

SCOPE



The Official Newsletter of the ASQ Orange Empire Section

February 2009

Section Chair Column - ASQ Letter from the Chair



I wish Happy New Year to you and your family. I hope you enjoyed your holidays. We started a Jan monthly dinner meeting to honor Dave Nagy, our Program Chair at the monthly dinner meeting on January 13, 2009. Dave has been

associated with our section for the past decade and has served different leadership roles in past 10 years. Dave serves as a role model and a leader, who leads by example by consistently going above and beyond the call of his duties. Dave is one of the ONLY FEW volunteers who attended all leadership committee meetings and monthly dinner meetings. I am fortunate to have worked with such a dedicated individual. ASQ Section 0701 was recognized as one of the best sections in the United States. On behalf of the members and the leadership committee of ASQ Orange Empire Section, I would like to thank all of you for your participation and involvement which made this possible.

In this issue, I would like to provide you an update on ISO 9001:2008 issued in November 2008. The changes made to ISO 9001:2008 were minimal such as rewording of the text, provide consistency in terminology, and provide clarification of approach and application.

Summary of changes:

Clause 0.1 (General):

- Added as a factor that influences the design and implementation of an organization's quality management system is "its organizational environment, changes in that environment and the risks associated with that environment." This requires the organization to consider its unique organizational environment and risk associated with the environment.

Clause 0.2 (Process approach):

- Emphasized the importance of processes being capable of achieving desired outputs by adding text.

Clause 1.1 (Scope):

- Clarification provided that 'product' to include comments regarding purchased products as well as product from realization process.
- Explanation provided that and regulatory requirements may be expressed as legal requirements.

Clause 4.1 (General requirements):

- Notes added to expand on outsourcing expectations relative to the types of controls that may be applied.
- Types of control that may be applied to outsourced processes must be defined. A note is added to explain outsourcing expectation, relationship to clause 7.4 (Purchasing), and clarification that the organizations are still responsible for outsourced processes and type of control that may be applied to outsources processes.

Clause 4.2.1 (Documentation)

- Clarified that QMS documentation also includes records and documents required by the standard may be combined.

Clause 4.2.3 (Documentation Control)

- Clarification provided that only external documents relevant to the QMS need to be controlled.

Clause 4.2.4 (Records Control)

- This section has been reorganized into three paragraphs but the requirement remains unchanged.

Clause 5.5.2 (Management Representative)

- Some organizations have chosen to outsource the role of the management representative to a consultant or a third party. The addition of the two words "the organization's" clarifies that management representative must be a member of the organization's own management.

Clause 6.2.1 (Human Resources)

- Clarification provided that competence requirements are relevant for any and all personnel who are involved in the operation of the Quality Management System.

- continued on page 2

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Clause 6.3 (Infrastructure)

- An information system was added as an example of supporting service.

Clause 6.4 (Work environment)

- ❖ Examples of conditions provided under which work is performed including physical, environmental and other factors such as noise, temperature, humidity, lighting, or weather.

Clause 7.2.1 (Customer related processes)

- Clarified much needed explanation of post-delivery activities to include:
 - Actions under warranty provisions and contractual obligations such as maintenance services.
 - Inclusion of supplementary services such as recycling or final disposal.

Clause 7.3.1 (Design and Development planning)

- Clarified that design and development review, verification, and validation have distinct purposes even if they are combined in your system.

Clause 7.3.3 (Design & development outputs)

- Clarifies that information needed for production and service provision includes preservation of product.

Clause 7.5.4 (Customer property)

- Explained that both intellectual property and personal data should be considered as customer property.

Clause 7.6 (Control of Monitoring and Measuring Equipment)

- Explanatory notes added regarding the use of computer software: “Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.”

Clause 8.2.1 (Customer satisfaction)

- Explained that monitoring of customer perception may include input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, and dealer reports.

Clause 8.2.3 (Monitoring / Measurement of process)

- A note has been added to clarify suitable methods for monitoring and measuring process.

I would like to wrap up by asking you to send us your feedback to serve you better.

Bob Mehta

Chairman – ASQ Section 0701

MSQA, MBA, B.S. (Chem), CQA, CSSBB, CQE, CBA, CSQE

January 13 Dinner Meeting



*Doubletree Hotel,
201 E. MacArthur
Blvd, Santa Ana*

Directions: [http://
maps.google.com/](http://maps.google.com/)

Clinic # 1 is entitled:
**Supplier Risk
Management –**

Tools and resources employed within an aerospace contractor presented by **Daniella Picciotti**. She will review some correct tool, and philosophies employed within an Aerospace Contractor in Southern Cal around the subject of managing supplier risk. Managing risk in today's aerospace industry goes beyond that of schedule slips or supplier escapes; it now includes technical/design, elements of a global supply chain strategy, and in today's economy financial stability. From this session, the attendee will:

- Gain an appreciation of the expanse of supplier chain risk and potential impact to programs.
- Be exposed to some tools/data elements that can aid in early detection of negative risk in a supply base.

The title of clinic # 2 is **Interview Skills Workshop** presented by **Ray Ellis**, from the Boeing Company. What you will learn in this interactive workshop:

- How to market yourself in a professional manner
- How to lower your anxiety during an interview
- How to respond to interview questions
- How to be the chosen candidate for the job
- What is SAR – Situation, Action, Results

Dr. Jack Revelle will be the dinner speaker. His topic will be **Increasing Customer Delight**. Many “experts” insist that customers don’t really know what they want; they have to be told. They’re dead wrong! Buyers, whether looking for a home, an appliance, or a car, do know what they want, but unfortunately they’re not proficient at describing their needs. When a home builder, a producer of appliances, or an auto manufacturer is aware of customer needs identified by Dr. Noriaki Kano, they are well on their way to better understanding their customers’ needs. Dr. Kano of Tokyo University has isolated and identified three levels of customer expectations. **Session Take-Aways:**

- Greater understanding of Kano’s two-dimensional model
- Detailed appreciation of Kano’s three levels of customer expectations
- Increased comprehension of the time vs. competition relationship
- Additional awareness of customer expectation management



Ray Ellis has worked for the Boeing Company for 24 years and is currently assigned in the Southern California region in support of Engineering Excellence / Lean+ at Integrated Defense Systems. Ray has a B.S. degree in Technical Management from Embry – Riddle Aeronautical University and is currently working on a Masters of Science in Organizational Development at Pepperdine University – Graziadio School of Business and Management.

Daniella Picciotti has over 18 years of experience within the aerospace industry including over 10 years of program and supplier quality management experience with Contractors such as Boeing, L3 Communications and now Raytheon. Currently in the role of Program Quality Manager for GPS & Navigations Systems in the ITP Business Area, Daniella is currently a Senior Manager for the Space & Airborne Systems division of Raytheon.



Dr. Jack B ReVelle is an adjunct professor in the UC-Irvine Extension Program where he leads courses in Lean Six Sigma. He is the immediate past Chair of Orange County SCORE-114 and a SCORE volunteer management counselor based in Santa Ana, CA. In addition, he continues to provide his advice and assistance as a consulting statistician to a variety of companies throughout the U.S. In this capacity, he helps his clients to better understand and continuously improve their processes through the use of a broad range of Lean Six Sigma, Total Quality Management, and Continuous Improvement tools and techniques.

Prior to establishing ReVelle Solutions, LLC in 1999, he was the Director of the Center for Process Improvement for Aerojet in Azusa and Sacramento where he provided technical leadership for the Operational Excellence program. Before this, he was the Leader of Continuous Improvement for Raytheon (formerly Hughes) Missile Systems Company in Tucson, AZ. During this period, he established and led the Hughes team that won the Arizona Governor's Award for Quality. He also established the Hughes team responsible for obtaining ISO 9001 registration. Dr. ReVelle's previous assignment with Hughes Electronics was at their Corporate Offices as the Chief Statistician. Prior to joining Hughes, he was the Founding Dean of the School of Business and Management at Chapman University in Orange, CA.

HIGHLIGHTS FROM LAST MEETING

January 13th Dinner Meeting Honoring Dave Nagy



Bob Mehta (Section Chairman) presents Dave Nagy (Programs Chair) a special recognition award honoring him for his service, dedication and leadership to the section over the past decade.



A picture of the award given to Dave, for his service to ASQ Orange Empire



An appreciative crowd, joining in the celebration of Dave Nagy's achievements.

More January 13 Dinner Meeting Highlights



Doug Hammer presented a clinic on **Sustainable Corrective Action** in which he summarized his many years of problem solving and management systems experience into a set of “ground rules’ and a 6 step process approach.

Manuel Marco presented a clinic on *ISO/IEC 20000 IT Service Management & ISO/IEC 27001 Information Security Management Systems* standards and their applications.



Jim Kelton discussed hidden IT threats and the secrets to finding them applicable for not only business data but also your personal information.

Upcoming Certification Courses



Certified Quality Engineer Exam Refresher/Prep Course

Location: Alcon Laboratories, 15800 Alton Prkway, Irvine, CA

Exam Date: June 6, 2009 **Exam Application Deadline:** April 17, 2009

Course fee: \$500 plus cost of textbooks. Scholarships are available - contact Education Chair.

Time: 6:00 pm - 9:00pm. 4.2 RU's will be given for this 42 hr course.

Session/Dates: 14 sessions total: Wednesdays from Mar 4, 2009 to June 3, 2009.

Will Cover: Management & Leadership in Quality Engineering; Quality Systems Development, Implementation, and Verification; Planning, Controlling, and Assuring Product and Process Quality; Reliability and Risk Management; Problem Solving and Quality Improvement; Quantitative Methods; and exam tips.

Reference Books: CQE Primer + Solution Text, Quality Council of Indiana (required). Cost \$105.

Purchase the text directly through the Quality Council of Indiana at 1-800-660-4215 or www.qualitycouncil.com prior to the first class

The Certified Quality Engineer Handbook (recommended),

Gryna, Quality Planning and Analysis, Latest edition (recommended).

TI 36X Statistical Calculator (required).

Instructors: Linda Howe Garriz (Linda.Garriz@Alconlabs.com). Mark Lindsey (Mark.Lindsey@disney.com), cell: 714-273-2678

Enrollment: Open through April 17, 2009. Class fee must be paid by the 3rd session. No refunds after the 3rd session.

To Register For the Class: go on-line at www.asqorangeempire.org/calendar/calendar.htm. Class fees must be paid no later than 3rd session.

To Register For the Exam: go on-line at <http://www.asq.org>

Announcements

Wanted – ASQ Certification Preparatory Course Instructors

Looking for instructors to teach sessions in the following areas: Quality Engineer, Quality Auditor, Biomedical Auditor, Black Belt, Green Belt, Reliability, Mechanical Inspector, and Quality Technician

Rewarding Work - Competitive Compensation – Great Team

If you are a good public speaker and want to share your love of quality concepts, you might like to become an ASQ Certification Preparatory Course instructor.

Qualifications

Membership: You must be (or become) a member of ASQ Section 0701.

Certification: You hold a current ASQ certification in the area you plan to teach. You must maintain the certification in the area that you teach.

Speaking: You should be a comfortable and effective public speaker.

Time: You must be prepared to make the time investment to be a knowledgeable and effective instructor. You will be expected to keep abreast of the developments in your field. You may also be asked occasionally to volunteer your time to the Section by participating in Clinic Presentations at the Monthly ASQ 0701 Section Meetings.

Preparation: You be expected to prepare powerpoint presentations and handouts for each class you teach.

Demonstrated Teaching Ability: As part of the selection process, you will be asked to make a 45 minute presentation on a topic within the Body of Knowledge to a panel of ASQ Section Officers and/or Members. You will then be observed in the first several sessions that you teach.

Instructor Training and Meetings: You may be asked to attend training and/or instructor meetings through the year.

Interested parties should send a resume and summary of qualifications to Linda Howe Garriz, e-mail

Linda.Garriz@alconlabs.com , or mail to Linda Howe Garriz, Alcon Laboratories, Inc., 15800 Alton Parkway, Irvine, CA 92618.

Special Announcement from ASQ Headquarters

There is a trade show and conference (MD&M West) being held at the Anaheim Convention Center February 10-12, 2009 that ASQ is taking part in. We are wondering if there are any section members in the local area that would be interested in volunteering to help us staff our booth. I have attached a link to the conference site and included the dates and hours we will be exhibiting. If you could please spread the word to your section members and give any interested parties my contact information it would be greatly appreciated.

<http://www.devicelink.com/expo/west09/index.html>

Show Location, Expo Dates and Hours:

Anaheim Convention Center

800 W. Katella Avenue
Anaheim, CA 92802

Tuesday-Wednesday

February 10-11, 2009

10:00 AM* to 5:00 PM

Thursday

February 12, 2009

10:00AM* to 4:00PM

Announcements

Quality Management Division's Conference Returns to Irvine!

The 21st Annual Quality Management Division conference will be held at the Hyatt in Irvine on March 5 and 6, 2009. This conference will be presented jointly by the Quality management Division and the Software Division. There will be preconference courses on March 2, 3, and 4 and several certification refresher courses. The QMD will host the local certification exams on March 7 at the Hyatt.

The 18th Annual conference was well received in Irvine in 2006 and the 21st conference will include expanded topics and many sessions presented by subject matter experts. Some of the featured speakers and course presenters include:

Speakers

- Peter Andres, ASQ President-Elect
- J.R. McGee, President & CEO X-Stream, LLC
- Tom England, Global Director-Six Sigma Tyco Electronics
- Mike Murphy, President & CEO Sharp Health Care
- Shane Young, Owner Competitive Solutions, Inc.

Course Presenters

- David Little, Failure Modes and Effects Analysis
- Linda Westfall, Certified Software Quality Engineer
- Doug Wood, Cost of Quality
- Duke Okes, Financial Thinking for Quality Professionals
- Jim Duarte, Strategy Deployment Methods for Optimizing Lean Six Sigma

For more information, please visit the QMD website at www.ASQ-QM.org.

If you are interested in volunteer opportunities as room monitors or moderators during the conference, please contact David Vu at vu_david@att.net.

The local conference representative is Milton Krivokuca (milt619@cox.net).



American Society for Quality
Orange Empire Section 0701

Beginning Statistics for Quality

Presented by: Linda Howe Garriz

Seminar Date: Tuesday February 24th, 2009 from 8:30 AM to 4:30 PM

Abstract

Do you consider yourself LOST when it comes to statistics? Do you wish there could be some way to make learning statistics FUN? If so, this course is designed with you in mind! After a fun-filled, highly interactive day of group exercises and games, you will be on your way to a whole new way of thinking. And just think...the worst that can happen is that you get a cool new calculator to impress your friends!

Attendee Takeaways

Understanding of the concept of variation through the Deming Bead Box experiment, distinguishing between variable versus attribute data, calculating the mean, median mode, range, and standard deviation for a set of data, understanding the normal distribution and its use in quality, and the development and use of basic control charts/capability analysis. Plus a cool TI-30X Statistical Calculator!

Location: Jazz Semiconductor, 4321 Jamboree Rd, Newport Beach CA. 92660
(Atlantic Building which the 3 story building)

Registration & Continental Breakfast at 8:00 AM, Lunch is included.

Cost if Registered by February 13th: ASQ Section 701 Members \$115.00 & All Others \$145.00

Cost after February 13th: ASQ Section 701 Members \$145.00 & All Others \$175.00.00

Payment by Check (payable to ASQ Section 701) or Credit Card via online.

1.0 R.U. / For more information: Ed Matthews at ed.matthews@honeywell.com You can also **register on-line** at: <http://www.asqorangeempire.org/>

If you have any special needs (food, access) let us know.

Seminar Registration Form (Checks by mail)

Participant Name: _____

Work Phone: _____ Home Phone: _____ Email: _____

Street Address: _____ City: _____ Zip: _____

Amount: Check: _____ Membership # _____

Mail registration to Ed Matthews, 6 Via Topacio, Rancho Santa Margarita CA 92688, or Fax 714-844-9116. If you want confirmation of receipt of payment by check send Ed an email.

If you have any special needs (food, access) let us know.

If **paying by Credit Card** please go to <http://www.asqorangeempire.org/> and select Calendar to find the event. The select register now to provide registration by secured access credit card. Membership is verified against membership roster. System will send confirmation to email address you enter at time of registration. This is also your receipt of payment.

Mail registration to Ed Matthews, 6 Via Topacio, Rancho Santa Margarita CA 92688.

Announcements

L. Buck Consulting ISO 9001: 2000 Training Courses Fax registration to:(714) 577-8846.

See our Web Site www.lbuckconsulting.com

Send Payments to: L. Buck Consulting, 1427-A Prospect Avenue, Placentia, CA 92870

ISO 9001: 2008
Internal Auditor Course

2-Days \$995

February 2009
2-3 Santa Ana, CA

April 2009
13-14 San Diego, CA

May 2009
18-19 Santa Ana, CA

August 2009
10-11 Santa Ana. CA

October 2009
12-13 San Diego, CA

December 2009
1-2 Santa Ana, CA

Aerospace
AS 9100 Rev B
Internal Auditor Course

2-Day \$995

February 2009
4-5 Santa Ana, CA

April 2009

May 2009
20-21 Santa Ana, CA

August 2009
12-13 Santa Ana, CA

October 2009
14-15 San Diego, CA

December 2009
3-4 Santa Ana, CA

IRCA approved
ISO 9001: 2008 series
Auditor/Lead Auditor
Training Course - Batalas
(A17043)

4-1/2 Days \$1,795

February 2009
9-13 Santa Ana, CA

April 2009
20-24 San Diego, CA

May 2009
11-15 Santa Ana, CA

August 2009
17-21 Santa Ana, CA

October 2009
19-23 San Diego, CA

December 2009
7-11 Santa Ana, CA

Discounts available to current ASQ Members

On-Site 2-Day Internal Audit Course up to 9 students \$4,900
On-Site ISO 9001: 2008 5-Day Lead Auditor Course up to 6 Students \$8,400
On-Site 1-Day Refresher Course up to 9 students \$2,900
AS 9100 Rev B (Aerospace) On-site courses available
ISO 13485: 2003 (Medical) On-site courses available
ISO 14001 (Environmental) On-site Courses available
Call (714) 577-8846 for quotation

Name _____ Title _____

Company Name _____

Address _____

City _____ State _____ Zip _____

Phone _____ FAX _____

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Circle Course

Lead Auditor Course
offered through
Batalas Limited –
UK

Call (714) 577-8846
for on-site classes or
E-mail

Leadership Team 2009

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E-mail: bobasq0701@gmail.com

Vice Chair

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Secretary

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Treasurer

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Programs Chair

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W: (626) 330-3425
E-mail: dshibley@adamscampbell.com

Please contact the Leadership Team and tell us how to serve you better

Welcome New Members



Nora Abanes
Harry Acosta
Mohammed J. Aslam
Paul Bailey
Viph Chengpraseuthsack
Basil Dedman
Anthony D. Edwards
Kamila Granadino
Augusta L. Helmick
Guy J. Jackson
Christopher A. Karner
David C. Kohl
Kevin Lukomski
Alexander Rogayan
Edward Santa Anna
Steve Siamidis
Robert Sk. Wang
Kevin J. Wertel

Not receiving e-mail notifications of upcoming events? Call headquarters at 800-248-1946 and request the necessary changes, or e-mail them at help@asq.org

Mail Recertification Packages to:

Mark Belgen, ASP , Johnson & Johnson, 33 W. Technology Drive, Irvine, CA 92618

Course	Next Exam Prep Start Date	Exam Dates	Application Deadline
CQA - Biomedical	January 14, 2009	Mar 7, 2009	Jan 16, 2009
Certified Mgr of Quality/ Organizational Excellence	January 5, 2009	Mar 7, 2009	Jan 16, 2009
CQI/CQT	Jan 5, 2009	Mar 7, 2009	Jan 16, 2009
CQE	Mar 4, 2009	Jun 6, 2009	Apr 17, 2009

Why Become Certified? In today's world, where quality competition is a fact of life and the need for a workforce proficient in the principles and practices of quality control is a central concern of many companies, certification is a mark of excellence. It demonstrates that the certified individual has the knowledge to assure quality of products and services. Certification is an investment in your career and in the future of your employer.

SCOPE Ad Rates:

Ad Size	Inch Size	1 Issue	6 Issues	12 Issues
Full page	8.5" x 11"	\$200	\$1,100	\$2,000
1/2 Page	7.5" x 4.912"	\$110	\$605	\$1,100
1/4 Page	3.667" x 4.912"	\$70	\$385	\$700

Ad Size	Inch Size	1 Issue	6 Issues	12 Issues
Business Card (1/8 Page)	3.667" x 2.36"	\$35	\$195	\$350
Checks should be made to: ASQ Orange Empire Section, and mailed to ASQ, PO Box 14183, Irvine, CA 92614, with ad copy, instructions for placement, and frequency. SCOPE Editor: Dan Shibley 626-330-3425 or dshibley@adamscampbell.com .				

Quality in the Trenches



Letter from the Editor:

In this month's **Quality in the Trenches** we will be looking at how the quality community of professionals can

build and encourage one another during these tough economic times. I hope that I can pull the clouds back for at least one ray of sunlight.

Dan Shibley
E- Scope editor.

“ The true test of the American ideal is whether we’re able to recognize our failings and then rise together to meet the challenges of our time. Whether we allow ourselves to be shaped by events and history, or whether we act to shape them. Whether chance of birth or circumstance decides life’s big winners and losers, or whether we build a community where, at the very least, everyone has a chance to work hard, get ahead, and reach their dreams.”

BARACK OBAMA, speech, Jun. 4, 2005

In June of 2005, now president Obama was neither addressing the current economic situation or his first moves as the president of the United States of America. President Obama was quoted, “A key to success is to recognize our failings and meet our current challenges to reach our dreams.” It seems as if everyone that I meet has been hit by the recent events of our economy. It was eerie to read last week that two out of every hundred homeowners will be facing foreclosure this year.

Friends, family and co-workers face an unprecedented world of unemployment and financial instability.

Okay, enough of what you already know. If you take a deeper look into the quote of President Obama you see several keys that will help to reach your dreams. For the record, I did not vote for President Obama, so I am not pushing a political point of view. However, I am pushing his quote to the front of the line.

Recognize your failings. One step to a brighter future is to learn from the past. We have all heard the quote by George Santayana:

Quality in the Trenches - *continued from previous page*

- “if we do not learn from history, we are doomed to repeat it,” is all too true. Recognize and learn from what went wrong. Know your weaknesses. Gather support for it and move forward. For example, last summer I wanted to go camping. However, I only had a Toyota Forerunner. I did not want to pull a trailer due to the high gas prices. So I recognized my failings, it was not a Ford F350 that could haul a ton of gear. So I searched the net for a lightweight carrier, found one for \$89 and it worked perfectly for my needs. Recognizing our failings (or for better terms, shortcomings) can lead you to the right answer to the problem at hand.
- Rising together to meet the challenges. One of the great moments of WWII was when a leader of a small group of fighters used “duct tape and bailing wire” to hold his planes together, as in December 1941, his supply line was cut off. Through several months, his team had to rise together every day to meet the unknown. No supplies, no funds and no replacements. Only his team.

Many of you know the results “Pappy Boyington” became a famous ace and his “black sheep squadron” became world known. His team rose together against all odds and became creative well beyond any training had provided them. They were a team. Together they were great! The pilot, cook, mechanic and engineer all worked through unparalleled events that would

change their lives and the lives of others, forever.

- Build a community. We are so blessed to be a part of our ASQ section. Many of you, have supported me whether speaking, writing or as one of my suppliers or customers. Thank you. Keep an eye on your quality team. Look for ways to share ideas and encourage each other. When one falls, pick them up, lend a hand, share a success story (often!). When you see each other in the quality arena, look for ways to encourage.
- Work hard, get ahead and reach your dream. Don't give up! Keep pushing for improvement in your workplace; don't let your dream die! The new idea that will save your company thousands of dollars, still exists, new cost saving techniques, new lean ideas and a greater performance incentive still can be alive!

I certainly do not have a clue on when this will be over, but I do believe in each one of you. Working alone we are good, working together we are great!

Daniel Shibley
Quality Manager; the Adams Campbell Company

Daniel Shibley has been in the Quality field since 1976 and currently is the Quality Systems Manager at the Adams Campbell Company and has been the editor of the Orange County Scope since 2001. Questions and comments regarding this article may be e-mailed to:

dshibley@adamscampbell.com

Meet the Leadership Team

Meet the Leadership Team will be a regular feature article for the year 2009. This month, in honor of “Dave Nagy Month”, we feature Dave Nagy, our section Programs chair. Dave is a true professional and a gentleman, and we are truly grateful to have him on the Leadership Team.



Dave Nagy brings over 30 years of experience in operations, strategic planning, quality systems implementation, training and senior level management focusing on eliminating waste and non-value added activities while driving financial results to the bottom line. Dave has led lean implementation and self-directed teams for over 20 years.

As a principal of Bolero Associates LLC, Dave’s efforts have been focused on change management, leadership development, driving financial improvements, teaming, and team problem solving, and implementing a lean quality management system. Dave has been providing consulting and training to client companies including:

◆ County Government - San Bernardino: Faculty member in the Management Leadership Academy

- ◆ Medical Groups
- ◆ Industry: Service and International Manufacturing
- ◆ Non-profits:
- ◆ Dave is a certified Lead Auditor for ISO9000:2000 and TS16949
- ◆ Authored more than 30 articles for publication on change management, trust, leadership, team effectiveness, and developing teams in a lean self-directed organization
- ◆ Public Speaking and Keynote speaker at numerous Associations and Conference events on “Making Change Work”, “Change at the Speed of Light”, “Networking For Professionals”, “Changing the Way We Work”, “Human Side of Change”, and “Communication: Building an Effective Strategy”.

AFFILIATION INVOLVEMENT

- ◆ Goodwill Industries International
 - ◆ Served 8 years in various capacities on the Goodwill Industries of Orange County Board of Directors, including 2 years and Chairman of the Board
 - ◆ Served 2 years on the Goodwill Industries Western Region Council as Chairman of the Board
 - ◆ Received Goodwill International’s “Founder’s Award” for outstanding dedication to excellence
- ◆ ASTD – America Society for Training & Development
- ◆ ASQ – Orange County
 - ◆ Served 10 years in various capacities on the Section Leadership Committee, including Secretary, Vice-Chair, Lead Proctor, Program Chair, and 2 years and Section Chair
 - ◆ Senior Member
 - ◆ Received the Section 701 “Volunteer Excellence” award
 - ◆ Presented numerous clinics, seminars, and dinner programs as one of the Section’s highest rated speakers

Meet the Leadership Team

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ACADEMIC INVOLVEMENT

Dave has also been considerably involved in providing programs through several universities that support leadership development on the journey to high performance. Some of the programs that Dave has taught include.

Adjunct Faculty Instructor

California State University, Fullerton - Department of Extended Education

Courses include:

- ◆ “Business Management for Supervisors”
- ◆ “Understanding the Organization”
- ◆ “Effective Leadership & Team Building”
- ◆ “Case Studies for Supervisors”
- ◆ “Leadership Case Studies”
- ◆ “Creating Communication Synergy in the eWorld”
- ◆ “Developing Your Leadership Style”
- ◆ “Problem Solving Skills for Outstanding Performance”
- ◆ “Plain Speaking: How to Communicate Successfully”

Adjunct Faculty Professor

University of California, Irvine - Department of Extended Education

Courses include:

- “Elements of Supervision and Assessment”
- Brazilian Executive MBA 2005 Summer Program – presented 1 day programs on Managing Change and Delivering Results, Project Management, and Supply Chain Management.
- “Essential of Management” Mgmt 490.1

California State University at Pomona

School of Business, Department of Technology, Operations and Management

- ◆ Industry Advisory Council
- ◆ Speaker and presenter at 2003 & 2004 Department Senior Award and Industry Banquet

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Jay C. Perry	1963
Paul S. Vigneault	1963
Alan L. Forsha	1964
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A. Ridgely Park	1964
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Frank F. Feher Jr.	1968
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Eddie Rose	1974
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Donald A. Middlebrook	1977
Dale E. Becker	1977
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Daryl M. Gutting	1986
Valerie H. Williamson-Weed	1986

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John J. Malloy	1986
Michael W. Schultz	1986
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Patricia M. Mancilla	1986
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Peter L. Andres	1986
Jerry R. Duarte	1986
Le Ann L. Bloemke	1986
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Robert K. Fujimoto	1989
Gail A. Benard	1989
Muhammad I. Chaudhry	1989
Diana Merryman	1989
James P. Walden	1989
Jeff James	1989
Nannette Monreal	1989
Kosaku Yoshida	1989
Dominic D. Cortella	1989

Vincent S. Fesunoff	1989
Andrew M. Sageman	1989
David G. Hunt	1989
Ronald G. Davis	1989
John E. Lamirande	1989
Terry L. Knox	1989
Michael G. White P.E.	1989
Stephen D. Griffith	1989
Cindy L. Caldwell	1989
David J. Steen	1989
Jack C. Vankann	1989
Sophia C. Castanien	1989
Ngoc V. Tran	1989
Melanie K. Cummings	1989

“I want you to know I will not make age an issue in my campaign; I am not going to exploit, for political purposes, my opponent’s youth and inexperience”

- Ronald Reagan during a presidential debate with Walter Mondale



Congratulations to **28 Members** (Section 0701)
who passed the 12/6/2008 certifications tests.

Certified Quality Auditor (12)

Arciga-Morales, Maria
Culhane, Thomas A.
Espejel, Magali
Godfrey, Greg P.
Isbell, James M.
Lindwall, Peter L.
Maier, Mark
Rangaraj, Cumbum N.
Schwartz, Fred
Stochlia, Michael B.
Tan, Shirley
Tejwani, Karishma

**Certified Quality Engineer
(12)**

Brooner, Cody A.
Cook, Adam
Das, Balaka
Do, Minh
Gergis, Basim S.
Hansen, Jennifer H.
Kossoff, Matthew
Kunkle, Kelly S.
Morgan, Thomas J.
Payami, Houman
Samuel, Ari
Thiensirisak, Sirilada

**Certified Software Quality
Engineer (2)**

Lal, Anshoo
Mehta, Bhavan V.

**Certified Six Sigma Green
Belt (1)**

Uitzeller, Shelley

**Certified Calibration
Technician (1)**

Rhodes, Michael E.

CONGRATULATIONS

Career Opportunities

Manufacturing/Process Engineer Los Angeles, CA

Responsible for providing process and equipment development for the manufacture of medical devices and products.

Responsibilities:

- Product Development Engineering to ensure design for manufacturability.
- Evaluate and challenge product designs for manufacturability
- Provide innovative and successful processes and equipment to meet project schedules and budget targets.
- Participate with Product Development during the pilot manufacturing activities.
- Develop work center layouts, estimate production times, staffing requirements and related costs.
- Identify equipment and processes required to manufacture new products.
- Establish preliminary BOMs and routers for input into the ERP system.
- Design and develop special equipment as required.
- Identify, evaluate, and implement improvements to existing equipment and processes.
- Work with Production Supervisor to train production personnel on new equipment and processes.
- Oversee production, installation, operation, maintenance, repair and development of new, modified and/or existing equipment and fixtures.
- Develop project budgets, schedules, timetables, and capital equipment justification as needed.
- Define and generate all required documentation (IQ, OQ, PQ) for validation of equipment and processes.
- Develop all manufacturing work instructions and procedures.
- Maintain process documentation, bills of materials, drawings, procedures, routers, validation plans, protocols and reports.

Experience/Education: BS in Manufacturing/Mechanical Engineering or

related engineering field. 4+ years manufacturing experience, medical device manufacturing preferred. Devising and applying Lean Manufacturing principles and DFM. Experience setting up, qualifying and validating manufacturing required. Experience with packaging equipment and manufacturing processes for medical device manufacturing. Experience in the transition of new products into manufacturing. Automation design experience (including PLC, pneumatic and hydraulics). Statistical Process Control (SPC) analysis, and working knowledge of SolidWorks. Strong project management background required. Experience with a variety of assembly and packaging equipment, and automation required. Demonstrated hands-on process validation experience, including IQ, OQ, and PQ. Working knowledge of medical device manufacturing requirements and QSR's/ISO 13485 compliance guidelines.

Quality Engineer Los Angeles, CA

Works with the Director, QA/RA and appropriate departments to develop and implement appropriate Quality procedures, quality improvement activities; internal auditing and assists in advancing quality improvement principles.

Responsibilities:

- Assist Quality Assurance Inspectors in performing inspections which include: first articles, parts in process, receiving and final using inspection tools such as calipers, gages & master blocks, optical measuring instruments such as Smartscope, Comparator and microscope and other appropriate tools.
- Participate in MRB/NCR nonconformance report activities; including trend analysis and report of such activities.
- Plan, Develop and implement an internal audit program in accordance with the requirements of Quality and Regulatory Standards.
- Review trends that result from internal audits.

Understand geometric and tolerancing principles to determine acceptability or rejectability of dimensional requirements and data analysis.

- Assist the QA Inspectors in completing their task by providing guidance and direction.
- Review and implement the requirements of Quality Standards such as ISO 13485, FDA 21 CFR 820 and the Medical Device Directive by developing procedures to comply with aforementioned standards.
- Monitor and process all NCRs for action, including data entry into Navision, communicating with internal and external customers for resolution of NCR, and notification to suppliers, including follow-up on NCR disposition.
- Interface with vendors by performing supplier evaluations, audits, and resolving quality issues.
- Perform trend analysis of supplier performances and report .
- Participate in registrar, customer, regulatory and third party audits.
- Assist in reviewing policies, procedures and engineering drawings prior to release.
- Adhere to department quality and productivity standards.
- Participate in various Quality Improvement Teams.
- Follow standards and procedures and comply with legal regulations.
- Willing to participate in educational opportunities and reading of technical publications.
- Must be able to handle and prioritize many tasks simultaneously.
- Must work well with minimal direct supervision.

Educational/Experience Requirements:

- BS/BA in a scientific discipline or engineering is preferred.
- 5 years experience in QA Inspection and auditing required.
- Must be able to lift 20 pounds.

For inquiries of these positions, please contact: **Cheryl Jones**
Med Exec International Phone: 818-552-2036 or **800-507-5277 ext 412**
Email: recruiter@medexecintl.com Web: <http://www.medexecintl.com>

Career Opportunities

Director, Regulatory Affairs – Consumer Products Westchester, NY

Reports to the SVP, Science and Technology and have the authority and responsibility for corporate-wide leadership of the Regulatory Affairs Function.

Responsibilities: Lead the regulatory affairs activities and have the authority and responsibility for corporate-wide leadership of the Regulatory Affairs and R&D Function. Manage a diverse set of projects and personnel with a focus on product and process innovation, quality, safety, and effectiveness. Formulate regulatory plans and budgets, setting corporate & departmental goals and priorities. Development of patents and other intellectual property. Work with Marketing and Senior Staff to develop new product plans and strategies; with manufacturing and quality assurance to ensure new products are of high quality and are readily manufacturable; with clinical research to ensure products are safe and effective. Refine and enforce Regulatory and R&D policies to ensure compliance to the Quality System and external regulatory standards including ISO 13485, FDA regulations. Regulatory Review of labeling and advertising. Work with the Operations Department and Brand Managers to support all US and Canada product development and brand activities (claims, ingredients, packaging) and provide them with proactive understandings on current and future regulatory environments. Open the door to new claims and new positioning that are made possible by aggressive interpretation of existing and emerging changes in regulations and provide regulatory opinion. Point person to the FDA and EPA and provide awareness of changes in regulations. Responsible for internal and external quality FDA audits on all 510k and NDA applications. Responsible for maintaining quality system, including ISO 13485 2003 CMDCAS and CMDR (Canadian Medical Devices Regulations), Mandatory Problem Reporting (Canada) QSR, CAPA system, documentation and reporting to top management. Ensure complaints are documented and investigated. Support product registrations, notifications and licensing activities of Plants (State, Federal) and FDA/EPA registrations and draft and review regulatory and safety SOPs.

Education/Experience: B.S. in Chemistry or an equivalent technical field, or equivalent experience, is required; Advanced degree: M.S. or Ph.D. is highly desirable. Strong knowledge of cGMP, ISO and FDA submission regulations. Broad experience in Regulatory and R&D technologies and strategies. Knowledge of human resources, purchasing, facilities, security, and quality control procedures and programs and understanding of related legal and regulatory requirements. Minimum of **10** years experience in R&D with **5** years of progressive management responsibility, including at least **5** years in the pharmaceutical industry. Demonstrated track record of success as Director of Regulatory and R&D functions in a pharmaceutical company through all development phases.

Regulatory Affairs Specialist Ventura County, CA

Responsibilities: Ensure compliance with FDA and other applicable regulations and Develop regulatory strategies to facilitate submissions. Prepare, analyze and submit reports to governing agencies to comply with regulatory requirements including ISO, local, state and/or federal requirements. Review regulatory publications, documents and websites to stay informed about proposed regulatory changes from the FDA & other worldwide regulatory authorities to develop strategies to adjust to required changes and report on the impact of these changes. Maintain external references along with lists of national and international regulations, standards and FDA guidance documents that affect products and operations. Communicate with regulatory agencies on administrative and submissions. Participate in training and education seminars to learn regulatory requirements and demonstrate RA knowledge. Document, consolidate and maintain communications with FDA, notified bodies and registrars. Assist with filing annual notifications, annual establishment (state and federal registrations) and product changes of FDA, Health Canada, EU, notified bodies, etc. Compile and submit device experience reports as per FDA Medical

Device Reporting System, EU Device Vigilance System, etc. Support the design control process and provide regulatory review for design control. Ensure consistent application of law, regulation and guidance across design projects. Participate in and conduct internal audits, coordinates customer on-site audits and confer with representatives of material and component vendors regarding supply quality, capacity of vendor to meet orders, and vendor quality standards. Interact with responsible departments to manage collection, reviewing and assembly of scientific, clinical, manufacturing and administrative sections of submissions. Participate in third party audits of the quality management system and develop responses to support audit corrections and rebuttals. Participate in product recovery process and generate regulatory risk assessments for product issues with customer exposure. Assist with development/maintenance of regulatory files, records and reporting systems. Review change control documents to ensure regulatory compliance. Communicate and interface with international sales managers and international distributors to assist in international regulatory issues. Formulate and establish company policies, operating procedures, and work instructions. Responsible for the coordination of quality system training program for all company Medical Division personnel This position has direct responsibility for Logistics Quality Control Inspectors.

Education and/or Experience
Bachelors Degree (B.A.) from four-year college or university plus three years in a medical device regulatory environment with demonstrated supervisory/managerial progression OR 5 to 8 years related experience/training; or equivalent combination of education and experience .
Knowledge of current CFR 21 Part 820, 801, 803, 814, 806, 807, 821, 822, GMP, QSR, ISO 14971, ISO 13485:2003 and EU 93/42/EEC.
Training/experience in internal auditing. ASQ/RAPS certification preferred.

Please contact:
Cheryl Jones
Med Exec International
Phone: 818-552-3673
Email: cjones@medexecintl.com
Web: <http://www.medexecintl.com>

Career Opportunities



Document Control Clerk Ventura County, CA

Summary

Organize and manage Quality/Regulatory Compliance Documents

Responsibilities:

- Establish and maintain files for each type of regulatory required documents
- Facilitates timely approval and documentation of changes to documents
- Compiles and maintains control records and related files to release drawings, engineering and quality system documents
- Establish files for each piece of maintainable equipment
- Examines documents (SOPs), work instructions, drawings, change orders, and specifications to ensure compliance with regulatory and internal procedure requirements, verify completeness and accuracy of data
- Consults with document originators to resolve discrepancies and compiles required changes to documents
- Posts changes to computerized or manual control records, releases documents, and notifies affected departments
- Will be occasionally exposed to moving mechanical parts, fumes or airborne particles
- Other duties may be assigned.

Education/Experience

- 2-3 years in a medical device regulatory environment with a Bachelor's Degree OR
- 5-8 years related experience and/or training
- Knowledge of current CFR 21 Part 820, ISO 13485:2003 and EU 93/42/EEC

Please contact:

Lewie Casey

Med Exec International

Phone: 818-552-4173

Email: lcasey@medexecintl.com

Web: <http://www.medexecintl.com>

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Dave Nagy, Principal



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ASQ Member since August 1990
Sustaining ASQ member since 1997
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