ASQ Section 305—New Haven

MONTHLY MEMBER NEWSLETTER

OCTOBER 2017 | VOLUME 2, ISSUE 1

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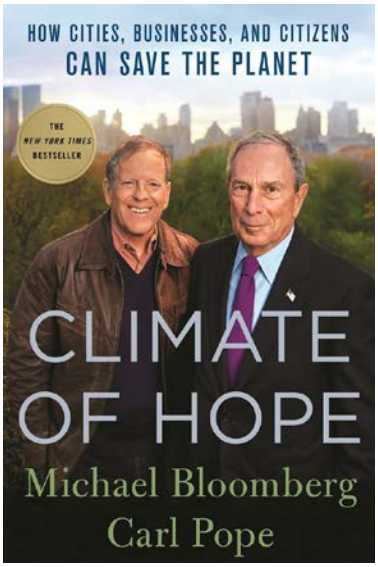
Special Interest Articles

Book Review:



Highlights

- Book Reviews
- Last Month's Meeting
- New Members
- Program Schedule
- ASQ Board List
- Job Opportunities

Upcoming Program

CONNECTICUT FOOD BANK TOUR!!

The Connecticut Food Bank (CFB) is a nonprofit organization, whose mission is to provide nutritious food to people in need. Founded in 1982, the Connecticut Food Bank is committed to alleviating hunger in Connecticut by providing food to people in need through a network of community-based programs, including food pantries, soup kitchens, emergency shelters, residential programs and day programs that serve adults and children. Additionally, we distribute food directly to people in need through our Mobile Pantry; GROW Truck and Kids' Backpack programs. Beyond providing food, we promote public awareness of the problem of hunger and advocate for policies to provide long-term solutions to alleviate hunger in Connecticut.

History and development

In July 1982, Connecticut Food Bank began distributing food to 70 agencies throughout Connecticut from a 2,000 square-foot warehouse in New Haven at the corner of Ferry and Water Streets. At the beginning of 1983 it distributed 400,000 pounds of food. Connecticut Food Bank operates two branch warehouses in Waterbury and Fairfield, and has two affiliated distribution centers in New London and Stamford. It serves nearly 700 food-assistance programs in Fairfield, Litchfield, Middlesex, New Haven, New London and Windham counties and distributes an average of 40 tons of food per day. Governor Dannel Malloy visited the Connecticut Food Bank warehouse in East Haven to discuss the organization's mission with its staff and volunteers.

MEETING PLACE AND CONTACTS

Date: October 11, 2017
Place: CT Food Bank Tour, Wallingford, CT
Networking: 5:00;
Tour: 5:30-7:30; Dinner: 7:30
Meal: Pizza
Cost: $15.00

Online: WWW.ASQNEWHAVEN.ORG
Bill Folsom: (203) 494-4002 or email: asqguy@gmail.com

DIRECTIONS TO CT FOOD BANK

From South: Follow I-91 N to CT-68 E in Wallingford. Take exit 15 from I-91 N. Continue on CT-68 E. Take Research Pkwy to Thorpe Ave. Turn right onto CT-68 E. Turn left onto Research Pkwy. Turn left onto Joseph Carini Rd. Turn left onto Thorpe Ave. Destination will be on the left.

From North: Follow I-91 S to CT-68 E in Wallingford. Take exit 15 from I-91 N. Continue on CT-68 E. Take Research Pkwy to Thorpe Ave. Turn left onto CT-68 E. Turn left onto Research Pkwy. Turn left onto Joseph Carini Rd. Turn left onto Thorpe Ave. Destination will be on the left.

BOOK REVIEW: "CLIMATE OF HOPE: HOW CITIES, BUSINESSES, AND CITIZENS CAN SAVE THE PLANET" BY MICHAEL BLOOMBERG AND CARL POPE

After reading *Climate Of Hope: How Cities, Businesses, and Citizens Can Save The Planet*, I have a new hero from our political world, New York Mayor Mike Bloomberg for his practical approach on climate change. He gives us hope by delivering some cool strategies against our serious environmental problem with global warming. He decries for leaders to dream big to assure our future and be progressive in our search for a cleaner environment, or else face some very negative consequencs if we continue down a fossil fuel path.

Bloomberg teams up with former Sierra Club Chairman Carl Pope in presenting some sound views towards saving our planet. In a time when our current national leadership seems focused on denying the facts of climate change and derailing efforts of past leaders, these authors propose that smaller-scale efforts are more likely to produce the desired results. They call for empowerment of cities, regions, businesses, and citizens to accelerate the progress they are already making on their own. Pope looks at ways in which electrical utilities can lead the way in shifting to renewable sources of power as opposed to being forced into it, one measurable result of which has been a big negative for coal workers. He notes that the future of climate change is not yet written, though sticking to a reasonable and useful approach of energy consumption, may take some time to get moving.

Bloomberg shows some techy knowledge of his own where he cites for good measure a projected role of the automobile: "more city leaders are recognizing that when the interests of cars and people diverge, people should come first." Bloomberg also talks about the role of buildings in climate change as sourced for some 70% of greenhouse gas emissions.
They further elaborate about how we can reduce the number of children who have asthma attacks, save thousands of Americans from dying of respiratory disease, cut energy bills, increase the security of our energy supply, make it easier for everyone to get around town, increase the number of jobs in their community; all while increasing the long-term stability of the global climate.

They further remark that changing climate should be seen as a series of manageable problems that should be attacked from all angles, each with a solution that can assure our health along with a sound economy. In these times of such fiery political polarity, Bloomberg and Pope lay out a powerfully believable argument about how cities can play a huge role in fighting and reversing the dangerous effects of a hot planet. Together they lay out the economic and personal health reasons for businesses and individual citizens to support climate change action plans.

Hey, if you're into reading stories about sports read *The Boys in the Boat* by Daniel James Brown. It's about the 1936 Olympics and how our rowing team beat the Nazis for the gold. Brown centers on one of the oarsmen, Joe Rantz, a poor boy whose determination to overcome odds make him an ideal hero. Brown learned the details of Rantz's brilliant rowing career from the athlete himself. But this story wasn't just about him as he includes all nine athletes, sons of farmers, fishermen, and loggers. All of them who managed to unite into a rowing team that would march confidently into the 1936 Olympics under the warmongering eyes of Hitler, emerging victorious over rival crews from Germany and Italy. I would love to see this book made into a movie with all of its intense moving race scenes, should spark a whole lot of national pride.

Larry Spinello
ASQ New Haven Section Chair

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Last Month's Program Highlights

TRANSITION TO ISO 9001 2015 STANDARD WITH JAY KRISHNAMOORTHY

Last month we were lucky to hear an excellent talk about some interesting points from Jay Krishnamoorthy on the Transition to ISO 9001 2015 Standard. He started by giving a history of the Quality Management System (QMS) standards from 1959 with Mil-Q-9858 to present. Under the new ISO 9001:2015 he explained how all the Annex SL Directives (ISO 20000, ISO 22301, etc.) now all aligns together. He then told us that the Plan, Do, Check, and Act method has been streamlined with new standard grouping clauses to match the whole QMS with these features:

- 10-clause structure for all Management System Standards
- Leadership
- More compatible with services and non-manufacturers
- Organization's context "one size doesn't fit all"
- Organization Risks and Opportunities
- Process approach /more explicit
- Documented information
- Externally provided products and services
- Preventive action is now risk identification and mitigation
- Improvement

The new standard talks heavily about a process based approach where the systematic management of processes and their interactions that are used to achieve intended results. He told us about some tools to consider with SIPOC and the Turtle Diagram with a side-by-side comparison of ISO 9001:2008 vs ISO 9001:2015. He remarked that they added two new sections as breakouts from the 2008's Management Responsibility as Leadership and Planning and the Measurement, Analysis and Improvement section split up as Performance Evaluation and Improvement.

He redefined some key terminology, with the biggest being the removal of the requirement for a quality manual, management representative and preventive action. They added in a context of organizations and actions to address risks and opportunities, as an organization's internal context is the environment in which it aims to achieve its objectives. He cited that internal context could include its approach to governance, its contractual relationships with customers, and its interested parties. He discussed how the leadership requirements refer to taking accountability for the effectiveness of the QMS while ensuring the integration of requirements into the organization's business processes. All that will help promote the use of the process approach and risk-based thinking while communicating the importance of effective quality management and conforming to all requirements. The organization will determine the knowledge necessary for the operation of its processes towards achieving conformity of products and services.

He cited that the risk based thinking on analyzing and prioritizing your risks helps you learn from experience. The organization will determine the risks and opportunities to give assurance that the QMS can achieve its intended result while preventing, or reducing undesired effects.

Jay then went onto to tell what the new standard would not require anymore. ISO 9001:2015 will not specifically require any Quality Manual, Procedures Manual or Work Instructions. The reason being that organizations could theoretically achieve certification without any of these documents, however auditors will still be required to verify consistency with the applicable requirement, consequently the organization will need to be prepared to show a consistent, effective process for whatever activity is being reviewed. If this can be accomplished without a procedure/quality manual, it will be accepted.

He also talked about the elimination of the Management Representative. The title of "Management Representative" does not appear within the ISO 9001:2015 standard. The implication is not that this responsibility has been eliminated, but rather that many of this party's key functions should now fall to top management itself. This reflects the current "in practice" arrangement for many of the companies already certified.

After hearing all of this radical stuff, he rhetorically asked if everyone now has to change their current system, where he stated, no. As one of the goals of the TC176 committee in writing the new standard, they sought to improve its inclusiveness. Telling over a million worldwide registered firms that they have to overhaul their system is not very inclusive.
In summary, determining the organizational context enables a more effective implementation of the QMS and greater emphasis on processes being managed to achieve planned results. The alignment with strategic direction as well as integration of the QMS into organization's business processes enables us to better determine our risks and opportunities while increasing the effectiveness of the organization's QMS. A change in management has been expanded to add emphasis that the QMS should be carried out in a planned manner. The concept of organizational knowledge helps to introduce and ensure that the organization acquires and maintains the necessary knowledge.

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Membership Update

WELCOME NEW MEMBERS!

NELLY ANGAH
TAWFEEQ JAMAL ALDEEN
DANA BOCHAN
MICHAEL BRADSHAW
HARRY E. BROOKS
ROB BROPHY
ANTHONY CAVALLARO
DAVID CHABER
MARK CRAWFORD
SHIVANI DESAI
JENNIFER E. DESMARAIS
LINA FRAZER
SCOTT HAEFFNER
LUIS ISTURIZ
TANIA HINDS
JO-ANN HUTCHINSON
BRIAN JONES
AJITH KUMAR ALLAM
DAVID LONG
WILLIAM LOCASCIO
JOHN MALEK
MICHELLE A. MALONE
LYNN MATHEWS-FROEHLICH
DAVID MICHAELS
J DEBRA MRAZ
JEAN NDJOMOU
SCOTT NEJFELT
ADITYA OZARKAR
DANIEL OSTRAVAGE
JOHN H. PIZZONIA
KEITH PORTER
JASON ROMAN
ROCIO SANTANA VILLA
RACHEL RUSSICK
J DEANNA SCIACCA
JUSTIN SCHLAUDER
RICHARD G. STINE
STACY ST. JOHN
AARON SUMMERS
NINAD TAMBE
BLANCA G ACA-TECUANHUEHUE
MICHAEL VAGELL
AMBER WELLS
ELIZABETH WONG
KYLE ZUKAUSKAS

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OUR MISSION STATEMENT

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

PROGRAM SCHEDULE 2017-2018

DATE	TOPIC	SPEAKER/ FACILITATOR	PLACE	COMMENTS
OCTOBER 11, 2017	CT FOOD BANK TOUR	MULTIPLE	WALLINGFORD CT	JOINT WITH APICS AND ISTM-CT
NOVEMBER 15, 2017	SELF DIRECTED WORK TEAMS	DAVID CADDEN	HONEYWELL OF NORTHFORD, CT	JOINT WITH APICS AND ISTM-CT
JANUARY 21, 2018	EIGHT WASTES A LEAN INTERACTIVE TOPIC	ANTHONY ZAMPELLO	HONEYWELL OF NORTHFORD, CT	JOINT WITH APICS AND ISTM-CT
FEBRUARY 18, 2018	TBA	TBA	TBA	
MARCH 17, 2018	ICE CREAM SUNDAE PRODUCTION	MIKE FORD	HONEYWELL OF NORTHFORD, CT	JOINT WITH APICS AND ISTM-CT
APRIL 21, 2018	TBA	TBA	TBA	JOINT WITH SOUTHERN SECTION
MAY 19, 2018	TBA	TBA	TBA	

SECTION LEADERSHIP COMMITTEE

Section Chair and Newsletter Chair:
Lawrence Spinello (203) 248-4085

Vice Chair and Education Chair:
Diego Dussan (203) 648-7583

NEQC Rep, Treasurer, Nominating and Past Chair DRD:
Bill Folsom (203) 494-4002

Secretary and Membership Chair:
Suzette Herrick (774) 239-6743

Web Chair:
Don Wilson (Newly Assigned)

Programs:
Unassigned

Audit and Placement Chair:
Gene Contardi (203) 795-6914

Certification
Frank Tyszka and Art Bystryk

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Job Opportunities

QUALITY ENGINEER WANTED:

Title: **Quality Systems and Compliance Manager**
Location: Near New Haven, CT.
Direct reports: 8 Inspectors
Industry: Aerospace - sensors

The Quality Systems and Compliance Manager develops, implements and maintains the Quality Management Systems to assure compliance with AS9100 standards. In this position, they will effectively assure compliance of customer requirements by managing quality policies, standards, procedures, programs and practices while driving other functions in the organization to do the same. The QS&C Manager is also responsible for maintaining all FAA, EASA, CAAC, DER, NADCAP and any additional quality certifications necessary for the business.

Essential Duties and Responsibilities

- Develop, implement, and maintain the Quality Management System to assure compliance with AS9100 standards.
- Manage all regulatory and industry specific certification programs including but not limited to FAA & FAA Repair, EASA, DER, CAAC, NADCAP and others.
- Function as primary point of contact with the FAA, EASA, DER, CAAC and AS9100 bodies to establish and coordinate site surveillance audits, documentation changes affecting the Quality Management System
- Manage the internal audit program through development and issuance of a yearly audit schedule, creation/revision of audit checklists, performing audits, and issuing status reports to management.
- Complete customer-issued Supplier Surveys or certifications
- Follow and stay current with AS9100 procedures, policies, manuals, and subscriptions
- Collaborate with product quality engineers to support plant-specific requirements and changes
- Support the corrective and preventive action program (CAPA) and Corrective Action Requests issued internally, received from customers, or resulting from third party audits as needed.
- Coordinate required certification audits with outside contractors to maintain certificates
- Support the document creation and document control processes to ensure compliance with quality systems manual
- Create and facilitate training for employees and plant leaders to support understanding of the quality manual.
- Maintain training records for any unique certifications (FAA Repair, NADCAP, etc.)
- Provide guidance to product quality teams and plant leaders regarding compliance with quality systems.

Travel: Up to 15% travel (domestic and/or international) as necessary.
Citizenship: Must be a "US Person" as defined by US Govt. and able to work without restriction with ITAR related data

Qualifications and Experience

- Bachelor degree in Quality or related field such as Engineering, or equivalent experience
- Seven or more years of experience in a quality systems or product quality role including 5 years of experience with Quality Management Systems; experience in Aerospace strongly preferred.
- Ideal candidate will be a certified auditor.

To Apply: Send resume to susan@hrgvs.com and a day phone number

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QUALITY CONTROL INSPECTOR

Cambridge America is looking for a Quality Control Inspector. This job posting is for internship to hire position. We are looking for someone with a **strong attention to detail, team oriented, and with Microsoft Excel skills** in data sheets and formulas. Our business is quickly growing, and we are pursuing *applications now* for the Quality Department. If you are a student, this internship would be **perfect** for someone looking to learn and build experience in Quality Control/ Assurance.

Responsibilities:

- Read and understand drawings and specifications
- Monitor or observe operations to ensure that they meet production standards
- Recommend adjustments to the process or assembly
- Inspect, test, or measure materials or products
- Measure products with rulers, calipers, gauges, or micrometers
- Accept or reject finished items
- Remove all products and materials that fail to meet specifications
- Discuss inspection results with those responsible for products
- Report inspection and test data

Qualifications:

- 1+ years experience in Quality Control
- Currently ongoing or completed Quality Program at College level.
- Team-oriented, strong communication, and adaptable
- Capable in many excel functions and data sheets.

PREFERRED SKILLS

- ISO: 9001 Knowledge, is a plus
- Certified by ASQ as associate or above, is a plus

Applicants can submit resumes and info at Office Manager's email: patrandol@cambridgepcb.com or to billbansavage@cambridgepcb.com. All applicants are welcome to apply, please leave all contact info in email or resume.

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THE ESTÉE LAUDER COMPANIES

JOB DESCRIPTION: Global QA Supply Chain Audit Director

JOB REQUIREMENTS & QUALIFICATIONS

- Minimum Education level: BS
- Travel Time: 60%
- Minimum 5 years experience of auditing external suppliers.
- Good knowledge of applicable regulations and guidance documents, able to apply critical thinking skills to evaluate requirements.
- Knowledge of global cGMP standards.
- Working knowledge of 21 CFR 210, 211, Health Canada GMP's, ISO 22716, EFfCI and ICH Q7.
- Computer literate with good working knowledge of Microsoft products. (SAP knowledge an added advantage).

POSITION SUMMARY: Lead or co-lead quality audits to analyze and ensure that the basic processes of our plants and suppliers are effective. Evaluate suppliers and our quality systems to ensure full compliance to ELC and all applicable regulatory requirements. This position is a member of the Global Quality Assurance Audit team.

Performing audits of suppliers will account for 60% of this job. Audit activities include, defining the audit objective, defining audit requirements scheduling audits with suppliers, conduction opening & closing meetings and performing audits as the lead or co-auditor for Components, Raw Material, Third Party Manufactures (TPM), Estee Lauder manufacturing sites and third party testing laboratories. Ensure that audits are conducted according to EL policy and requirements, that every audit has a timely audit report issued, and that corrective action/preventative action (CAPA) plans are identified for every audit.

For 15% of this job, updating the audit tracking database with audit schedule, audit report and audit observations. Ranking suppliers according to EL risk profile. Participate in collecting and reporting quality matrix.

For 10% of this job you must collaborate with of members of the QA organization and other functions at ELC in continuous improvement of the audit program.

Lastly for 15% of this job you will be responsible for other duties as assigned may include management and processing of OTC complaints and processing new supplier audit request.

QUALITY ASSURANCE COMPLIANCE SPECIALIST

Sigma Systems of New Haven CT is seeking a Quality Assurance Compliance Specialist who…

- Ensures Quality and Compliance for global product complaint program activities against internal policies and procedures as well as domestic and international GMP regulations.
- Partners with internal cross-functional areas, to execute a best in class GMP Global Complaints program by supporting the organization's operational excellence of ongoing compliance and continuous improvement activities.
- Supports review of finished product contract packaging and shipping batch records and performs lot disposition to certify compliance with specifications and procedures and ensure that product is delivered on time of supply need.
- Interacts with local and global Quality Assurance team members to ensure global complaints are processed, investigated and managed as per Global procedures
- Evaluates Product Quality Complaints related to product quality issues or adverse event reporting, working effectively with internal/external partners as require to include; sample evaluation, thorough lot/product history trend analysis, and product impact assessment.
- Assist with the management of CAPA related to Global product complaint investigations as required and in collaboration with local Quality staff.

Skills and Experience:

- Minimum of 4-8 years cGMP related experience in biopharmaceutical / pharmaceutical or related industry with 3-5 years direct QA experience in a cGMP environment
- Knowledge of domestic and international regulatory requirements related to cGMP operations
- Experience with respect to product quality complaint management systems
- Experience with electronic Quality Management systems such as SAP, TrackWise, firstDocs, etc.

Education: BS Degree in Biology or Chemistry
Contact: Venkat Amarakanti "Amar" Recruiter
201 Boston Post Road West, Suite 201, Marlborough, MA 01752
Tel: 508-925-9441 | Fax 508-357-6301
vamar@sigmainc.com| http://www.sigmainc.com

QC INSPECTOR FOR CHESHIRE, CT AREA PACKAGING COMPANY (FDA REGULATED ENVIRONMENT)

Responsibilities:

- Performs inspection of incoming materials, in-process and finished products, approves per specification, documents in accordance with cGMP procedures
- Follow quality processes and procedures in compliance with FDA requirements & cGMP
- Document all instances of rejected product or raw material problems in daily production reports and maintain all logs.
- Create and maintain files for all quality related correspondence.
- Support investigations as needed
- Report any unusual discrepancies or problems promptly to management.
- Suggest new testing or inspection methods to minimize inspection efforts required.
- Train co-workers in quality control concepts as requested.
- Participates in Regulatory agency (EPA, OSHA, FDA, AND ISO) visits/audits
- Other Duties as assigned Skills:
- Self-starter
- Able to follow both written and verbal instruction
- Organized
- Extremely dependable
- Must possess good judgement skills
- Knowledge of production environment and processes
- Awareness of Quality and Safety
- Ability to take direction from supervisor
- Knowledge, including practical application of FDA QSR, ISO regulations
- Strong Team Player
- Able to work under pressure
- Able to work in fast-paced environment

Must be able to lift up to 50lbs and have at least 3 years of experience in an FDA environment Associate's degree preferred.

Please submit resumes to:
Suzette Herrick MBA, CQA Quality & Compliance Manager of Unipharm, Inc
sherrick@unipharmus.com

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ASQ NHS BOARD MEMBER REQUEST

We are looking for ASQ members to join our Section Leadership Board. We have an opening for Programs Chair….

Programs Chair: Tasks for this position would be to ensure that section meetings and/or programs occur regularly. Determine focus of section meetings and programs. Solicit speakers to match topics and setup the arrangements, if applicable, to coordinate speaker needs. Work with newsletter editor to publish events in a timely manner. Attend SLC meetings and general membership meetings. As many of our meetings these past few years have been shared with APICS, ISTM and our Southern Section ASQ, finding speakers and great topic ideas have been a team effort. ASQ Board also plans to work with the new Programs chair on a variety of approaches for help.

Last dinner meeting of those in attendance…

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