quality Leadership Development; and has completed the Harvard Business School Course on Innovative Leadership.

Steven Niedelman retired from the FDA where he served as the Deputy Associate Commissioner for Regulatory Affairs and as Chief Operating Officer of the Office of Regulatory Affairs. He ensured the consistent interpretation of FDA's regulatory policies by directly overseeing offices at the headquarters of the Office of Regulatory Affairs (ORA), including the Office of Regional Operations, Office of Enforcement, and Office of Criminal Investigations. Additionally, Steve assisted in the day-to-day management of FDA's nearly 3,400 field staff responsible for investigative and laboratory operations. Presently Steve serves as lead quality systems and compliance consultant to the FDA & Life Sciences practice team at King & Spalding, specializing in regulatory, enforcement and policy matters involving industries regulated by the U.S. Food and Drug Administration. He provides strategic advice, insight and guidance to the medical device, pharmaceutical, biologics and food industries to ensure compliance with the requirements of the federal Food, Drug and Cosmetic Act.

Sally Thorsen is the Senior Director for Global Quality Management Systems and Complaints at CR Bard. She is responsible for overseeing the management of Bard's quality system for the firm's five business units. She has over 27 years of management experience in the medical device industry. During her career, she has held leadership positions at St Jude Medical, MiMedx Group, Alcon, and Beckman Coulter. Sally received her master's degree in Management Information Systems from Nova Southeastern University and her bachelor's degree in professional management from Nova University. She is an ASQ Certified Manager for Organizational Excellent and passed the examination as a lead Quality Auditor with Special Reference to Medical Devices. Throughout her career, she has been recognized by her employers for her outstanding performance and dedication.

An Expert Panel Discusses Getting Buy-In for Regulatory Compliance

Facilitated by Daniela Drago, PhD, RAC Assistant Professor at George Washington University's School of Medicine and Health Sciences

Panelists:

Christine Comerci, MBA Quality Assurance at Reckitt Benckiser

Rita McIntyre, VP of Compliance Strategy and Analytics at Johnson and Johnson

Michael Viscido, RAC Senior Director Quality and Technical Services at Mallinckrodt Pharmaceuticals

Abstract - As a quality professional, you encounter challenging situations every day. The way you handle these situations is key as it can either enhance your credibility or create hurdles for your future success. During this engaging session, the moderator will poll the attendees on how best to handle a number of challenging scenarios. Then a panel of seasoned quality and compliance professionals will provide their insights.

About the facilitator–

Daniela Drago, PhD, RAC is an Assistant Professor and the Director of Regulatory Affairs Programs at George Washington University's School of Medicine and Health Sciences. Prior to joining academia, she worked in the pharmaceutical and medical device industries for many years. She has held senior positions in global regulatory and medical affairs at F. Hoffman-La Roche, Vifor Pharma, Reckitt Benckiser, and Bausch

& Lomb. Daniela has written and reviewed more than 300 global regulatory submissions, participated in numerous meetings with regulatory agencies, and provided strategic regulatory advice. She serves on the board of directors of the Association of Graduate Regulatory Educators (AGRE). She is the Chair of the Regulatory Affairs Professional Society (RAPS) DC/Baltimore Chapter and the Expert Advisor on regulatory competencies for The Organisation for Professionals in Regulatory Affairs (TOPRA). She received her Ph.D. in Chemistry from the Swiss Federal Institute of Technology (ETH Zurich).

About the panelists-

Christine Comerci, MBA has over 30 years of experience in the quality arenas of quality assurance at the local and global level. Her areas of focus have included quality systems, facilitation of regulatory inspections, management of critical quality issues, qualification and validation, as well as training and mentoring future quality leaders. In her current role Christine leads the logistics quality team, fostering the implementation of quality principles within the supply chain operation of her current company, Reckitt Benckiser. In Christine's roles in global quality at Hoffmann La Roche and QA for Technical Research and Development at Novartis in Switzerland, she was immersed in quality management and compliance from both the US and EU perspectives. She worked with an EFPIA committee to describe the role of the QP in the changing framework of the pharma industry with increasingly more complex supply chains. Christine received a bachelor's degree in chemistry from College of the Holy Cross in Worcester MA, and masters in chemistry from Rutgers University. She earned an MBA from NYU Stern School of Business.

Rita McIntyre is the Vice President for Compliance Strategy and Analytics in the Johnson and Johnson's Office of the Chief Medical Officer. She is currently responsible for oversight of medical safety compliance and inspection readiness across all Johnson & Johnson sectors, including compliance in quality systems that support pharmacovigilance. Her broad background includes CAPA, medical device risk management, quality systems and compliance, product complaint and MDR reporting. Rita has spoken extensively on subjects including risk management, CAPA, and MDR's. She holds a BS in Nursing from The University of St. Joseph; is a graduate of Johnson & Johnson Executive Quality Leadership Development; and has completed the Harvard Business School Course on Innovative Leadership.

Michael Viscido, RAC is the Senior Director, Quality & Technical Services at Mallinckrodt, Inc. in the Hospital Therapies business unit. In this role, he is responsible for leading the development and implementation of Supplier Quality Systems, Internal Quality Compliance, Quality Engineering, Product Monitoring & Technical Services activities in addition to providing site quality leadership for both domestic and international sites. Michael holds an M.S. in Engineering Management, is a Senior Member of the American Society for Quality (ASQ), holds four ASQ Certifications (CQA, CQE, CRE, CQM) and is RAPS RAC-US certified. He has over 25 years of experience in the practice of Quality Assurance in the Medical Device and Pharmaceutical Industries and serves on the George Washington University Regulatory Affairs Program Advisory board.

Track 4 -

Moderator: Long P. Nguyen

Overcoming Adversity with Attitude

JR McGee, Certified Lean Six Sigma Master.
X-Stream

Abstract - Every day and in every situation, we each face some form of adversity. Our professional reputation as Quality Professionals depends upon how well we address and overcome these adverse situations in order to achieve our goals and objectives. Our approach determines how effectively we deal with people as we get things done. Understanding how to recognize the different sources and forms of adversity allows us to use the best technique to overcome the situation and making progress.

During this Leadership Series Session, we will look at sources, recognition and understanding, reaction versus strategy, understanding the "Circle of Resistance" and explore some effective techniques to ensure YOU are effective in a world that seems bent on making life as hard as possible for you! *Remember! We Never Choose Our Adversity…We ALWAYS Choose Our Attitude!®*

About the speaker(s)–

JR is a Certified Lean Six Sigma Master Black Belt Sensei and 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. Current Chairman for Professional Development for the LEAN Enterprise Division of the American Society for Quality. 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 world-wide. 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 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 Div); 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.

9 Steps to Designing Flow in Manufacturing Offices

Tim Healey
Senior Faculty, Institute for Operational Excellence

Abstract - During this session, Tim Healey, who co-wrote *Operational Excellence in Your Office: A Guide to Achieving Autonomous Value Stream Flow with Lean Techniques* with Kevin Duggan, will highlight the challenges in many manufacturing office environments – from purchasing to engineering – including employees constantly making subjective decisions and judgement calls about which tasks are most important and should be worked on next. With everyone filtering priorities through their own, often unique, prioritization mechanism, it is nearly impossible to connect processes to

create flow that moves information between people, departments, suppliers or customers at a predictable cadence so that the product is delivered on time.

By using the principles and guidelines of Operational Excellence, however, Tim will explain how companies can design an office where information flows from activity to activity along fixed pathways at preset, predefined times. That way, everyone will know where they get their work from, when to expect it, where they should send their work when finished and at what time. Guidelines will also enable an office to describe how information will be delivered to the customer, how the office will respond to the customer, and establish a guaranteed turnaround time.

Tim will also share how, by designing the way an office should flow information, or "normal" flow, any flow condition outside this design can be defined as abnormal flow. And that is central to Operational Excellence, since things will go wrong and it is how an office operates when they do that matters. Typically, when flow starts to become abnormal, management will intervene to help fix the problem and resume normal flow. If managers cannot resolve the issue quickly, they will call a meeting – or multiple meetings. This process can take a lot of time and effort. Instead, when an office achieves Operational Excellence, the time management will need to spend managing the services the office provides will be greatly reduced. In fact, the need for management intervention will be almost eliminated. Instead, the office will run autonomously.

About the speaker(s)–
Institute for Operational Excellence Senior Faculty Member **Tim Healey** specializes in teaching the principles of Operational Excellence in the business process sector in areas such as product development, finance, HR, engineering, and marketing. He is the co-author of the book *Operational Excellence in Your Office: A Guide to Achieving Autonomous Value Stream Flow with Lean Techniques*, has been published in *Quality Digest* and *InSide Counsel*, and is a frequent speaker on lean office topics at conferences such as IIE Annual Conference and the Mid-Atlantic Lean Conference and the Institute's Operational Excellence in Your Office live training workshop. Tim has worked globally with organizations such as Parker Hannifin, United Technologies Corporation, Bayer Healthcare, and Curtiss Wright. Prior to joining the Institute, Tim served as national business manager for H.J. Heinz in Sydney and as a brand manager for British American Tobacco.

Have You Been Put in Charge of a Process Improvement Team when You're not the Boss?

Paul Armstrong, Teambuilding Ideation and Strategy Consultant
eNthusaProve

Abstract - Have you been put in charge of a process improvement team when you're not the boss? Need to lead a team of peers? This topic will share how to lead when the going gets tough and when you don't have the mantle of authority to stand behind. Based on the powerful mandate from W. Edwards Deming to managers that their job was to "enable joy in work," this presentation will unpack what that means and what "joy in work" really is all about. Surprisingly, it's not about happy hours or even necessarily making work pleasant or fun. While those may help, this presentation will give you a concrete set of guides on how to enable "joy in work". Weaving in the work of Herzberg, Sinek, Pink and Kano, we will unveil the elegant simplicity of the Deming mandate with three basic human needs followers thirst for and leaders must provide or remove their barriers. The concept is both descriptive and prescriptive, allowing you to assess what you need to do and then have some ideas on what to do. Interactively delivered, this high-energy topic is long overdue. While intended for

those who need to lead teams when they aren't the boss, the Deming concepts are equally applicable even if you are the boss.

About the speaker–

Paul Armstrong is best described as enthusiastically passionate about helping people improve how they accomplish their goals, and a system thinker who is never thinking inside the box. Paul started and led the Performance Improvement efforts at a major defense contractor for 15 years before starting eNthusaProve, a consulting firm that helps teams enthusiastically reach for and achieve amazing results. With a strong understanding of Deming's System of Profound Knowledge, Paul has devoted over ten years to understanding and implementing Deming's frequent advice to enable joy in work, and has recently published a book on this topic. Paul has a degree in Marine Engineering from the U.S. Merchant Marine Academy, an MS in Industrial Engineering from the University of Pittsburgh and is a licensed Professional Engineer. Paul resides in Lancaster, PA with his bride of 35 years, a joyful chocolate lab looking for every opportunity to be with his giggling grandkids.

Update on the European and US Drug Supply Chain Security Act (DSCSA) and the Drug Tracing Pilot Programs

William Fletcher, Managing Partner

Pharma Logic Solutions, LLC

Abstract -

- Discuss the design and goals of pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain
- Uncover challenges associated with pilot projects, including consideration of the size and role of supply chain entities
- Identify the system attributes needed to accomplish the DSCSA's requirements
- Assess the ability of trading partners to accomplish the DSCSA's product tracing requirements, to verify product to identify suspect and illegitimate products and utilize the electronic, interoperable system of product-tracing information across the pharmaceutical distribution supply chain

About the speaker–

Mr. William (Bill) Fletcher's background spans over 35 years in pharmaceutical, enterprise software and healthcare systems. Since 2006 he has focused on traceability and serialization in life sciences. Mr. Fletcher leverages his deep subject matter and project management experience to help solve complex business problems.

Mr. Fletcher is currently focused on pharmaceutical serialization, track and trace and anti-counterfeiting for both commercial and clinical goods. He has developed serialization, traceability (track and trace) and e-Pedigree strategy, project roadmaps, user and functional requirements, vendor selection, pilot planning and tests, validation, risk or REMS assessment and project planning for multiple companies. He has been recently helping companies implement projects to comply with serialization and tracking regulations around the world, including the US Federal Drug Quality and Security Act of 2013 (DQSA), Drug Supply Chain Security Act (DSCSA), China, EU, Turkey, Argentina, India, Saudi Arabia, Brazil and others.

In July 2017, he completed his 39th commercial serialization and traceability project for global life sciences companies. In addition, he has completed multiple related projects in clinical and commercial supply chain, electronic data interchange (EDI) and business-to-business (B2B) integration, pharmaceutical and biologic packaging automation design and ERP and warehouse enhancements.

His unbiased approach has resulted in projects involving business systems such as SAP (Aii/OER/ATTP/WM/eWM), Axway, Tracelink, Frequentz (formerly IBM Traceability Server), Oracle (OPM/OPSM), JD Edwards, Acsis, rfXcel, Bosch, Cognex, ACG, Jekson, Optel Vision, Uhlmann, Körber Medipak/Seidenader, ROC-IT, TAKE Solutions, Navitas, Systech, Laetus, Xyntek/Antares Vision, Mettler Toledo/PCE and others. In addition, he has experience in regulatory compliance, validation of operating systems (computer and manufacturing) in accordance with CFR Title 21 Part 11, GxP, RUP, GAMP 4 and 5, business intelligence and knowledge systems (including portals).

Mr. Fletcher has spoken and published numerous times on issues within the pharmaceutical industry, including in the US Capital Building to congressional staff leading up to the development of the Drug Quality and Security Act of 2013 and its Title II Drug Supply Chain Security Act (DSCSA) requirements.

He is a member of several industry advisory groups and as such has had an impact on guiding the way organizations navigate the issues driving business strategy. He has managed teams of technology professionals and projects throughout the pharmaceutical lifecycle.

His experience in life sciences includes supply chain security, designing packaging/labeling execution systems (PES) and machine vision inspection systems, product serialization and labeling projects, barcoding, radio frequency identification (RFID), warehouse management, distribution systems, chain-of custody drug pedigree messaging standard (DPMS) e-Pedigree, Electronic Product Code Information Services (EPCIS), Advanced Shipping Notices (ASN) and partner integration for serialization, supply chain track and trace and improving overall equipment effectiveness (OEE). Mr. Fletcher holds an engineering degree, is a long standing member of the Project Management Institute (PMI), GS1 (traceability, RFID and barcoding standards) and has received various industry certifications, including training for configuring and maintaining SAP Auto identification infrastructure (Aii), SAP Advanced Track & Trace for Pharmaceuticals (ATTP) serialization and the GS1 Certified Professional (demonstrating a detailed understanding of barcoding and serialization standards).

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