# ASQ Section 305—New Haven

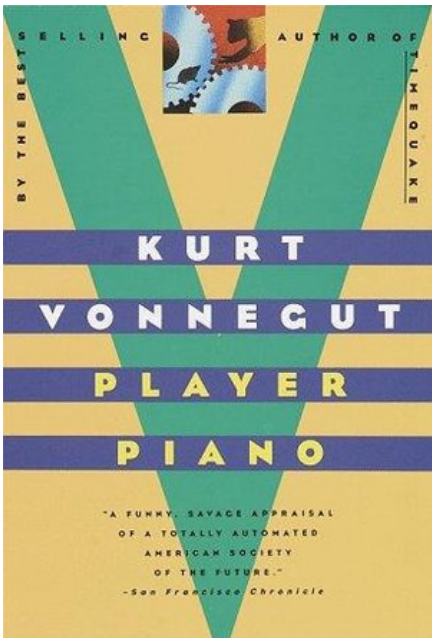
MONTHLY MEMBER NEWSLETTER

JANUARY 2021 | VOLUME 5, ISSUE 1

## IN THIS ISSUE

### Special Interest Articles

**Book Review:**




### Highlights



# Upcoming Program

## LIFE BEHIND THE QUALITY DYKES (DAMS) AND WHY WE NEED QUALITY MANAGEMENT TODAY WITH JURAN'S JOE DEFEO

A quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. Benefits of a documented quality management system includes both the customer's and the organization's requirements.

By meeting customer's requirements, it helps to instill confidence in the organization, in turn leading to more customers, more sales, and more repeat business. Consequently by meeting an organization's requirements, ensures compliance with regulations and provision of products and services in the most cost- and resource-efficient manner, creating room for expansion, growth, and profit.

Juran's CEO Joseph A. DeFeo will examine supplier quality manage-ment system. He will examine the supplier: selection, assessment, segmentation, monitoring and the rewards of excellence in the supply chain. Learn how to develop an effective relationship with your suppliers and remove the burden of being shut down because your supplier did not understand your requirements or thought all your purchasing protocols were cost driven and not for better quality. Dr. DeFeo is recognized as one of the world's leading experts on transform-ational change and breakthrough quality management. For 27 years, he has worked as a trusted adviser helping business leaders increase sales, reduce costs and improve customer experience through the deployment of performance excellence programs.

**MEETING PLACE AND CONTACTS**

**Date**: **January 20, 2021**

**Place:** Zoom Virtual Meeting...A Zoom link with meeting id number and password will be sent prior to the meeting.

**Time**: 6:00 PM EST

**Online: WWW.ASQNEWHAVEN.COM**

**Bill Folsom: (203) 402-9111 or email: ASQGUY@GMAIL.COM**

**Zoom Master: Don Wilson**
**Email: dwilson25@snet.net**

# ASQ Section 305—New Haven Newsletter

## JANUARY 2021 CHAIR MESSAGE

Looking to see a much better year than 2020, heck right now not much can go worse. Looking to collaborate with APICS on zoom meetings, the one scheduled with Joe Defeo of the Juran Institute this month should be great. If you haven't gone or Zoomed to a meeting with Joe you're in for a treat. The man is amazing and full of Quality knowledge. He has a fine speaking voice and quickly reels you into whatever he wishes to discuss. I always enjoy watching this guy in action.

In February, another great speaker Michel Ford will be talking about Life Long Lessons Learned. He's another very gifted speaker with a very accomplished background in quality and engineering. I was at a seminar he gave a few years back where he got everyone involved with some fine discussions on a variety of poignant topics that made you think. I am hoping in the months to follow we can Zoom in Laurence Bush on Steamships. Last year the Covid pandemic stopped us all in our tracks, so maybe this year we can hear the man out.

Of late, we have become Zoom experts, which may in the long run be our mainstay of operations for meeting attendance. I have to assume when Covid is under control we can carry out our regular dinner meetings with a Zoom link up as well. See how we can get it done with our Zoom Master Don Wilson. Incidentally, we may be lucky to see another Water Company meeting this spring in the Zoom environment. There was another great learning experience for many of us.

Well I hope everyone is staying safe and watching for when it's your turn in line to get that awesome well engineered vaccine. I said this before this vaccine is an absolute miracle to be ready for use in such quick order almost a if its was a divine event. I know many of us may have lost loved ones and friends this past year so wherever we can push to move ahead with this vaccine the better for those you know who may be prime comorbidity targets…So remember to assure social distancing and wear that mask!!! Larry Spinello ASQ New Haven Section Chair

## DECEMBER'S VIRTUAL MEETING: STEPPING STONES OF LEADERSHIP WITH JIM ZELEM

Last month's virtual Zoom meeting Jim Zelem talked about his book *Stepping Stones of Leadership* along with some info of his Podcast site: https://anchor.fm/jim-zelem. He started discussing his book and relating a number of stories that enveloped it with his experience on being a good leader.

He told us that we often have to ask a great deal of questions, which may also include questioning authority. The scope in this questioning is to maintain a trust with everyone. Trust being different from honesty, a human moral object, whereas trust is one of emotion. In your efforts to bring about any decisions in your life over time, he told us honesty does not buy emotion. Trust is like a payback in the bank you deposit. He then used a sports analogy as an excellent example. To trust everyone in any sport requires that you follows the rules and develop a strategy.

Next, he talked about managing results. He talked about a time when he worked for a company that secured data and records for safekeeping where their average pace was about 1,800 good page records per day. In a best-case scenario they could possibly muster up 2,200 good pages in 10-14 hours with an hour beak along the way. In one case, he talked about a guy who was an expert his trade who often took extended breaks. Management was not in favor of this disregard to the rules, as it was not making money for the company. Jim on other hand was more concerned about the quality of work that this guy was able to push out versus the amount and time he took. He allowed him to carry on with extended breaks so long as he pushed out excellent work. In efforts to explain it to his boss who cares about the time, he pointed out that time watching bosses are not always good leaders. A good leader cares about the quality of product at delivery and not so much how long it takes.

He talked a little about his hero, Stephen Covey an American educator, author, businessman, and keynote speaker. Covey wrote a few books on leadership one being his most popular book *The 7 Habits of Highly Effective People*. Covey was great influence on Jim as what makes a good leader. Covey was big about the unfortunates being caught in paradigms and never knowing you're caught. He paraphrased Covey that you must trust yourself to be on the same page and learn from the experience of others.

ASQ
The Global Voice of Quality™

He spoke about discipline being always required for a quality mindset. Discipline cannot demand all the time, but must be a part to managing people. Talking to people in private as a coach is the best way to be versus balling them out in public. Open criticism in public for all to hear only keeps everyone from playing the game at their best.

He spoke about changing a problematic process needing to be delicately and effectively worked so that disruption is kept to a minimum with the people doing the work. Sometimes you may need to live with the problem to avoid chaos. In turn, managing things by perception and understanding it all can you gain enough experience.

He felt a good leader must always try to be helpful to assure the best results with a good try at fixing something. Being wrong may end up as the right thing to do. Leaders have followers. Follow the leader is a basic factor one should know. He stated that there is never too little to learn when managing teams colleagues as a boss. Training and coaching he pointed out often requires a certain amount of feedback. Keeping in mind that feedback is not criticism or vice versa.

Lastly he pointed out a common aspect of being a leader, they must strive be friendly but cannot extend themselves with having all their followers be their friends.

## BOOK REVIEW: "PLAYER PIANO" BY KURT VONNEGUT

Over the holidays, I read an old book by Kurt Vonnegut that was published in 1952 called *Player Piano*. It was Vonnegut's first novel of an alarming story of engineer Dr. Paul Proteus, who must find a way to live in a world dominated by a super computer and run completely by machines. His rebellion is a dark satirical look at modern society.

Paul is a key architect of EPICAC, who faces a dreamlike crisis of the automated world. As he comes to awareness of the predicament of Homestead, those who are basically poor semi-employed on a fixed government income, he is placed into competition for a leadership position by his opportunist wife, Anita. As he tries to validate the dignity and worthiness of the Homesteaders he chances losing his easy comfort. The story heightens with the advent of the "Ghost Shirts", a revolutionary group that seeks to rectify the injustice of the engineers and the worker bees for something meaningful to do for society.

A closer aspect is added with the introduction of the notable Shah of Bratpuhr, a curious despot visiting from a slave practicing country. Paul consistently finds and points out similarities of oppression that his fellow engineers must clumsily justify. As the Shah is driven around the city, they seek to solicit an ordinary looking woman for prostitution. To Paul's surprise, he is successful. The woman confesses she has never before engaged in prostitution, and has only been driven to it by her writer husband's being fired for his refusal to write according to socially dictated scripts for the mass market. I can imagine there may be many people right now experiencing this desperation due to Covid's severe economic effects.

The overall message of *Player Piano* is so ahead of its time and strikingly prophetic. Some of the things Vonnegut talks about in 1952 has already come to past showing some gifted foreshadowing ability. Like our current outsourcing of so much labor and technology, all very dangerous and worrisome.

In past ASQ meetings, I often voiced my opinions about the fears of an excessive free market with hardly much government involvement. How much longer can we go on until all the work we offloaded and replaced with by machines affords much of anyone to buy what America is selling? With so many of us out of work or dependent on machines, exactly where can we go but towards full government socialism? The perfect irony here, when we allow business to do what it wants, we inadvertently drain out our humanity forcing us into a complete government run system, or should I say an automated run society.

# PROGRAM SCHEDULE FALL 2020

| DATE | TOPIC | SPEAKER/ FACILITATOR | PLACE | COMMENTS |
|---|---|---|---|---|
| January 20, 2021 | LIFE BEHIND THE QUALITY DYKES (DAMS) AND WHY WE NEED QUALITY MANAGEMENT TODAY WITH JURAN'S | DR. JOSEPH DEFEO | VIRTUAL MEETING | APICS JOINT MEETING |
| February 24, 2021 | LIFELONG LEAN LESSONS LEARNED | MICHAEL FORD | VIRTUAL MEETING | APICS JOINT MEETING |

## SECTION LEADERSHIP COMMITTEE

| | |
|---|---|
| **Section Chair and Newsletter Chair** | **Web Chair and Zoom Master:** |
| Lawrence Spinello (203) 248-4085 | Don Wilson (203) 467-8053 |
| **Treasurer Chair:** | **Education and Programs Chair:** |
| Bill Folsom (203) 494-4002 | Jay Krishnamoorthy (203)589-5350 |
| **Certification, Secretary and Membership Chair:** | **Nominating, Audit and Placement Chair:** |
| Frank Tyszka (203) 386-4859 | Gene Contardi (203) 795-6914 |

ASQ
The Global Voice of Quality™

# Membership Update

Dennis Aguilar
Asim Ahmad
Nicole Bremer
Mike Castillo
Juan Danilo Castro
Maria Cavallo
Donald Claing
Dennis J. Daniels
Aniket Dapke
Brenda Dawson
John Dechello
Matthew D'Errico
Ajinkya Ashok Desai
Eric Dunsker
Diana Dupraw`
Charles Eldredge
Charles Esposito
John R. Facenda
Rachel Galvan
Anthony L Garrett, Sr
Tyler Garrison
Tyler Gawel
Heller Genao
Kathleen Genera
Michael Gonzalez
Anasha Green
Lynne Halpin
Marisa Hammond
Chandler Hartford
Gregory Humphries
Puranjit Kar
Maria Lavorgna
Jason McCabe
Deanna Modica
Karla Oliva
Godspower Omokhunu
Michael Oneill
Racquel Orencia
Brian Parker
Bhavana Praveenrao Pawar
Alicia Perez
Felicia Piel
Lutfur Rabbani
Cesar Ribas
Michele Roberts
Kaleigh Ryder
Samuel R. Simons
William Thompson
Mark Toomey
Michael Vail
Shawn Varela
Thiru Gnana Sampath Kumar Velusamy
James Villano
Evans Williams
Todd R. Zeigher

ASQ
The Global Voice of Quality™

## OUR MISSION STATEMENT

***PROVIDE COMMUNICATION, NETWORKING, AND DEVELOPMENT OPPORTUNITIES TO SUPPORT KNOWLEDGE, SKILLS AND ABILITIES IN QUALITY PRINCIPLES AND CONCEPTS.***

# Job Opportunities

## SR SOFTWARE QUALITY ENGINEER

Position location: Woburn MA
Industry: Medical Device
Position: Sr Software Quality Engineer
Salary: $85-$105,000
Position type: Permanent Full time Employee
Relocation Assistance: Provided
Not considering visa candidates.

Join a passionate team! This is a great group of people to work with and growing company. Apply today! In this exciting role as a Sr. Software Quality Engineer, you will serve as a subject matter expert by leading and providing technical design quality support for the new product development and sustaining projects. The individual will act as a subject matter expert and provide guidance to the business in interpreting and executing against Company quality system elements including software/system work products to ensure compliance. This individual will ensure that all system-level project / program work products (e.g., plans, requirements, specifications, tests, test results, traceability, risk management documents, reports) meet Company's quality, reliability, and compliance requirements. This individual will ensure Design Quality Assurance-driven initiatives meet objectives in delivering highest quality products, with supporting tools and processes.

**MITG**

The Minimally Invasive Therapies Group strives to enable earlier diagnosis, better treatment, faster complication-free recovery, and enhanced patient outcomes through less invasive surgical solutions. SURGICAL INNOVATIONS sets the standard for Minimally Invasive Surgery (MIS) by creating innovative surgical products and services that focus on obesity and diseases and conditions of the gastrointestinal tract, lung, abdominal wall, pelvic region, and the head and neck.

A Day in the Life
• Leading large and complex medical device product development per the FDA design controls starting from design planning through design transfer.
• Collaborating with project / program teams to ensure work products comply with Company procedures, acceptable qualitative and quantitative criteria, and global standards, regulations, and guidance.
• Working very closely with the development teams during early development of requirements & design (algorithm development and code) and providing feedback to the design based upon SFMEA/Hazard Analysis.
• Ability to read software code and participate in detailed technical design and code reviews.
• Understanding of the interdependencies of program work products and guide the teams in execution strategy and participating in development, review and approval of all program work products (e.g. plans, requirements, specifications, tests, test results, traceability, risk management documents, reports).

• Generating and driving risk management deliverables like SFMEA and Hazard Analysis and preferably experienced in facilitation / execution of the SFMEAs.
• Chair cross-functional change control boards.
• Utilizes knowledge of various Software Development Lifecycles (SDLC).
• Training and coaching cross-functional peers on maintaining compliance to internal and external Quality requirements and regulations in support of the deployment of the different BU strategies and products.
• Driving clarity and consistency in documentation.
• Leading CAPA projects and assisting post market analysis.
• Participating in support of external regulatory audits and inspections.
• Driving Process improvement activities.
• Work under consultative direction toward predetermined long-range goals and objectives. Assignments are often self-initiated. Determine and pursue courses of action necessary to obtain desired results through consultation and agreement with others rather than by formal review of superior.
• Performs other related duties as assigned.

Must Have: Minimum Requirements

• Bachelor's Degree in Engineering or Science with 4+ years of work experience in Quality and/or Software Development
• OR Advanced Degree in Engineering or Science with 2+ years of work experience in Quality and/or Software Development.
• Experience working in a regulated industry (e.g., FDA-regulated).

Nice to Have (Preferred Qualifications)

• Master's Degree in Engineering, Quality, Regulatory, or related.
• Working knowledge of embedded and mobile application development for medical devices.
• Working knowledge of ISO 13485, ISO 14971, 21 CFR 820, IEC 62304, IEC 60601-1 and MDD.
• Ability to author technical reports, business correspondence and standard operating procedures.
• Ability to apply knowledge and work with development and supply vendors to ensure compliance to Company requirements.
• Strong verbal and written English communication skills with an ability to effectively communicate at multiple hierarchal levels in the organization.
• Ability to multi-tasks, prioritize, meets/exceed deadlines and hold themselves, and others accountable.
• Self-Starter with a sharp focus on quality and customer experience. Excellent growth opportunities.

*PLEASE CHECK YOUR EMAIL / A RESPONSE TO YOUR APPLICATION WILL TYPICALLY ARRIVE VIA EMAIL WITHIN 24 HOURS.

Please also check SPAM. ** Also, the system can only accept resumes in PDF or WORD format.

# Quality Engineer

Have you worked for at least five years as a Quality Engineer for a 24/7 manufacturer with continuous operation and or batch processing in a fast-paced environment?
While self-motivated and driven, do you have significant team leadership experience and success in getting work accomplished through others who are not direct reports?
Do you have certifications – lean, Six Sigma, and ASQ, etc. – that attest to a deep understanding of continuous improvement and the ability to effectively/efficiently execute on it?
Are you a strong problem solver – forward thinker – analytical – always looking for new, innovative, and better ways to improve processes coupled with expert knowledge of using process control tools and technology?
Have you worked directly with external customers vs. only working with your company's salesforce?
If yes, then read on . . . My client, Bethune Nonwovens, in Bethune, South Carolina area is seeking a quality engineer who will be based in their facility. This is not a remote position. While local candidates are preferred, my client will consider candidates willing to relocate and will assist with relocation.
In this position, you will plan and implement the plant's quality assurance / control policy, procedures and standards, so that the site complies with regulations and laws. The business impact of doing this involves using judgment, initiative and authority to address quality assurance/control issues and analyze and improve current ways of working.
What are the KPIs?

- Quality claim rate
- Plan audits to fulfil quality expectations

What are the main accountabilities?

- Promote a strong safety and quality culture where both safety and quality are core values of everyone. Full compliance to all safety and Quality related policies, procedures and practices.
- Supervise implementation of quality assurance / control rules and regulations according to company policies, standards, corporate tools and programs, and local regulations.
- Conduct quality assurance / control audits to identify risks and development possibilities and support gap-closing actions.
- Work closely with Process Engineers to evaluate the organization's production processes, systems, and technology and recommend changes that will improve adherence to quality standards and reduce the risk of non-conformity.
- Coordinate the education and training of the organization's workforce on quality assurance / control issues to ensure that they understand and comply with the organization's policies and standards.
- Liaise with and influence for relevant internal / external stakeholders - local management and authorities - and advocate quality assurance / control mindset across the organization.
- Implement and ensure adherence to Operations Core Principles and the specific Core Principles defined by the function.

What are the responsibilities?

- Gather quality data information to utilize for customer complaints and work with the team for a resolution and response back to the customer..
- Support the quality manager and process engineers to determine frequency and type of product testing.

- Have an understanding of the Six Sigma Management Systems and its core applications.

What is the Education level and Work and Technical experience required?
- Bachelor's degree or higher (desired)
- Minimum 5-7 years of experience in production related position and in relevant industry.
- Experience with / exposure to SAP
- Computer proficiency with Microsoft Office: Word, Excel, PowerPoint, and Outlook

What are the personal attributes you need to be successful in this position?
- Excellent communication skills – verbally and in writing
- Strong listening skills – really hears what others are saying
- Proactive, self-reliant – takes initiative – driven to excel
- Strong emotional intelligence and self-awareness
- Highly interactive – engaging; strong team-based orientation; yet, can take ownership and direct others who are not direct reports
- Organized / pays close attention to details
- Creative and innovative – can think independently
- Energized by problems – with strong analytical skills
- Hands-on – gets out on to the production floor and works with the process engineers
- Upbeat, enthusiastic, energetic, positive attitude – eager to learn
- Confident in one's own ability – yet willing to consider input from the team
- Committed to continuous improvement and finding better ways of doing things
- Encourages brainstorming and takes into account others' ideas and suggestions
- Keen understanding of working with different personalities – different audiences – learns to speak their language and meet their needs
- Safety and quality conscious
- Demonstrates integrity, respect and is diplomatic
- Quickly establishes credibility and gains others' trust and buy-in
- Strong work ethic and sense of time management
- Professional demeanor

If this position is strongly aligned with your background / experience and interests and you can hit the ground running, we would like to hear from you. Resumes should be emailed as Word documents to: karlahammond@sbcglobal.net; 860-267-2690