



San Diego
Section
The Global Voice of Quality™



2017 ASQ San Diego Quality Conference

Quality and Culture Change

Conference Theme

“Quality and Culture Change”

Organizations build and incrementally improve the capability and functionality of their quality systems to improve the effectiveness and efficiency of their business system, leading to higher productivity, cost savings, and superior employee morale. To be successful, a potent quality system impacts and reshapes an organization’s culture to not only embrace quality but live it daily. Many of the quality tools applied within our quality systems impact and modify the way we think, solve problems, and innovate.

Focus Areas:

'Creating Value through the Quality System'

Description: How does your organization’s quality system create value for customers, employees, and your leadership? How is the quality body of knowledge applied within a quality system? What are the key elements of value creation? How can we improve our ability to create value and innovate for our customers and organizations?

'Discovering the Tools of Quality and Culture Change'

Description: What are the best tools used to implement and sustain the Quality System? How can quality tools be used to improve, innovate, and change the quality culture? What new tools have been developed for use in your organizations?

'Shaping the Quality Culture'

Description: What techniques and methods are applied in your organization that mold and shape a high performance quality culture? What does it take to drive incremental cultural change in today's workplace environments? How do leaders ensure a quality culture is sustainable?

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Conference Sponsors

HOST Sponsor:



HOLOGIC, Inc., 6333 Sequence Drive, San Diego, CA

Hologic is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective molecular diagnostic products and services that are used primarily to diagnose human diseases, screen donated human blood and ensure transplant compatibility.



Silver Sponsors:



ASQ Aviation, Space, and Defense Division

Since 1954, the Aviation/Space and Defense Division has been devoted to quality-related activities as they involve the aviation, space and defense industries.

Among the areas of involvement, the most significant contributions have occurred at the Secretary of Defense level regarding government standards, specifically MIL-Q-9858 and MIL-I-45208. Accordingly, the Division has influenced the interpretation and implementation of basic specifications. Beginning in the 1960s, the Division originated and sponsored DCAS forums that served to educate and update industry on quality policies and new developments within the DoD.

In the 1980s, the Division began to organize major conferences addressing commercial aviation, space, defense and international maintenance issues: the Conference on Quality in Commercial Aviation (CQCA), the Conference on Quality in the Space and Defense Industries (CQSDI), and the International Maintenance Symposium (IMS). The IMS was merged with the CQCA in 1999. All of these meetings bring together an international audience and involve key leaders from such organizations as the FAA, other civil air authorities, the armed forces, NASA and several international space agencies.

[View Schedule](#)

2017 ASQ San Diego Quality Conference

Quality and Culture Change

ASQ Conference Schedule

Friday November 3rd, 2017

5:30p.m. – 7:30p.m.	Opening Reception and Networking Happy Hour Karl Strauss Brewery, 9675 Scranton Rd, San Diego, CA
---------------------	---

Saturday November 4th, 2017

7:30 a.m. – 1:00 p.m.	Conference Registration		
8:00 a.m. – 8:30 a.m.	Continental Breakfast on the Patio		
8:30 a.m. – 9:30 a.m.		Keynote: <u>Peter Merrill</u>, Innovation Leader Co-existence of Innovation and Quality cultures	
TRACKS:	Creating Value through the Quality System: Learning Center A	Discovering the Tools of Quality & Culture Change: Learning Center B	Shaping the Quality Culture: Café'
10:00 a.m.–10:50 a.m.	<u>Great Design Principles Applied to Manufacturing Experiences</u> Abe Chohan	<u>Common Sense Quality</u> Charlie Gragg	<u>Leadership to Improve Human Performance</u> Steve Greer
11:00 a.m.–11:50 a.m.	<u>Foreign Object Debris Control In Aerospace and Defense Manufacturing</u> Matt Strickland	<u>Value Stream Operations: Turning a startup into a mature operation</u> Nadeem Saeed	<u>STEM Apprenticeships: Shaping the Quality Culture</u> Rose Marie Christopher
12:00 p.m.–1:00 p.m.		Keynote and Lunch: <u>Dr. Jerry Mairani</u> Quality Requires Attitude	
1:00 p.m. – 1:30 p.m.	Networking Break		
1:30 p.m. – 2:20 p.m.	<u>Human Centered Design</u> Amanda Cheyney & Sandy Bauler	<u>Advanced Facilitation Techniques for Culture Change</u> Dr. Carolann Wolfgang	<u>Utilizing Audit and CAPA to Drive Cultural Evolutions in an Organization</u> Marie Graves
2:30 p.m. – 3:20 p.m.			<u>Auditing to ISO 13485:2016 and ISO 9001:2015</u> Nancy Pasquan
3:30 p.m. – 4:20 p.m.	<u>Panel Discussion: Business Leaders share techniques for Quality and Culture Change</u> Johan Deneke – Illumina, Franklin Davis – Genentech, Marisela Reyes - UTC		
4:30 p.m. – 5:00 p.m.	Closing Remarks and Conference Certificates		

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Keynote Address: Saturday November 4th

Keynote Speaker

Peter Merrill



Peter Merrill has been acknowledged as one of the world's leading keynote speakers on Innovation and has keynoted at events such as the World Conference on Quality USA, the India Innovation Summit, Oasis of Excellence Conference in France and the Asia-Pacific conference in Shanghai. As Chief Executive of one of the leading Design Brands in Europe he has been an Innovator in one of the most demanding markets.

Peter is Chair of the ASQ Innovation Think Tank and also Chair of the Canadian National Committee on Innovation for ISO. He led the International Working Group which developed the Guideline on 'People Involvement' in Management Systems and is one of North America's foremost authorities on Management Systems which he has implemented in such innovative companies as IBM, A.I.G. and R.I.M. Peter is president of Quest Management Systems which provides a unique self-assessment tool for Innovators.

He is also the Innovation Columnist for Quality Progress and author of the books 'Innovation Generation', 'Executive Guide to Innovation' and 'Innovation Never Stops'.

Peter has a Bachelor of Science in Chemical Engineering from the University of Birmingham and a Postgraduate in Management Studies from Aston University; both universities are located in Birmingham, England.

Lunch Speaker

Dr. Jerry Mairani



Dr. Jerry Mairani has done extensive research on the establishment and sustainment of quality systems. His data indicates that 30 to 40 percent of organizations fail to meet their expectations in this area, with the primary issues residing within top leadership organizational engagement. He has lectured extensively on this subject.

Jerry has a Baccalaureate in Human Relations and Organizational Behavior and a Masters in Human Relations and Organizational Science from the University of San Francisco and a Bachelor of Arts, Master of Arts and Doctor of Philosophy (PhD) in Quality Management from California Coast University; both universities are located in San Francisco.

[View Schedule](#)

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Conference Workshop Descriptions

Great Design Principles Applied to Manufacturing Experiences

[Abe Chohan](#)

Although the application of Lean and Six Sigma principles has helped reduce complexity in manufacturing processes, it is important to apply the principles of great user design in order to rise to the next level of performance.

Chohan's company (Inova) implemented design thinking to study workplace and process annoyances to fully integrate quality into its culture. He will share how Inova created an environment of openness, making everyone a design expert. In addition, he will describe Inova's system to allow all employees to own a solution through its stages (building consensus with the team; prioritization; plan, do, check, act, and celebrate).

Common Sense Quality

[Charlie Gragg](#)

Does your QMS cost your organization or benefit your organization?

Would 19th-century American humorist Henry Wheeler Shaw believe that your QMS is based upon his Common-Sense definition ("Common sense is the knack of seeing things as they are, and doing things as they ought to be done.")?

Your QMS should not be "Off-the-Shelf" and shoehorned in but should be tailored not only to your organization but how it functions within your organization.

Leadership to Improve Human Performance

[Steve Greer](#)

Leadership creates and reinforces the culture of quality in an organization. A common cultural challenge is human error, which can lead to poor quality, significant costs, customer service outages, and significant regulatory risk. The keys to improving human performance lie in changing our approach to leadership and creating a strong quality culture.

This session uses case studies from the personal care industry, where a site reduced human error by over 50% and achieved significant improvement across all business KPIs. Learn the 5 leadership keys to success for improving human performance and become a change agent in your organization.

Foreign Object Debris Control in Aerospace and Defense Manufacturing

[Matt Strickland](#)

Foreign Object Debris (FOD) control is more than just an airplane concern. The products manufactured in the Aerospace and Defense industry are critical to American defense and the survivability of our nation's warfighters. This presentation will focus on the need to instill a culture of "Attention to Detail" during the manufacturing process to ensure products are FOD free when delivered to customers. Tools and strategies to instill a FOD free culture will be a focus of the discussion.

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Conference Workshop Descriptions

Value Stream Operations: Turning a Startup into a Mature Operation

[Nadeem Saeed](#)

As Vice President of Quality and Customer Success at INRIX, Nadeem Saeed's role was to help INRIX go to the next level in their Quality journey. Through 10+ years of existence INRIX had grown into a global Data as a Service (DaaS) and Software as a Service (SaaS) leader leveraging Big Data, location technologies and the Internet of Things (IoT) to deliver apps, services and analytics tools that connect cars for smarter cities worldwide. INRIX served more than 400 blue-chip customers in more than 45 countries around the world. With this growth came the challenge to scale processes and operations that ensured consistency in delivery of services and guaranteed high customer satisfaction.

Nadeem used his experience at Motorola and Microsoft to establish an end-to-end quality strategy for INRIX globally that encompassed Sales and Marketing to engineering to infrastructure to services and operations. This presentation is about that journey and how quality is being institutionalized at INRIX.

STEM Apprenticeships: Shaping the Quality Culture

[Rose Marie Christopher](#)

Adopting Apprenticeships for STEM jobs improves the rate of success of new hires. Strategies and tools for attracting, developing and retaining top talent that include on the job online and classroom learning, together with on the job training and mentorship ensure the shaping of a culture of quality in the organization.

Human Centered Design

[Amanda Cheyney](#) and [Sandy Bauler](#)

Human-centered design (HCD) is a creative approach to problem solving. It's a process that starts with the people you're designing for and ends with new solutions that are tailor made to suit their needs.

HCD consists of three phases. In the Inspiration Phase you'll learn directly from the people you're designing for as you immerse yourself in their lives and come to deeply understand their needs. In the Ideation Phase you'll make sense of what you learned, identify opportunities for design, and prototype possible solutions. Finally, in the Implementation Phase you'll bring your solution to life, and eventually, to market. And you'll know that your solution will be a success because you've kept the very people you're looking to serve at the heart of the process.

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Conference Workshop Descriptions

Advanced Facilitation Techniques for Culture Change

[Dr. Carolann Wolfgang](#)

Our organizations are in a natural state of flux and evolution. Whether it's a planned initiative for which change management practices are being followed or unplanned cultural changes, there are tools to assist with the uncertainties and chaos. Attendees will learn different techniques to assist teams with strategies for organizational change. These include facilitation tools that may be used in different ways depending on the situation, leading to robust communication and stakeholder planning for change. Attendees will practice with their own organizational change situation that they bring to the workshop and share ideas and solutions with each other.

Utilizing Audit and CAPA to Drive Cultural Evolutions in an Organization

[Marie Graves](#)

This presentation highlights using 'best in class' CAPA and Internal Audit practices to create value propositions and drive changes in your organization. We will cover how to create relatable, risk-based problem statements as 'mantras of change'. Next, we will take a deep dive into the challenges of creating value propositions for change, and then tackle tools to help you successfully overcome those barriers. Lastly, I will share with you my personal story of how I used those tools to build a 'Cross-Functional Culture of Quality' and transformed a company from *waiting for the warning letter* to *proactive leaders of quality improvement*.

Auditing to ISO 13485:2016 and ISO 9001:2015

[Nancy Pasquan](#)

Nancy performs certification audits for ISO 13485:2016 and ISO 9001:2015, often simultaneously, for numerous companies, including those who make and market medical devices or make components for them. Some are subject to FDA scrutiny. In this presentation, she will describe her approach to the audits such as which artifacts she asks to see and what she is looking for in terms of evidence of compliance with the standards. The presentation will cover how the updated standards are being interpreted in the industry and how that interpretation may affect the audit.

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Conference Workshop Descriptions

Business Leaders Share Techniques for Quality and Culture Change

[Johan Deneke](#), [Franklin Davis](#) and [Marisela Reyes](#)

Panel members are assembled to share their experience and successes for the benefit of our attendees. The objective is to pass on tools, techniques, and methods for others to use and apply thus improving the success of quality professionals within our community.

Three questions will be posed to each panel member:

- 1) What one Quality tool or technique has provided great benefit to your organization? Please provide a short explanation of its use.
- 2) In what ways has strategic planning played a part in your organizations culture change? Please explain.
- 3) It is widely known that leadership involvement in a Quality Management System is important. How have you leveraged leadership involvement to implement and grow your quality movement?

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Speaker Biographies

Keynote Speaker: Peter Merrill

Peter Merrill has been acknowledged as one of the world's leading keynote speakers on Innovation and has keynoted at events such as the World Conference on Quality USA, the India Innovation Summit, Oasis of Excellence Conference in France and the Asia-Pacific conference in Shanghai. As Chief Executive of one of the leading Design Brands in Europe he has been an Innovator in one of the most demanding markets.

Featured Lunch Speaker: Dr. Jerry Mairani

Dr. Jerry Mairani has done extensive research on the establishment and sustainment quality systems. His data indicates that 30 to 40 percent of organizations fail to meet their expectations in this area, with the primary issues residing within top leadership organizational engagement. He has lectured extensively on this subject.

Sandy Bauler

Sandy has over 25 years of experience in workforce development in multiple sectors that include education, WIOA, private and non-profits. As a keynote, Sandy speaks to 10,000 annually around personal growth, job development, customer center design, career pathways, entrepreneurial, safety education, diversity, and motivation. Her experiences and multiple passions, creates an environment to help you observe things differently. Sandy and her team recently presented at the White House for their Customer Center Design project. Sandy is known for her ability to inspire, empower and connect her audience to success.

Amanda Cheyney

Amanda Cheyney is a Client Associate with California Manufacturing Technology Consulting (CMTC). Her areas of expertise are compliance, monitoring, contract management, program management and strategic partnerships. She has worked in workforce development, technology, healthcare and non-profit sectors. Amanda has led change management initiatives through policy development, training and technical assistance in the areas of legislative transitions, program development and data management. Amanda presented her human centered design work at the White House, Employment and Training Administration (ETA) and the National Association of Workforce Development Professionals (NAWDP) Youth Symposium. Amanda attended San Diego State University and studied abroad with Semester at Sea. She is certified in Human Centered Design by IDEO and has completed coursework in non-profit management at University of San Diego and Harvard Business School Alumni Club of San Diego.

Abe Chohan

Abe Chohan is a Chemical Engineer with an MBA and a Black Belt in Lean Six Sigma. He has cross-industry experiences ranging from Aerospace to Medical Devices and various Operational Leadership roles. He also serves on the Board of the San Diego Youth Symphony, a non-profit organization. He has a passion for people, processes and the intersection of the two.

[View Schedule](#)

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Speaker Biographies

Rose Marie Christopher

Rose Marie Christopher, a graduate of the University of Southern California with an MA in Communication Management, holds positions in the American Society for Quality (ASQ) Food, Drug and Cosmetic Division (FDC). Rosemarie has 29 years of experience in executive search and staffing services for the life sciences, placing mid-senior level STEM professionals. Through STEM Apprenticeships, Rx Research Services addresses the direct hire and staff augmentation issues of the rapidly advancing 'gig' economy and the needs of new graduates, displaced mid-career scientists and Veterans to gain entry into increasingly complex STEM jobs.

Franklin Davis – Genentech

Franklin Davis has over 15 years of experience implementing lean in different industries such as medical devices (Boston Scientific, Alere), aerospace (Space Systems Loral) and life sciences/pharmaceuticals (Danaher, Genentech/Roche).

He currently works as an Operational Excellence Leader in Genentech Roche Oceanside, his second Genentech Site. As an operational excellence leader, Franklin is involved in all areas of process improvement (site strategy, mentoring Green Belts, facilitating Kaizen, lean leadership, etc.). He has also managed manufacturing/operations groups and is an avid mentor to other leaders. Franklin has an MS in Engineering Management & Leadership (Santa Clara University), a BS in Industrial and Systems Engineering (San Jose State University) and is a certified Lean Six Sigma Black and Master Black Belt. He was a mentor to graduating engineering seniors at SJSU and often taught seminars in that campus.

Johan Deneke – Illumina

Johan Denecke is the Vice President of Life Cycle Management (Manufacturing Engineering and Science) for Illumina, whose sequencing and array technologies fuel advancements in life science research, translational and consumer genomics, and molecular diagnostics. He has a strong passion for driving world-class processes and results through strong engineering and manufacturing competency and best in class self-directed work teams.

Johan's process improvement experience includes multiple site transformations (Molecular Probes and Ambion) including an *Industry Week* "Top 10 Manufacturing Plant Award." He was also the director of Process Excellence Program at Applied Biosystems (Life technologies) responsible for their Lean Six Sigma program and the director of the lean manufacturing practice of Advanced Integrated Technologies with implementation experience in the aerospace, automotive, metals, chemical and engineered products industries. Johan also founded Lean Systems Inc. spending two years at the Lockheed Martin Skunkworks Product Development Center transforming the aircraft maintenance business.

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Speaker Biographies

Charlie Gragg

Charlie launched Software Engineering Applications Solutions (SEAS, Inc.) in 1997 and is currently the CEO. He has been leading corporate and government compliance, quality and process improvement for over 30 years. Charlie's common sense philosophy is that Quality and Compliance:

- Provide real value
- Be accomplished for the right reasons
- Be embraced by the organization
- Conducted in a "We" atmosphere

Charlie was an Adjunct Faculty member at California State University San Marcos for eight years teaching Systems Analysis and Design and Information Systems in the School of Business (High Technology Management) and MBA program. Charlie is an Advisory member to the School of Engineering and Applied Science, Miami University.

Marie Graves

Marie is a QA Compliance professional with 12 years of experience in regulated medical devices who has a proven record of success. She is currently the Quality Manager, Regulatory Affairs and Quality Assurance at NuVasive and has held previous leadership roles at pfm medical Inc., ImThera Medical, and Gen-Probe (Hologic). Marie brings an expert level of FDA and ISO auditing experience, QMS process risk management implementation (14971), supplier / distributor management, Complaint, Investigation, Nonconformance and CAPA management.

Steve Greer

Steve Greer is the External Engagement Leader in Corporate Quality Assurance for the Procter & Gamble Company. In this capacity, he is responsible for building collaborative relationships with global boards of health and industry associations. Steve is also responsible for GMP intelligence and strengthening internal quality capability to deliver consumer delight and regulatory compliance of our products.

Steve is on the core team of the ISPE Quality Metrics initiative and is also co-chair of the Quality Assurance Committee of the Personal Care Products Council. He has previously served as the chairman of the Puerto Rico Pharmaceutical Industry Association QA committee.

Nancy Pasquan

Nancy Pasquan holds a BS in Computer Science and is an ASQ Certified Software Quality Engineer (CSQE) and Certified Biomedical Auditor (CBA). She has nearly 30 years of experience working with software across (mostly) regulated industries including military, aerospace, pharmaceuticals, and medical devices. She has conducted formal and informal audits of both software and non-software organizations for the last 20 years. Over the last four years she has been conducting ISO 13485:2003 and 2001:2016 certification audits around the world.

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Speaker Biographies

Marisela Reyes – UTC

Marisela Reyes is the Sr. Director for Quality, ACE, SAP, Aerostructures, based in Chula Vista, California. Marisela became Sr. Director in April 2015, after serving as Director for the Operations Strategy & Development group in Windsor Locks CT. Marisela joined the company in 2008 as part of the ACE central office. Prior to joining the company the company, Marisela worked at Six Sigma Systems as a Senior Consultant in Lean Manufacturing. Marisela began her career at Ford Motor Company and served in various roles of increasing responsibility in Operations and engineering. Marisela holds a Bachelor of Science in Industrial & Operation Engineering from the University of Michigan and a Master of Science in engineering from Purdue University, and is currently pursuing an Executive MBA at the University of Michigan.

Nadeem Saeed

Nadeem Saeed is a senior technology executive with extensive experience leading major operational and business improvements in the mobile, wireless, infrastructure and enterprise software spaces. With Honeywell, Motorola, Microsoft and INRIX, Nadeem has led engineering and operational teams for category leading software and systems offerings that are being used in retail, logistics, healthcare, enterprise, government and consumer sectors. In engineering leadership positions, based in the US, Europe and AsiaPac, Nadeem has focused on setting up large off-shore operations. Over the past 10 years Nadeem has effectively used Quality and Customer Experience as a strategy, to enhance portfolio differentiation, optimize efficiency, while building and growing globally distributed teams. Nadeem has also led integration teams during medium to large scale M&A activities at Motorola and Microsoft. Nadeem is a certified Digital Six Sigma Software Master Black Belt from Motorola.

Matt Strickland

Matt Strickland is currently the FOD/ESD Program Manager for L3 Telemetry and RF Products in San Diego CA. He has been involved in FOD/ESD control since 2009 and in 2011 named as the Chair for the L3 Technologies FOD/ESD resource teams. Matt currently serves as a Co-Chair of the Aerospace Industries Association NAS412 standard revision committee and is an active member of the Ground Based Mid-Course Defense (GMD) FOD council.

Matt joined the L3 Technologies team in 1997 after retiring from 20 years of naval service. He obtained a Bachelor of Science Degree in Occupational Safety from Columbia Southern University in 2013.

Dr. Carolann Wolfgang

Dr. Carolann Wolfgang currently works as the Continuous Process Improvement Manager at Naval Facilities Engineering Command, Expeditionary and Engineering Warfare Center, Port Hueneme, CA. She has a PhD in Natural Resources Management and specializes in quality programs, occupational safety and health, and conflict coaching. She has ASQ certifications including CMQ/OE, CQA, and SSGB and is a Certified Safety Professional. She has extensive training in mediation/collaborative negotiation and facilitation. She has worked internationally with a broad range of organizations, projects, and cultures.

[View Schedule](#)

2017 ASQ San Diego Quality Conference

Quality and Culture Change

Conference Volunteers

ASQ San Diego Quality Conference Planning Team:

It takes a team of individuals working together to make an event like this a success. Our team of volunteers has worked for months to build an event that we hope you will enjoy and find especially beneficial. Our volunteers will be wearing the ASQ Blue Polo shirts so please let them know you appreciate their hard work and support. As there are too many volunteers to mention we make note of a few key members here;

Maria Rihana; Hologic Representative; Excellent support from the whole Hologic team.

Daniella Piciotti; ASQ Collaboration and Speaker coordinator ; Always ready to step up and get things done.

Elizabeth Rietow; Registration team lead; Consistent team support.

Lars Carlson; Book booth and materials review; Ready to lend a helping hand.

Michelle Vargas; Education and Membership booth; Speakers; “whatever you need help with”

Patricia Vilalata; Certificates, Registration Table, and material review.

Nancy Pasquan; Speakers, Registration help, and idea person.

Frances Donnelly; Publicity, and ready to help when needed.

Max Roshensky; USB loading, Registration table, and helping hand.

Craig Roberts; Conference Program.

Adriana Varvara; Education and Membership Booth.

Brooks Carder, Supplies and Keynote Speaker coordinator; Steady and constantly delivers

Jeffrey Andersen; Section Chair and Web Site updating.

Nicole Gooble; Treasurer. Keeps the bills paid.

Maria Hamilton; Friday evening networking event

Runquan Zhang; Web site updates.

Mark Claywell, 2017 ASQ Conference Chair

We hope you enjoy the conference!

[View Schedule](#)