ASQ Section 305—New Haven

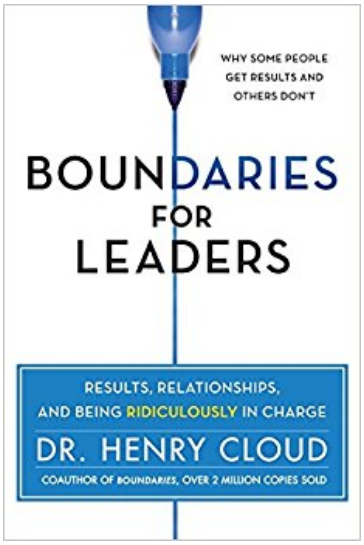
MONTHLY MEMBER NEWSLETTER

SEPTEMBER 2017 | VOLUME 2, ISSUE

IN THIS ISSUE

Special Interest Articles

Book Review:



Highlights

Upcoming Program

TRANSITION TO ISO 9001 2015 STANDARD WITH JAY KRISHNAMOORTHY

With the publication of ISO 9001:2015, organizations now face the next steps of implementing, learning to audit, and transition to a new certification. This overview session will blend these different concepts to understand the requirements and implementation.

We will discuss about the changes from ISO 9001:2008 to ISO 9001:2015 and how these will affect your organization so you can start putting transition arrangements in place. This will enable you to identify the core changes and requirements of ISO 9001:2015. It will assist you with the implementation of the changes within your business.This session is particularly valuable for individuals directly involved in the planning, implementing, maintaining or auditing of an ISO 9001 Quality Management System (QMS).

Jay Krishnamoorthy is a Lean Black Belt Professional with 26+ years of experience in Operations, quality, project management and product development in various industries. He is currently working at United Technologies as Direct or Quality. In addition to working, he is also an adjunct professor at UNH, Sacred Heart and Fairfield universities teaching Operations Management, Project Management, Six Sigma Implementation, Business intelligence, Information systems and Engineering Economics for graduates and undergraduates. Jay held a past executive board role for ASQ New Haven's Section Chair, as well as Education, Web and Program Chairs.

He holds Electrical and Electronics Engineering from Karnatak University, India and MBA from University of New Haven. He is also a member of APICS New Haven section

MEETING PLACE AND CONTACTS

Date: September 20, 2017
Place: 91 Diner, New Haven, CT
Time: Networking: 5:15;
Dinner: 5:30; Speaker: 6:30
Meal: Beef, Fish & Chicken entrées
Cost: $25.00

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

DIRECTIONS TO 91 DINER

From the North: Follow I-91 S to New Haven and take Exit 8 for Middletown Ave. Use the left lane to turn left onto Middletown Ave then turn left again at next light, destination will be on the left at 420 Middletown Ave.

From the South: Follow I-91 N to Middletown Ave in New Haven and Take Exit 8 Middletown Ave toward. Take a slight left and go straight at the light down Middletown Ave, destination will be on your left at 420 Middletown Ave.

BOOK REVIEW: "BOUNDARIES FOR LEADERS: RESULTS, RELATIONSHIPS, AND BEING RIDICULOUSLY IN CHARGE"

Dr. Henry Cloud is an acclaimed leadership expert, psychologist, and best-selling author. "Boundaries for Leaders" was named one of the top five leadership books in 2013 and Dr. Cloud was named one of the top 25 most influential leaders of 2014. While Dr. Cloud has written several books on leadership, relationships and personal growth, this review focuses on Boundaries for Leaders: Results, Relationships, and Being Ridiculously In Charge.

There are seven leadership boundaries that Dr. Cloud presents:

1) Help people's brains work better
2) Build the emotional climate that fuels performance
3) Facilitate the connections that boost people's functioning
4) Facilitate thinking patterns that drive results
5) Build high performance teams that achieve desired results
6) Lead yourself in a manner that drives and protects the vision

Boundaries are important for leaders because boundaries determine what will exist and what will not. If a leader sets boundaries that allow undesirable behaviors, undesirable behaviors will follow.

As leaders advance, it is necessary for them to develop skills that deal with getting people to work toward the vision; to lead the "right people" to do the "right things" in the "right ways" at the "right times". Dr. Cloud uses the term "ridiculously in charge" to describe leaders. Leaders make decisions, they influence change. Leaders are given the power to direct others toward a common goal. When faced with a problem, leaders must ask themselves, "Why does this problem exist?" Often, it exists because the leader has allowed it to exist.

Focusing on the individual is an important aspect of leadership. Leaders must understand the requirements for a brain to excel at its job. The brain must be able to focus, remain uninhibited, and be able to retain and build on relevant information. Once these executive functions are working well, the brain is then able to execute behaviors which product results. Some of these behaviors include goal selection, flexibility, and self-regulation. This leadership style results in the people being engaged, creates an environment for growth and learning, and drives results.

Dr. Cloud also emphasizes "being hard on the issues, and soft on the person". The goal is to work toward the vision and to create an environment of "positive fear" where the people are motivated to make reality better and avoid bad outcomes.

Another important characteristic is developing unity and connection. Some ways to build unity are to collaborate, resolve conflicts, regulate one's emotions, and listen. While these sound like simple concepts, leaders can often fail by allowing their emotions to get in the way, being hands-off, and neglecting to follow up on issues that the group feels are important. These can very easily diminish the power of—and the respect for—the leader.

When we think of a leader, we think of someone in control. Dr. Cloud proposes that a great leader gives control away. A great leader focuses on helping his or her people get in control of themselves so that they can more effectively impact results. Once the people and the leader are in control it becomes easier to work toward the shared vision, the common goal, and the results that are expected will be achieved.

Discover more about Dr. Cloud and his work at https://drcould.com.

Suzette Herrick
ASQ New Haven Membership Chair

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Last May's Program Highlights

BUILDING THE FIRST "STEAMSHIP" IN HISTORY WITH JOHN BUSCH

Last May we were lucky to listen to a great discussion about one of our greatest historic creations, the Steamship. John L. Busch the author of Steam Coffin began his talk about what it meant to be back in time in the early 19th century, a recalibration if you will. He spoke about the types of travel they used back then where the most advanced was by ship. In looking ahead it was all about reducing the hours needed to travel.

Starting the whole steamship revolution he started off talking about Robert Fulton and Robert Livingston who introduced the steamboat in 1807. The design of the steamboat had paddle wheels made of wood and an upright vertical boiler. Although the design was fine for still waters use but for ocean travel it was considered quite dangerous. Since the paddle wheels were made of wood they were highly subject to the harsh salt water environment and rough seas, not to mention since they hung far below the hull of the ship presented a drag when the ship went under sail.

In addition to the dragging paddles they had concerns about fire safety by flying cinders off the steam engine smoke stack since they used wood to burn. Coal was expensive and there were few mines in America at that time so whatever coal they used had to be imported from England.

On the engine design since they used salt water to boil for steam salt would clog up the pipes causing heating loss and steam suppression. Since the engine and its housing stood vertical it represented a stability problem. Should the ship run through rough waters and waves, hitting the steam engine portion of the ship chances were great of capsizing.

John then told us to be classified as a steamship it had to have four mast sails otherwise it was not a ship. Robert Fulton died before he could see a full ocean going steamship make its first voyage across the Atlantic Ocean.

Picking up the baton on this project was a man by the name of Moses Rogers of New London CT. His was a steamboat captain as far back as 1809, but longed to be a steamship captain. So he partnered with William Scarborough to establish the Savannah Steamship Co..

Their next goal was to get the right people and business to make such a vessel. They first approached a company called Fickett and Crocker shipyard of New York for the bulk of the hull and masts. They then contracted out the Nicholl Company that supplied all the necessary marine equipment and materials for shipbuilders like special live oak wood.

With the bulk of the ship set for build they needed a contractor for the boiler so they tasked Daniel Dod to design the boiler who worked with Allaire Iron Works of New York that supplied the ship's engine cylinder while the rest of the engine components and running gear were manufactured by the Speedwell Ironworks of New Jersey. There they casted all the parts and used wrought iron processes to make the drive train. By using separate contractors Rogers was able to cut costs substantially by allowing each to spend more time in assuring the best quality. Had they used one builder to do the whole job, they risked possible high cost runs and poor workmanship, as well as schedule delays. Rogers made sure that he picked the best builders of that time who in themselves were all excited about doing something no one else has done before. So they took great pride in doing the best they could.

When the ship was built they took to sail on 1819 for its first voyage to England. They named it Savannah. The trip was a success that made news around the world with a record 29 day trip. In the course of the trip they estimated 4 days of the 29 were run by steam with the rest by wind sail. Soon after this ship made this trip others were to follow. In 1838 an English ship made the first voyage to America on continuous steam.

John concluded his talk about steamships by remarking about how important it was to make people feel safe that the vessel was an ocean ship and not a river boat.

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Membership Update

WELCOME NEW MEMBERS!

NELLY ANGAH
ROBERTO BALLESTER
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
RYAN O'CONNOR
JOHN H. PIZZONIA
KEITH PORTER
JASON ROMAN
ROCIO SANTANA VILLA
RACHEL RUSSICK
J DEANNA SCIACCA
JUSTIN SCHLAUDER
RICHARD G. STINE
STACY ST. JOHN
ANDREW STILLSON
NINAD TAMBE
RICHARD TOMER
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
SEPTEMBER 20, 2017	ISO 9001 2015 STANDARD	JAY KRISHNAMOORTHY	Hmmmm?	
OCTOBER 18, 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:
Randy Messinger
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 NEW HAVEN BOARD NOMINATIONS

It is time to nominate candidates for 2018 Section Officers: Chair, Secretary, and Treasurer. If you wish to submit someone (must be an ASQ member in good standing) for one of these positions please send your nominations to our Secretary, Suzette Herrick sherrick@unipharmus.com no later than September 30.

Each month we hold our Section Chair meetings at a local restaurant, if anyone is interested in joining us for your insights on improvement ideas or a possible position on the board again contact Suzette…Oh and have a **FREE** meal on us…

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.

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