North Jersey Section
The Global Voice of Quality™

ASQ NORTH JERSEY SECTION 304
SPRING QUALITY CONFERENCE

2019

QUALITY NEVER STOPS

Thursday, April 18, 2019

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

Four Concurrent Tracks with Sixteen Presentations

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

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

"QUALITY NEVER STOPS"

You are invited to attend the ASQ Spring Quality Conference

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

There are sixteen different presentations: Leading Execution with Lean Six Sigma in the 21st Century Across Risk, Sustainability, Innovation, and Process Excellence; Retrospective analysis of 10 fully implemented lean interventions at NYU Langone Health and key conditions that ensure success; Business Strategy Part 1 and 2, ISO 9004:2018 Overview and vital clauses; Leading through Change; Optimizing Accuracy and Reliability of Medical Diagnostic Device; Leadership Game!; ISO 14971 and TR 24971 Update for FDA Regulated Industries; Warning Letters, the Forgotten Five; Integrating Critical to Quality (CTP) metrics into medical device product and process design; Design Control and Risk Management for Combination Products; Making your supply chain Faster, Better, Cheaper; Value Stream Mapping at Boeing; Leading Collaborative Innovation ñ The team of the future is everywhere Around Us; Risk Assessment in Good Manufacturing Practice for Pharmaceutical Excipient Ingredients.

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

Date: **Thursday, April 18, 2019**

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: $400 until February 10, 2019, Regular fee $450 until April 10, 2019, $500 after April 10, 2019.

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 **March 16, 2019**
- No refunds after **April 10, 2019**

Registration information: Visit our Website at ***www.asqnorthjersey.org***.

Conference Chair: Stephen W. Becker, *swbecker3@comcast.net*
Program Chair: Mike Parrillo, *parrillosr@aol.com*
Exhibit Chair: Carl Perini, *cperini@njit.edu*
Registration Chair: Archana Kakirde, *a_kakirde@hotmail.com*
Marketing Chair: Linda Lanotte, *llanotte@plastomatic.com*

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

Beau Keyte

Is there a soft landing in your future?

Beau Keyte

Most of us see a path to travel on our organization's future and transformation. How does that fit with reality? Beau will challenge your thinking in how to best position your operations for success, the path that might be best to choose, and your role in it.

About the speaker –

Beau began his "lean" consulting career in the mid-80's in the automotive industry, transitioned to adapting lean techniques to service and administrative processes in 1992, and has since progressed from implementing tools and techniques to developing and teaching the kind of self-sufficient thinking that challenges work and management processes, improves organizational performance and alignment, and sustains culture change. He now spends most of his time creating new ways for organizations to engage, learn, grow, and succeed within strategic transformation efforts.

In addition to assisting companies in implementing lean strategies, he is a faculty member and instructor for curriculums at the Lean Enterprise Institute, the University of Dayton, and the Shingo Prize Institute. Beau is the co-author of a number of journal articles and the Shingo-prize winning books The Complete Lean Enterprise: Value Stream Mapping for Office and Services (2nd Edition 2016); and Perfecting Patient Journeys (2012). Beau holds BSE and MBA degrees from the University of Michigan.

Track 1 -

Moderator: Jennifer Page, Weapons, FC and SW Quality, Reliability and Safety Engineering Picatinny Arsenal

Leading Execution with Lean Six Sigma in the 21st Century Across Risk, Sustainability, Innovation and Process Excellence

Lesly Regis, Certified GE Master Black Belt

Abstract- FDA and other regulatory bodies are rethinking their approaches to better streamline the premarket regulation of medical devices. Examples of this include the Premarket Approval (PMA) Critical-to- Quality Pilot Program, Digital Health Software Precertification Program, and Medical Device Single Audit Program. The integration of critical-to-quality (CTQ) metrics into the traditional design controls cascade addresses product quality and manufacturing processes by the utilization of a "holistic" or total product lifecycle approach. This is a more comprehensive mechanism for product and process design in the development phase. Additionally, having these metrics in place allows for a more robust method for evaluating changes to product or process. Used in conjunction with risk management and continuous improvement methods, the CTQ approach can better address the changing global regulatory landscape and improve the speed and quality of the products brought to market. The aim of this presentation is to describe how CTQ indicators may be developed, how risk assessment tools may be used to address product and process design, and product lifecycle management may be improved as a result of this approach.

About the speaker(s)–

Lesly Régis' passion is to improve individuals, teams and organizations. He implements complex improvement initiatives within functions and across enterprises by transforming business operating models to deliver effective solutions. He is adept at Team Problem Solving across the product life cycle, from concept to production through working in a wide variety of industries, including Manufacturing, Chemical and Financial Services, on products ranging from nuclear power plants and land combat systems to credit cards and retail banking. Lesly has worked in over nine businesses within GE and HSBC Bank. He managed the Quality Assurance function for two GE businesses. He has strengths in Risk Management, Lean Six Sigma, Process Control Engineering and Shared Services' creation and migration. His interest in Continuous Improvement and Problem Solving go back a long way. He started the 10th grade in New York City without knowing any English, completing high school in three years. He started his career as a hotel bellhop and worked his way to engineering school. He received a Bachelor's Degree in Industrial Engineering from Pratt Institute, Brooklyn NY. He is a certified GE Master Black Belt, and a Stanford University Certified Project Manager (SCPM). He has two patents for Process Migration & Accounting Center of Excellence Management. Lesly's drive and passion are to

tackle complex problems by building and coaching individuals or teams and helping others articulate goals and successfully execute their plans.

Retrospective analysis of 10 fully implemented Lean interventions at NYU Langone Health and key conditions that ensure success

Paola Torres, Director of Supply Chain Transformation and Integration
NYU Langone Health

Abstract- Attendees will walk out with a clear understanding of keyattributes required to successfully lead and implement a continuous improvement initiative within their organization.The Lean methodology promotes the use of Kaizen events or Rapid Improvement sessions as a key tool for process optimization. Kaizen events constitute one of the key Lean activities that NYU Langone Health currently deploysas part of their Lean Management Journey. To identify key attributes or conditions that contribute to the successful implementation of the outcomes of a Kaizen session, a retrospective analysis of 10 successfully implemented Lean interventions (FY 2016-2018) was performed. This presentation summarizes a qualitative analysis of essential attributes (pre, during and post Kaizen session) identified by the Lean team as essential for success.

3-5 Objectives:

- Identify conditions or attributes required to lead and implement a Lean initiative
- Gain a clear understanding of basic strategies to overcome Lean initiatives barriers
- Learn to anticipate organizational gaps that will impact the deployment of Kaizen events as a key Lean activity

About the speaker(s)–

Paola Torres is the Director of Supply Chain Transformation and Integration at NYU Langone Health. Paola received her Black Belt Certification from Rutgers University/Lockheed Martin in 2013. In her current role she is responsible for Identifyingopportunities to improve Supply Chain processes and implementing industry best practices. Prior to joining the Supply Chain team, Paola was a Senior Lean Six Sigma Facilitator in the NYU Lean Management Office. She has led over 35 Rapid Improvement Events, or Kaizens. In addition, she has been instrumental in spreading Lean culture at NYU by translating her on-the-ground experience into case studies that are used by the Lean Management office to train staff.

Paola has also worked with the Joint Commission and the Clinical Laboratory Sciences Institute as a subject matter expert to develop quality management standards for clinical genetic testing laboratories in the US.

Paola is currently certified in Lean Kata, Training within Industry (TWI) and a Prosci Change Management Practitioner. A native of Colombia, she received her Bachelor's degree in Microbiology from Javeriana University in Bogota and MPA in Health Care Management from New York University.

Business and Strategy, Part 1

Jose Mateo
Professional Speaker

Abstract- Strategy is typically perceived as a difficult or esoteric subject, generally left to the experts in very large organizations. José demystifies strategy, making it accessible to businesses of all sizes.

About the speaker(s)–
José holds a Bachelor's degree in Computer Science, and a Master's Degree in Computer Engineering. He holds professional certifications in Entrepreneurship and Innovation, Design Thinking, Project Management, and Lean Six Sigma. José has over 20 years of experience in Corporate America: Procter and Gamble, General Electric, and a small private equity owned firm. He has had worked in 5 different countries spanning two continents.

José runs a portfolio of real estate rental properties, and has passion and expertise in Design Thinking and Innovation, and Business Strategy. He currently leads workshops to help businesses develop winning strategies, and to help them design solutions that resonate with their customer base.

Business and Strategy, Part 2

Jose Mateo
Professional Speaker

Abstract- Strategy is typically perceived as a difficult or esoteric subject, generally left to the experts in very large organizations. José demystifies strategy, making it accessible to businesses of all sizes.

About the speaker(s)–
José holds a Bachelor's degree in Computer Science, and a Master's Degree in Computer Engineering. He holds professional certifications in Entrepreneurship and Innovation, Design Thinking, Project Management, and Lean Six Sigma. José has over 20 years of experience in Corporate America: Procter and Gamble, General Electric, and a small private equity owned firm. He has had worked in 5 different countries spanning two continents.

José runs a portfolio of real estate rental properties, and has passion and expertise in Design Thinking and Innovation, and Business Strategy. He currently leads workshops to help businesses develop winning strategies, and to help them design solutions that resonate with their customer base.

Track 2 -

Moderator: Bob Spinosa, QA Director, Multi-Packaging Solutions

ISO 9004:2018 Overview and Vital Clauses

Bill Levinson, P.E.
Levinson Productivity Systems

Abstract- The "identity of an organization" clause of ISO 9004:2018 deserves enormous attention. Frederick the Great actually identified it as a risk and opportunity more than 250 years ago; he warned of what might happen should a country arise with a national identity similar to that of the Roman Republic, in which all the citizens (relevant interested parties) felt they had a stake, in contrast to contemporary monarchies that had to rely on the lowest class of soldier available (because nobody who could find decent paying work would enlist). The French Revolution created such an entity, and the Prussian reaction—a corrective action in response to being used as a parade ground by the French—was to "do from above what the French did below," i.e. give all Prussians stakes in the country by abolishing serfdom, but with the reforms led by the King and the nobles. Henry Ford later proved (more than 100 years later) what worker motivation, empowerment, and engagement can do in a civilian industry. All this can be achieved without much if any monetary outlay for new technology or new equipment.

About the speaker(s)–

- Registered Professional Engineer (Pennsylvania)
- CPIM, CQE, CMQOE, CQA, CSSBB, CMfgE, CPC, FASQ, CM
- Coached clients on ISO 9001 and performed internal audits to allow correction of potential nonconformances prior to official audits by registrars.
- Developed and presented workshops in lean enterprise, Six Sigma, Theory of Constraints, design of experiments (DOE), acceptance sampling, and root cause analysis
- Regular columnist for Quality Digest (January 2011-)
- Book publications through Taylor and Francis/ Productivity Press
- The Expanded and Annotated My Life and Work: Henry Ford's Universal Code for World-Class Success (2013)
- Lean Management System LMS:2012 (2012)
- SPC for Real-World Applications (2011): first book of its kind, on handling applications that do not follow the textbook bell curve assumption.
- Beyond the Theory of Constraints (2007)
- Henry Ford's Lean Vision: Enduring Principles from the First Ford Motor Plant (2002). A complete reconstruction of Henry Ford's lean manufacturing and green supply chain system, and also his organizational and labor relations systems.
- Speaker at national quality and productivity conferences:
- Keynote speaker at Boeing's lean enterprise conference (April 2003) and International Conference on ISO 9000 and TQM (Scranton, April 2010)
- TOC World, ASQ World Conference, UBI Canon Quality Expo, AIAG Quality Conference, ISO World Conference
- Northeast PA Healthcare Reform Task Force (Dec. 2006—2011)

- Governor's advisory panel, Quality of Health Care (October 2005-January 2007)
- Society of Manufacturing Engineers' Lean Certification program (June 2005-Oct. 2006)
- Lean manufacturing training materials for Ford Motor Company (2003-2004)

Ed Barabas
President MSX Management System Xcellence

To Be Determined.

Optimizing Accuracy and Reliability of Medical Diagnostic Device

Kedar Phadke and Bernie McKay

Abstract- This discussion describes a case study of improving life and accuracy of a bodily fluid chemistry measurement device. It illustrates how a typical one year development project was completed in just four weeks. The task of developing high accuracy, high reliability instruments is a major challenge for healthcare diagnostic equipment manufacturers. Siemens Healthcare Diagnostics Company was challenged to improve life and accuracy of a chloride measurement device.

The complexity of the project meant that the team's prevailing R&D process could take a year or more to solve the problem. The lack of reliability and accuracy was impacting the organization's profitability, so there was urgency to improve the measuring device. The team utilized a new approach to mixtures experiments and comparative life measurement to optimize the design and improve life and accuracy of the measuring device in just four weeks. The result was about six fold longer life leading to major reduction in cost per test to Siemens and thus improved competitive position. There was huge improvement in accuracy, namely, 89% reduction in the standard deviation of the measurement error. The project was completed in four weeks rather than typically one year. The method facilitated successful invention on a new process and formulation and Siemens has applied to patent it.

About the speaker(s)–

Dr. Madhav S. Phadke is the Founder and President of Phadke Associates, Inc. is an engineer and a statistician who founded Phadke Associates, Inc., a leading software and services company for design and test optimization, and systems engineering process improvement. Phadke Associates develops and markets the rdExpert™ family of software tools for optimizing product designs for reliability and cost, optimizing test plans, and evaluating effectiveness of test plans. Dr. Phadke is an ASQ Fellow and a recipient of the 2011 IEEE Region 1 Innovation Award. He is the author of the first engineering textbook on Robust Design

Methods in the US titled, Quality Engineering Using Robust Design. Dr. Phadke received PhD in Mechanical Engineering and MS in Statistics from the University of Wisconsin, Madison, MS in Mechanical and Aerospace Sciences from the University of Rochester, and BTech in Mechanical Engineering from the Indian Institute of Technology – Bombay.

Bernie McKay - Sr. Reliability and Component Engineer at Marotta Controls Inc. Part Time Reliability Engineer performed prediction analysis on several defense project deliverables. Component Engineer review alternative parts due to unavailability or long lead item and life-time buys due to Diminish Material Sources (DMS) using SiliconExpert parts database. Coordinate proto-type Navy Control Panel and multiple Valve System including documentation, parts procurement, wiring with technicians. Conducted Environmental Stress Screening (ESS) on multi-voltage missile power supply.

Are you in the Game? Play the Leadership Game! Put your Leadership Skills to the Test!

Anna D. Banks, Corporate Trainer
The John Maxwell Team

Abstract- The Leadership Game is a fun, yet challenging experience designed to help you and your business or organization's team better understand core leadership principles and values.

Through this game, you will be able to raise the leadership awareness of your team, clients, and coworkers and introduce the timeless leadership principles that will bring about positive change through communication and connection!

- Test your grasp of everyday leadership values and practices
- Engage in open discussion with your colleagues in a relaxed atmosphere
- Discover ways to strengthen your team, colleagues and coworkers' leadership abilities

About the speaker(s)–
As a corporate trainer for Fortune 100 companies and an Executive Director of The John Maxwell Team, **Anna** is certified to facilitate, speak, train and coach individuals and groups in the areas of leadership development, professional skills and personal growth. Trained and mentored by John Maxwell and mentors of his world-class faculty, she is equipped with the tools, resources and experience to help you and your team improve your productivity, performance and profitability. Whether you are looking for a facilitator for group workshops, corporate training in leadership, speaking, sales, or coaching skills for your leaders, or a speaker for your next event, she has access to exclusive content that is only available through a certified Executive Director of the John Maxwell Team to help you reach your goals and objectives. Leadership is the difference maker and the deal breaker. It's how we grow organizations, communities, families and people. It's how we impact lives. But, as you also know, leadership cannot be an idea we simply talk about; leadership is the action we must live out. As a teacher, corporate

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Track Moderator Room	**Track 1 - Best Practices** **Jennifer Page** Weapons, FC and SW Quality, Reliability and Safety Engineering **Salon D**	**Track 2 - Leadership** **Bob Spinosa** QA Director, Multi Packaging Solutions **Gallery**	**Track 3 - FDA/ EU Regulated** **Carl Perini** Getinge / NJIT **Hanover**	**Track 4 -Quality Approaches** **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> Beau Keyte, Is there a soft landing in your future?, Organization Transformation and Performance Improvement Coach of the Kyte Group, Past Shingo Faculty Fellow, and past Adjunct Faculty member of the Lean Enterprise Institute.**			
Session A 9:30 - 10:30	**Lesly Regis** Certified GE Master Black Belt **Leading Execution With Lean Six Sigma in The 21St Century Across Risk, Sustainability, Innovation And Process Excellence.**	**Bill Levinson P.E. Levinson** Productivity Systems P.C. **ISO 9004:2018 Overview and vital Clauses**	**Edwin Bills** US Industry Co-chair of the AAMI **QM/WG04, on application of risk management to medical device ISO 14971 & TR 24971 Update for FDA Regulated Industries**	**Ed May Owner** President, Chief Consultant at Mayplewood Consulting **Making Your Supply Chain Faster, Better and Cheaper.**
10:30 - 11:00				
Session B 11:00 - 12:00	**Paola Torres** Director of Supply Chain Transformation and Integration at NYU Langone Health **Retrospective analysis of 10 fully implemented Lean interventions at NYU Langone Health and key conditions that ensure success.**	**Ed Barabas** President MSX Management System Xcellence	**Dan O' Leary** President at OMBU Enterprize LLC **Warning Letters, the Forgotten Five**	**Jonathon Andell** Master Black Belt & Senior Consultant Creato Performance Solutions **Value Stream Mapping at Boeing**
12:00 - 1:45	**Lunch - Networking - Exhibitors**			
Session C 1:45 - 2:45	**Jose Mateo** Professional Speakers with over 20 years of experience in Corporate America: Procter and Gamble, General Electric, and more. **Business Strategy part 1**	**Kedar Phadke** and **Bernie McKay** **Optimizing Accuracy and Reliability of Medical Diagnostic Device**	**Kanchana Iyer** Project Manager, RA at ZOLL Medical Corporation **Integrating critical-to-quality (CTP) metrics into medical device product and process design**	**Chris Boyd** Founder and Principal of Simply Best Practice, LLC. **Leading Collaborative Innovation - The Team of the Future Is Everywhere Around Us**
2:45 - 3:00				
Session D 3:00 - 4:00	**Jose Mateo** Professional Speakers with over 20 years of experience in Corporate America: Procter and Gamble, General Electric, and more. **Business Strategy part 2**	**Anna D Banks** Corporate Trainer with a Fortune 100 firm and an Executive Director of the John Maxwell Team. **Are You Game? Play the Leadership Game! Put your Leadership skills to the test!**	**Lori-Ann Woodward** Medical Device Director, Compliance Practice, at Lachman Consultant Services **Design Control and Risk Management for Combination Products.**	**Irwin Silverstein PhD** President IBS Consulting in Quality, LLC **Risk Assessment in Good Manufacturing Practice for Pharmaceutical Excipient Ingredients**
4:00 - 4:30				

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

Conference Chair: Stephen Becker
swbecker3@comcast.net

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

trainer, and entrepreneur more than 25 years, Anna's experience ranges from teaching elementary school to higher education to training executives in Corporate America. She has found, during this time, there is a global need for empowerment, mentoring, leadership and discipleship training. This passion to add value to the lives of others led Anna to seek the certification training and mentorship of John Maxwell and his team. She personally uses many of John's tools to enhance her own life and create balance and success. She knows these principles will serve you and empower you to create a life you love. This gift of helping people change their lives is Anna's calling.

Track 3 -

Moderator: Carl Perini, Getinge /New Jersey Institute of Technology

ISO 14971 and TR 24971 Update for FDA Regulated Industries

Edwin Bills, US Industry Co-Chair of the AAMI, QM/WG04, on application of risk management to medical device

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 27 year career in medical devices, **Ed** has held a number of quality and regulatory affairs positions. He is an ASQ Fellow and is ASQ Certified as Quality Engineer, Quality Auditor, and as Manager of Quality/ Organizational Improvement. Ed is also Regulatory Affairs Certified through the Regulatory Affairs Professionals Society and obtained BS and Masters degrees from the University of Cincinnati. Ed served as US Industry Co-chair of the Association for Advancement of Medical Instrumentation committee, QM/WG04, on application of risk management to medical device participated in the development of ISO 14971 risk management standard for medical devices. Ed is a current member of the ISO Technical Committee on medical device risk management. In 2016, he co-edited, with Stan Mastrangelo, "Lifecycle Risk Management for Healthcare Products from Research Through Disposal" published by Davis Publishing and available at www.pda.org. Ed has presented training courses for the American Association of Medical Instrumentation (AAMI) in the area of risk management and quality systems, and presented courses at the University of

Southern California and the University of Washington in their regulatory affairs graduate programs, and has served as an adjunct professor in the Health Products Risk Management graduate program at Virginia Tech. He has also authored several articles on medical device risk management and the chapter on risk management in "Combination Products: Regulatory Requirements and Unique Challenges", published by Davis Publishing. Currently, he is consulting in the area of medical device quality, regulatory, product liability and risk management.

Specialties: Medical Device Risk Management, Medical Device Quality Systems, US FDA medical device regulations, medical device international and US standards

Warning Letters, the Forgotten Five

Dan O'Leary, President
OMBU Enterprise, LLC

Abstract- Warning Letters to device manufacturers include the section of the regulation. Using an analysis of Warning Letters since 2008, it is easy to determine the most frequently cited sections. On this basis, one can make the case that the ten most frequently cited QSR sections represent an industry wide problem. This is particularly true if the rank order has been consistent over time. The most frequently cited QSR section is §820.100 Corrective and Preventive Action. This is often the subject of conferences, seminars, webinars, and articles. Typically, the top five cited sections get a lot of attention. However, the next five are also major problems but get little consideration in these settings. This presentation discusses these five cited sections (Process Validation, Production & Process Controls, Nonconforming Product, Quality Audit, and DHR), describes the problem types in theWarning Letters, and provides recommendations for effective implementation to avoid a 483 and a subsequent Warning Letter.

About the speaker–

Dan O'Leary has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. He has a Masters Degree in Mathematics. His professional experience relates to quality, reliability, project management, and operations management. Dan is the President of Ombu Enterprises, LLC, a company offering training and execution in Operational Excellence. He is an ASQ Certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; he holds an APICS certification in Resource Management.

Integrating critical-to-quality (CTP) metrics into medical device product and process design

Kanchana Iyer, Project Manager
ZOLL Medical Corporation

Abstract- FDA and other regulatory bodies are rethinking their approaches to better streamline the premarket regulation of medical devices. Examples of this include the Premarket Approval (PMA) Critical-to-Quality Pilot Program, Digital Health Software Precertification Program, and Medical Device Single Audit Program. The integration of critical-to-quality (CTQ) metrics into the traditional design controls cascade addresses product quality and manufacturing processes by the utilization of a "holistic" or total product lifecycle approach. This is a more comprehensive mechanism for product and process design in the development phase. Additionally, having these metrics in place allows for a more robust method for evaluating changes to product or process. Used in conjunction with risk management and continuous improvement methods, the CTQ approach can better address the changing global regulatory landscape and improve the speed and quality of the products brought to market. The aim of this presentation is to describe how CTQ indicators may be developed, how risk assessment tools may be used to address product and process design, and product lifecycle management may be improved as a result of this approach.

About the speaker–
Kanchana Iyer is currently Project Manager, RA at ZOLL Medical Corporation in Chelmsford, MA. She began her career as a biomedical engineer at the FDA where she was a premarket reviewer of device submissions in ODE. Kanchana recently participated in a roundtable discussion with FDA Commissioner Gottlieb that covered many issues including overcoming regulatory hurdles in the devices and drugs approval processes. Kanchana has a Master's of Science degree in biomedical engineering.

Design Control and Risk Management for Combination Products

Lori-Ann Woodward, Medical Device Director, Compliance Practice
Lachman Consultant Services

Abstract- This session will review a streamlined approach to develop medical device constituents for combination products. The session will begin with high level requirements established from the drug Target Product Profile and drill them down to Design Control requirements. We will walk through the combination product design control development process and discuss how Risk Management, Human Factors and Clinical Trials are harmonized to release safe and effective combination products for commercialization.

About the speaker(s)–
Lori-Ann Woodard is Director, Medical Device in the Compliance Practice at Lachman Consultants. With more than 20 years of experience, Ms. Woodard delivers expertise in the creation and implementation of Quality Management

Systems for Medical Devices including Software as a Medical Device (SaMD), and for Combination Products. She is an expert with extensive knowledge and application of the Code of Federal Regulations and International Standards in the Medical Device, Combination Product, and Pharmaceutical industries. This includes applied knowledge of current FDA guidelines for Mobile Medical Applications and FDA Software Precertification Planning. Ms. Woodard has hands-on experience in: Class I, II and III medical devices (including implants); biotech products as pharmaceuticals and as medical devices; IVDs; transdermal patches; respiratory products; polymer-based products; and prefilled syringes.

For nearly four decades, Lachman Consultants has been the leader in providing cost-effective consultation and remediation services to the worldwide pharmaceutical, biotechnology, biologic, medical device, diagnostic and dietary supplement industries. With its strong and extensive cadre of consultant specialists and an unparalleled management team, its Compliance, Science & Technology, and Regulatory Practices provide the most expert counsel and array of services available. Lachman Consultants is proud of its tradition of supporting industry efforts to develop and ensure safe, effective and high-quality medical products. It remains committed to helping the industry anticipate and address its challenges through the development and implementation of practical, sustainable.

Track 4 -

Moderator: Long P. Nyugen, Competency Dean, Reliability Engineering, Chief Reliability Management Office Quality Engineering and System Assurance Directorate

Making your Supply Chain Faster, Better, Cheaper

Ed May, Owner, President, Chief Consultant
Mayplewood Consulting

Abstract- This paper explores how today's Modern Supply Chain can (and must) be made faster, better and cheaper (in order for any given business to survive). This is possible when great management uses the most relevant Supply Chain tools to create and sustain excellence. Leadership which provides the right resources is required to develop and sustain excellence. Without an excellent supply chain businesses cannot survive.

About the speaker–
Director of QPS NJ. Teaches ASQ Certification Courses, Lean, Six Sigma, ISO 9001, Supply Chain. Years of Industry experience in Management, Engineering, Manufacturing, Service. ASQ CSSBB, CMQ/OE, CQE, CQA, CSQP. ASQ Senior member. Active in Section 304 North Jersey. BE from Stevens Tech, Harvard MBA

Value Stream Mapping at Boeing

Jonathon Andell, Master Black Belt and Senior Consultant
Creato Performance Solutions

Abstract- A VSM is effective at revealing bottlenecks and excessive inventory, along with depicting signals to relieve and replenish inventory. A spaghetti diagram qualitatively depicts physical movement through the workspace, and the 5S method lays out a workstation

for effectiveness and efficiency. However, none of these methods inherently quantify the distances and times wasted due to transport. There are tangible methods that can be followed to identify, quantify and reduce transport waste. Measurements can be used to estimate person-hours consumed during transport operations, and there are specific factors to consider for identifying and implementing improvements.

About the speaker(s)–
Jonathon L. Andell is a Master Black Belt at Verizon in Basking Ridge, NJ. When he performed the work and drafted the article, he was president of Andell Associates LLC, a quality consultancy based in Gilbert, AZ. He has a master's degree in metallurgy from Pennsylvania State University in University Park. Andell is a fellow of ASQ.

Leading Collaborative Innovation – The Team of the Future is Everywhere Around Us"

Chris Boyd, Founder and Principal
Simple Best Practice, LLC

Abstract- Lessons learned from cultivating and connecting the next generation of questions and answers. Practitioner insights from building and assessing global virtual teams and partnerships.

About the speaker(s)–
Chris is the Founder and Principal of Simply Best Practice, LLC. He brings over 30 years of global practitioner experience in pioneering quality and leading business improvement. His career resonates with the recurrent themes of partnering and collaborating to bridge organizational and customer gaps.

Blending his uniquely diverse operations and technology background with entrepreneurial know-how, Chris helps business leaders and service professionals address quality challenges and replicate client successes.

Risk Assessment in Good Manufacturing Practice for Pharmaceutical Excipient Ingredients

Irwin Silverstein, PhD, President
IBS Consulting in Quality, LLC

Abstract- This presentation will briefly discuss the rationale for using quality risk management as a foundation for development of the ANSI standard

NSF/IPEC/ANSI 363 Good Manufacturing Practice (GMP) for Pharmaceutical Excipients. The talk will identify those clauses of the Standard that rely on risk assessment with the application of risk assessment to identify the hazard and to mitigate the risk.

About the speaker(s)–

Irwin is a consultant in Quality and regulatory compliance with an emphasis on pharmaceutical excipients. He has been a sub-contracted expert consultant where pharmaceutical companies are involved in Consent Decree with the FDA

Formerly the ISP Corporate QA Director, he has worked since 1991 with IPEC to develop appropriate GMP requirements for excipients. He is currently the chair of the IPEC-Americas Training Team. He was VP and COO of International Pharmaceutical Excipients Auditing and achieved ANSI accreditation in 2010 for the IPEA Excipient GMP Certification program.

Dr. Silverstein is a member of the NSF committee that wrote the American National Standard (ANSI) for Excipient GMP. He is also performing dietary supplement verification audits for USP.

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